

The development of an electronic clinical decision support system to assist with the identification, assessment and management of suicidality in primary care.

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Thesis submitted to the University of Nottingham for the degree of Doctor of Philosophy.

30 May 2021

Declaration

I hereby declare that the work presented in this thesis has not been submitted for any other degree or professional qualification, and that it is the result of my own independent work.

M.D.Horrocks

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30.05.2021

Date

corrections completed 05/12/22

Abstract

Background: Primary care, is usually the first and last healthcare contact recorded by people who die by suicide. It previously been suggested that primary care holds potential to make a significant contribution to enhancing suicide and self-harm prevention. However, previous research highlights significant variability in the way GPs conceptualise, assess and manage patient suicidality, and previous attempts to offer GPs suicidality prevention training have generated inconclusive results. Previous research has identified a range of organisational and contextual factors negatively impacting on GPs ability to support patients in suicidality distress. As a result of these contextual considerations, GPs have previously suggested a clinical decision-making tool could support them in working with patient suicidality. Clinical decision support systems (CDSS) have been widely implemented in primary care for a range of ambulatory presentations, however no empirically evaluated CDSS exists to support GPs in working with patient suicidality. A CDSS could support GPs by guiding the consultation, supporting GPs' clinical decision-making and standardising the way the consultation is recorded in patient's clinical records.

Methods: A mixed methods approach was adopted to develop the content of the CDSS and provide an initial evaluation of the prototype. The CDSS was developed following four empirical studies within the thesis. The first two studies gained perspectives of GPs through one-to-one interviews, and patients with experience of consulting a GP in relation to suicidality, through embedded consultation groups. The third empirical study brought together patients, GPs and suicide prevention experts to participate in a modified Delphi and expert consensus workshops to agree and shape the CDSS content. The fourth empirical study provided an initial usability evaluation of the prototype CDSS.

Findings: Results of the studies corroborated known variation in the way GPs understand and conceptualise suicidality, and highlighted a range of contextual, organisational, and socio-cultural mechanisms which could influence GPs use of the CDSS. The studies shaped the content of the CDSS so that it was appropriate for the clinical and contextual demands of primary care practice. GPs reported the prototype CDSS possessed adequate usability and was acceptable in terms of its ease of use, content and ability to support their clinical decision-making.

Conclusions: This research shows that the prototype CDSS has potential to improve GPs' assessment and clinical management of patient suicidality in primary care. As an evidence-based quality improvement the CDSS could support GPs, and patients, to collaboratively discuss and care-plan in relation to suicidality and make an important contribution to promoting shared decision-making whilst enhancing suicide prevention efforts in primary care.

Publications associated with this research

Published protocol

Horrocks, M., Michail, M., Aubeeluck, A., Wright, N. and Morriss, R. (2018) An Electronic Clinical Decision Support System for the Assessment and Management of Suicidality in Primary Care: Protocol for a Mixed-Methods Study. **JMIR Research Protocols** 7(12): e11135.

Conference presentations and poster

Horrocks, M., Aubeeluck, A., Michail, M. and Morriss, R. (2019) The development of an electronic clinical-decision support system for the identification, assessment and management of suicidality in primary-care. **BSA Risk & Society Study Group Event - Tensions at the Front Line of Risk Work: Implications for Policy and Practice**. London: British Sociological Association. 09-10 December 2019.

Horrocks, M., Aubeeluck, A., Michail, M. And Morriss, R., (2019). The development of an electronic clinical decision support system, for the identification, assessment and management of suicidality in primary care. In: **RCGP Midlands Faculty Annual Education, Research and Innovation Symposium**, Keele University, Keele, Newcastle-under-Lyme, 23 May 2019.

Horrocks, M., Aubeeluck, A., Michail, M., Morriss, R., Rawsthorne, M. And Cresswell, A., 2019. Suicidality in primary-care where the 'life world' meets the 'systems world': experiences of talking about suicidality in GP consultations. In: **Annual Research Day, The Institute of Mental Health**, Nottingham, 21 May 2019.

Horrocks, M. (2018). Recognising and asking about suicidality in primary care - the case for an electronic guided decision-making tool. ESRC seminar series: **Future Directions for Digital Resources in Youth Mental Health. University of Birmingham.** 23 March 2018.

Horrocks, M., Michail, M., Aubeeluck, A., Wright, N., Callaghan, P. (2017). The development of an electronic Clinical Decision Support System to assist GPs with their identification, assessment and management of suicidal presentations in primary care. Poster at **Youth Mental Health in Primary Care - what role for Primary Care? The Institute of Mental Health.** Nottingham. 25 May 2017.

Acknowledgements

A lot has happened during the time that I have been engaged in this work and I would like to take the opportunity to thank those, whom without their support, I would not have been able to complete this thesis.

I would like to thank my research supervisors Professor Aimee Aubeeluck, Dr. Maria Michail, and Professor Richard Morriss, for their endless encouragement, belief in this project and commitment to using research to improve care and patient experience. I am grateful also for the previous supervisory insights of Professor Patrick Callaghan and Dr. Nicola Wright.

I would also like to thank my colleagues in the NHS and regional suicide prevention networks, who have listened patiently to me talking about this work.

I am lucky to have been surrounded by a wonderful group of academic colleagues and fellow PhD students in the School of Health Sciences and the Institute of Mental Health. Thank you all for your inspiration, friendship, and support. Additionally, I would like to thank NIHR CLAHRC East Midlands and the Academic Health Sciences Network for granting the funding to undertake this research.

My heartfelt thanks go to the General Practitioners, patients, and suicide prevention topic experts who gave freely of their time to participate in this research. Without their kindness and passion for improving suicide prevention this research would not have been completed.

Finally, I would like to thank my partner Julie, and our son Logan for their support, encouragement, and love, which helped me cope when the going was tough.

Thank you all for inspiring, challenging, supporting and encouraging me. I could not have done this without you.

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List of abbreviations

ACiPC	Achieving Change in Primary Care (theoretical model)
CA	Content Analysis
CDSS	Clinical Decision Support System
CDSSs	Clinical Decision Support Systems
CCG	Clinical Commissioning Group
CFIR	Consolidated Framework for Implementation Research (theoretical model)
CMHT	Community Mental Health Team
CR	Critical Realism
CRHT	Crisis Resolution and Home Treatment Team
CRQA	Critical Realist Qualitative Analysis
EHR	Electronic Health Record
GP	General Practitioner (Family Physician)
GPS^3	General Practice Suicidality CDSS
NHS	National Health Service
PCN	Primary Care Network
QoF	Quality and Outcomes Framework
STP	Sustainability and Transformation Plan
SUAG	Service-User Advisory groups
TA	Thematic Analysis

Chapter 1: Introduction

1.1 Background and aims

This body of work aims to contribute to suicide prevention efforts in primary care, through developing and conducting preliminary evaluation of a suicidality clinical decision-making tool for use in primary care. This thesis adds to our understandings of how, when and why General Practitioners (GPs) working in the English National Health Service (NHS) might use a clinical decision-making tool to help them work with patients who have suicidal or self-harm related thoughts, feelings, and behaviours. The views of GPs, and people with lived experience of consulting their GP about suicidality, are explored regarding the format, content and use of the clinical decision-making tool, in order to create a tool informed by research, clinical practice and lived experiences. Building on these insights, this thesis then reports on the development and initial usability testing of the clinical decision-making tool.

Prior research has highlighted problems reported by GPs in working with patients experiencing suicidality, including difficulty building the rapport required to explore such sensitive topics in short appointments (Fox et al., 2015). Moreover, exploration of suicidality is likely to be hampered by significant time and workload pressures impacting GP clinics (Clay and Stern, 2015). Compounding these factors are variations in GPs knowledge, skills and attitudes to working with patients who have suicidal or self-harm thoughts, feelings or behaviour. Many GPs report little formal training in these areas (Saini et al., 2014). Furthermore, individual GPs may display marked variation in their willingness to enquire about suicide or self-harm (Hooper et al., 2012), and some GPs have described this area of practice as a "bag of worms" issue, which they fear might be difficult to contain or could cause embarrassment for themselves, or their patients (Bajaj et al., 2008). Given these difficulties reported by GPs, prior research (Michail and Tait, 2016; Saini et al., 2015) has explored

GPs' attitudes and views on improving suicidality risk assessment and management. Within these studies, GPs have reported their difficulty in assessing suicidality risk, and determining the most appropriate care-planning options. GPs determination of risk and risk assessment falls within the broader area of clinical decision-making (Sequeira et al., 2019). GPs have also previously reported the necessity for a clinical-decision support tool to assist their clinical decision-making in relation to patient suicidality (Michail and Tait, 2016). Tools which support and guide clinical decision making, are often referred to as clinical decision support systems (CDSSs), which have been defined as "*any electronic system which aids clinicians in making patient specific decisions pertaining to clinical assessment or treatment*" (Kawamoto et al., 2005 p.765-766).

CDSS are increasingly used in primary care, in relation to a wide range of clinical presentations such as cardiovascular disease (Peiris et al., 2009), obesity prevention (Dryden et al., 2012) and depression care (Fortney et al., 2010), but at the time of writing there is a marked lack of evidence-base in relation to the potential for a CDSS to assist GPs with the identification, assessment, and care-planning in relation to patients who may be at risk of suicidality. Furthermore, there is no existing suicidality specific CDSS which has been co-produced with GPs and people with lived experience and subject to a degree of empirical evaluation.

This thesis will address this gap by examining the need for, format, content and use of a CDSS with reference to the academic and clinical practice literatures, and be informed by the perspectives of GPs, people with lived experience of suicidality and expert stakeholders, prior to developing a suicidality CDSS and conducting a preliminary usability evaluation.

1.2 Disputed terminology in the field of self-harm and suicide

It is important to operationalise here the position taken within this thesis on the lexicon of suicide and self-harm. There are no clearly agreed ways of naming, or defining the full spectrum of suicidal thoughts and behaviours, and the literature is replete with confusing and contradictory terminology (Silverman, 2016). Over the years, a number of different clinical terms have been suggested in relation to suicide, including completed or attempted suicide, parasuicide, deliberate self-harm, and non-suicidal self-injury (Kapur et al., 2013). However, concerns have been expressed at labelling any incident of self-harm as definitively non-suicidal, when any form of self-harm has been shown to increase risk for that person's future suicide (Hawton et al., 2015; Kapur et al., 2013).

The way in which self-harm might be described by people with lived experience can include "self-punishment", "something I deserve" or something giving a "sense of relief", and potentially experienced as "addictive" escalating in frequency or severity (Wadman et al., 2016). People with lived experience of contemplating or attempting suicide might use a range of terms including "doing myself in", "stopping it [life]" and seeking "a way out" (Reeves et al., 2004). There is therefore a discrepancy between the way in which various groups of people, including professionals, people with lived experiences, and suicidologists might talk about suicide and self-harm. Partly to acknowledge this complexity, and partly to find a term to account for the wide range of behaviours implicated in the pathway towards suicide, including self-harm or past attempts, this thesis will use the term 'suicidality' to refer to any behaviour which may relate to increased risk for suicide and linked behaviours. It has been argued that the term suicidality is insufficiently precise, and that specific terms such as ideation, behaviour, attempts or suicide are more useful (Meyer et al., 2010). Nevertheless, since the pathway to suicide is complex, the term suicidality will be used and deliberately subsume self-harm behaviours within this term.

Similarly, contested terms exist within the literature to describe people using primary healthcare services. Terms frequently used include patients, service-users, clients or survivors. It has been suggested that patient or client is preferred by people with lived experience of mental health distress over the generic term 'service user' (Simmons et al., 2010). In this thesis the term 'patient' will be adopted as the most accurate term to describe the service-recipient relationship of people using primary healthcare services, cognisant that whichever label is used to describe people identifies a power dimension and hierarchy of control (McLaughlin, 2008). Whilst the term 'patient' may be loaded with important historical, political and sociological nuances it remains the term arguably best suited to describe the relationship between a medically qualified caregiver and the person consulting.

In addition, it is important to note that various terms exist to describe the electronic medical notes systems used in primary care to record patient data. Terms used in the literature include patient notes, GP records, GP clinical information systems, and Electronic Health Records (EHR). This thesis will adopt the latter, as this term is commensurate with a large body of literature in relation to CDSS development and CDSS integration with primary care IT systems (Romano and Stafford, 2011; Sittig et al., 2008).

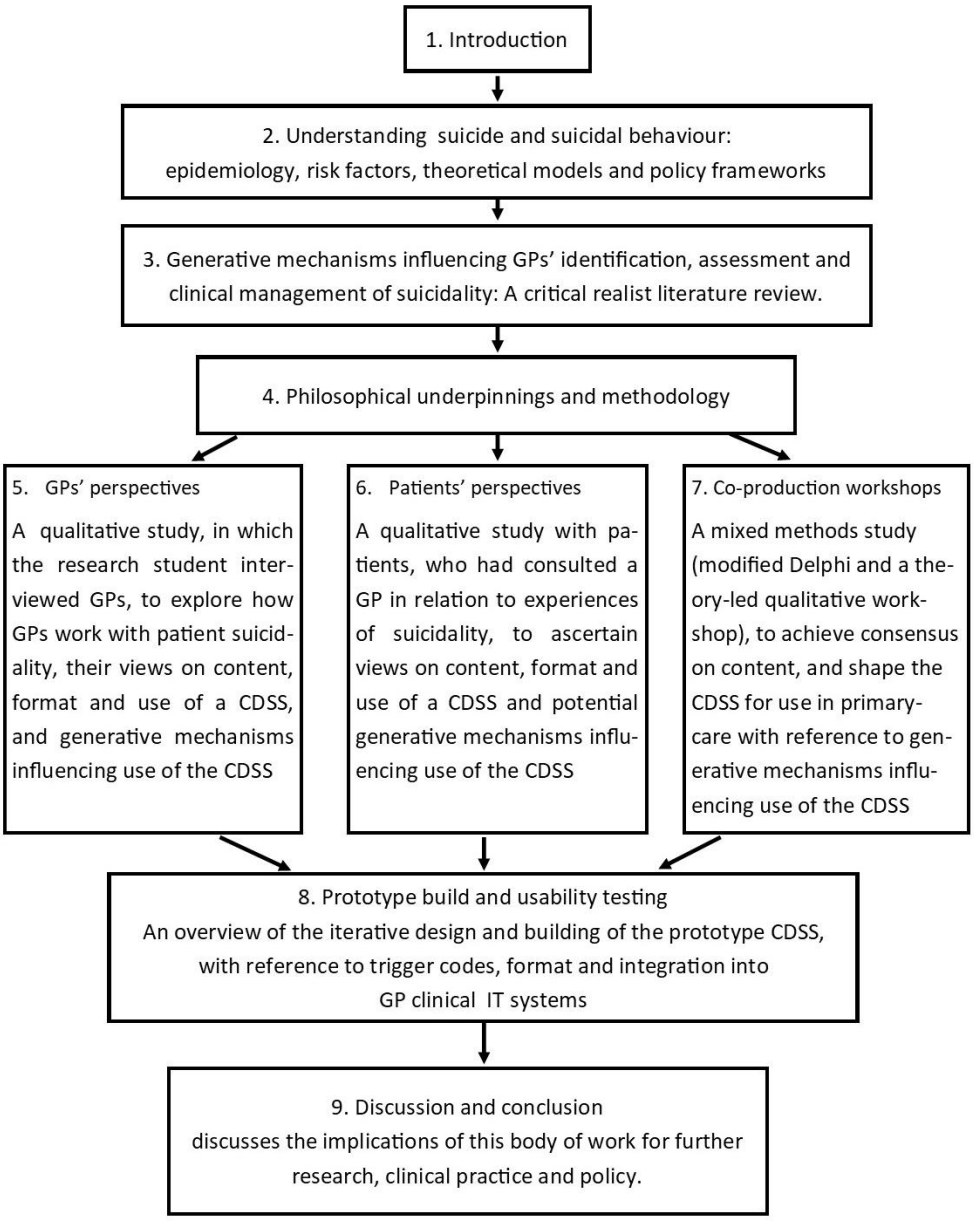
1.3 Reflexive statement

As the research student undertaking this work, it is important to reflect on my background and perspective that I bring to this body of work. I work as a qualified Cognitive Behavioural Psychotherapist within an NHS primary care psychological therapies service. In this role I have gained prior experience of supporting patients and GPs, in relation to patients' suicidality distress. Through my employment I have gained awareness of the demands of primary care practice and some of the factors impacting GP consultations in primary care contexts. These experiences have shaped my view of primary care consultations, service provision and the tripartite interface between patients, clinicians and systems of care.

1.4 Thesis structure

The thesis will present a structure consisting of a detailed literature review, in two parts (chapters 2 -3), contextualising suicide and suicidal behaviour, along with highlighting generative mechanisms potentially influencing use of the CDSS. The literature review is then followed by an overview of the philosophical underpinnings (chapter 4) and 4 empirical studies (chapters 5-8). The empirical studies then feed into the discussion and conclusion chapter (chapter 9). Figure 1-1 illustrates the thesis structure as a flow diagram:

Figure 1-1: Thesis structure flow diagram



Chapter 2: Understanding suicide and suicidal behaviour: epidemiology, risk factors, theoretical models and policy frameworks

2.1 Introduction

Chapters 2 and 3 present a literature review in 2 parts, both guided by Critical Realism as the underpinning philosophy for this thesis. The aims of the review are to:

i) Explicate the structure and context relevant to the phenomena of interest from the writer's point of view (Wynn and Williams, 2012). In a critical realist approach, this usually includes description of structural entities, constituent elements, and contextual conditions in which the phenomena of interest are situated (Wynn and Williams, 2012).

ii) identify potential generative mechanisms (e.g. individual, interpersonal, contextual or social) most likely to influence GPs' identification, assessment and clinical management of suicidality and GPs' potential use of a suicidality CDSS in primary care.

Therefore, chapter 2 considers epidemiological perspectives and known risk factors for suicidality. The economic costs and current suicide prevention theories and policy frameworks are also reviewed. Together these factors highlight the background, context and need relevant to the development of a suicidality CDSS for use in primary care.

Consequently, chapter 3 explores and identifies the factors, or generative mechanisms, most likely to influence GPs' identification, assessment and clinical management of suicidality and GPs' potential use of a suicidality CDSS in primary care. The literature review seeks to contextualise and highlight factors pertinent to GP's identification of suicidality, and factors which mediate their response to patients and GPs' potential use of the CDSS.

2.2 A Critical Realist approach to literature review

The literature review is guided by Critical Realism (CR) as the underpinning philosophical stance for this thesis. CR is a post-positivist approach which recognises limitations in both traditional positivist and interpretivist research paradigms (Lincoln and Guba, 2000). CR proposes reality is comprised of that which can be observed ('the empirical'), that which is occurring and which influences what is observed ('the actual') and the factor or factors which give rise to the empirical ('the real') (Bhaskar, 2008). Factors associated with 'the real' are thought to be general tendencies termed 'generative mechanisms', which cannot be observed, but when activated produce observable effects. CR informed research seeks to provide a nuanced account of what is observed and experienced by identifying suggested generative mechanisms and providing an explanation for how and when mechanisms might be activated (Mingers and Standing, 2017; Walsh and Evans, 2014)

Approaches to literature review grounded in the philosophical standpoint of CR have been put forward (Edgley et al., 2014; Okoli, 2015). Since generative mechanisms may be less obvious in certain descriptions or disciplinary approaches, CR allows consideration of broad literature including randomised trials and empirically published papers, as well as theoretical perspectives derived from a range of different academic disciplines, and practitioner knowledge (Edgley et al., 2014).

A CR informed review serves a theory building approach, drawing upon both realist and critical realist insights to highlight salient factors which may not be empirically observable (Edgley et al., 2014; Okoli, 2015). From this perspective, studies and material included in the review are treated as observations (the empirical), providing a documentation of events (the actual), which theoretically stem from underpinning generative mechanisms (the real) (Okoli, 2015).

The approach taken is explicitly not a systematic review of empirical papers, since academic literature may miss important insights from practitioner knowledge or other disciplines. Furthermore, there is likely to be a paucity of papers specifically relevant to GPs' identification, assessment and clinical management of suicidality and potential use of a suicidality CDSS.

Instead of a systematic approach, an iterative approach, designed to be broad in scope is used to examine a breadth of literature, whilst considering the most likely sources where relevant theoretical contributions may be found (Okoli, 2015). A CR informed review also directs attention towards gaps in current knowledge, highlighting issues that are implied but not stated, or under-explored in the existing literature, whilst aiming to explicate concepts and build theory (Edgley et al., 2014).

The interpretive stance of the CR review is therefore similar to other forms of narrative reviews, which seek to address broad questions, and provide interpretation and deepen understanding (Greenhalgh et al., 2018). Greenhalgh and colleagues (2018) contrast with the more focused, precise and conventional systematic review method and conclude narrative and systematic reviews are both useful, but answer different questions.

Adopting a CR perspective allows a creative approach to reviewing literature pertinent to GP consultations in relation to suicidality, and prospective use of a suicidality CDSS, since healthcare delivery is considered as simultaneously a clinical intervention and social practice

A key aspect of CR informed methodology involves the researcher's engagement in a hermeneutically based approach to understanding social events and practices, usually leading to qualitatively constructed explanation and understanding (Price and Martin, 2018). Key aspects of social structure and context relevant to the phenomena of interest are then examined, with a description of

structural entities, constituent elements and contextual conditions in which the phenomena of interest are situated (Wynn and Williams, 2012).

For Bhaskar this process, referred to as theoretical re-description, involves a deductive analysis considering the phenomena of interest with reference to likely generative mechanisms (Bhaskar, 2008). However, it is important to note that CR informed research, makes the assumption that open-systems ontology exists, meaning most events are seen as resulting from a multiplicity of generative mechanisms. From this perspective, the CR review seeks to highlight the interaction of potential key generative mechanisms occurring within wider structural contexts.

The CR review is at heart therefore an interpretive and creative process (Edgley et al., 2014), whereby the researcher seeks to build theory, and identify structural entities, contextual conditions and prospective generative mechanisms in the literature returned.

2.3 Method

This review draws upon Edgley et al.'s (2014) CR review method, beginning with a broad and tentative question, expressed in the format of Population (P), Interest (I) and Outcome (O). From this starting point, the search strategy is iterative, meaning a precise review question or format for the review is not specified in advance. The review is therefore designed to be open and to allow creative examination of the topic of interest, whilst being clear about the basis on which inferences are made (Edgley et al., 2014). The iterative nature of such a review can aid determination of the extent to which published research, theories, or data may contribute towards building a description and explanation of the phenomena under investigation (Ranyard, 2014).

The initial research questions were formed as outlined below:

Q1) *How do GPs (P) identify, assess and manage (I) patient suicidality in primary care (O)*

Search terms of interest were identified from the U.S. National Library of Medicine's curated medical vocabulary resource, known as MeSH (Medical Subject Headings). Search terms reflecting the P-I-O framing of the question were identified within the MeSH browser (https://meshb.nlm.nih.gov/search) and combined as Table 2-1

Table 2-2-1: RQ1 Search terms

Column terms combined with:	Population (General practice)	Interest (Suicidality)	Outcome (Identify, assess, manage suicidality
Or	1, General Practice (MeSH)	1, Suicide (MesH)	1, Risk management (MeSH)
Or	2, Family Practice (MeSH)	2, Self-Injurious Behavior (MeSH)	2, Risk Assessment (MeSH)
Or	3, Physicians, Family (MeSH)	-	3, Mass Screening (MeSH)
Or	4, Physicians, Primary Care (MeSH)	-	4, Diagnostic Techniques and Procedures (MeSH)
Or	5, Physicians, General Practice (MeSH)	-	-
Or	6, Primary Health Care, (MeSH)	-	-
	Combine 1-6 using 'AND'	Combine 1-5 using 'AND'	Combine 1-4 using 'AND'

A second question was then formed to incorporate additional broader MeSH headings in relation to the interest of clinical decision support and suicidality.

Q2) *How could an e-CDSS assist GPs to identify, assess, and manage suicidality in primary care?*

Table 2-2-2: RQ2 search terms

Column terms combined with:	Population (General practice)	Interest (clinical decision support)	Outcome Identify, assess, manage suicidality
Or	1, General Practice (MeSH)	1, Clinical Decision-Making (MeSH)	1, Risk management (MeSH)
Or	2, Family Practice (MeSH)	2, Medical Decision-Making (MeSH)	2, Risk Assessment (MeSH)
Or	3, Physicians, Family (MeSH)	3, Decision Support Systems, Clinical (MeSH)	3, Mass Screening (MeSH)
Or	4, Physicians, Primary Care (MeSH)	4, Decision Support Techniques (MeSH)	4, Diagnostic Techniques and Procedures (MeSH)
Or	5, Physicians, General Practice (MeSH)	5, Quality Improvement (MeSH)	5, Suicide (MesH)
Or	6, Primary Health Care, (MeSH)	6, Quality of Health Care (MeSH)	6, Self-Injurious Behavior (MeSH)
	Combine 1-6 using 'AND'	Combine 1-5 using 'AND'	Combine 1-6 using 'AND'

The search was restricted to English language papers since no resources were available for translation. Search dates were from database start to 29/04/2018. Search terms were entered across a range of academic bibliographic databases: MEDLINE and EMBASE, (medical and healthcare literature), PsychINFO (behavioural and psychological sciences) and ASSIA (social sciences literature). Additionally, search terms were entered into OpenGrey and GoogleScholar to identify relevant grey literature. The search-strategy also included iterative searching of study's references lists to find additional relevant material.

Following Edgley et al.'s (2014) CR review method, searches were undertaken iteratively, combining search terms into the databases and grey literature search engines. The search generated a large number of results.

Titles and abstracts were screened for relevance by the research student. Relevance was determined if the paper title or abstract pertained to self-harm or suicide (suicidality), primary care, risk

assessment and management, clinical decision making, quality improvement and healthcare delivery.

Duplicate studies were removed, and relevant studies retained with full-texts obtained and downloaded into EndNote X9. CR reviews are not intended to be systematic reviews, therefore full records of data-flow through the literature review are not necessary to a critical realist review. However, to aid transparency, an example of the results generated by the iterative combination of search terms is provided (table 2-3).

Table 2-2-3: Selected database search results

	Medline (Ovid 1946-2018)	Embase (1980 -2018 week 18)	Psychinfo (1806-week 4 April 2018)	ASSIA
1. Primary Health Care/ or family practice.tw.	73,413	64,798	18,069	50,726
2. suicid*.tw	59,372	81,876	58,341	29,946
3. Decision Support Techniques/ or Decision Making/ or decision making tool.mp.	99,119	208,722	67,154	47,015
4. Patient Care Planning/	37078	29,200	6757	22,162
5. (assessment or risk assessment).mp.	1,049,614	2,192,891	353,943	161,534
6. 1 and 2	563	354	456	5,860
7. 3 or 4 or 5	1,162,276	2,392,867	42,0556	47,015
8. 6 and 7	195	113	137	2,559
9. limit 8 to (human and english language)	192	101	133	2,559

The search was not intended to be systematic, since CRs reviews eschew systematic and quasi-systematic approaches (Edgley et al., 2014), instead proceeding in an iterative manner, as the research student developed theory relating to candidate generative mechanisms.

As papers were read, and additional sources obtained from reference lists, the research student sought to employ abductive reasoning to identify potential generative mechanisms of interest. The use of abductive reasoning in such-a-way is common in CR informed research (Wynn and Williams, 2012). The CR informed literature review employs abduction rather than induction or deduction, in attempt to provide the most plausible explanation for empirical observations (Miller and Brewer, 2003). Possible explanations considered to be most coherent and possessing greatest explanatory power in relation to the available evidence, are tentatively put forward as the best explanations (McEvoy and Richards, 2006). Within the CR literature, abduction is sometimes referred to as *retroduction* (an attempt to identify generative mechanisms underpinning observed phenomena) or *retrodiction* (the potential application of previously identified mechanisms to new settings or contexts) (Wynn and Williams, 2012). Retroduction has been defined as a distinctive form of inference which:

> *"posits that events are explained through identifying and hypothesising causal powers and mechanisms that can produce them"* (Hu, 2018) pp.122

CR informed research, employing abduction, retrodiction or retroduction is therefore an intuitive and creative process, which endorses a pluralist view of research in attempt to confirm or deny the existence of hypothetical generative mechanisms (Mingers, 2006). In order to identify potential generative mechanisms a broad sweep of the literature was conducted, to explore inferred interaction between structural entities, and specific contextual factors (Wynn and Williams, 2012), in order to provide theoretical explanation relevant to the research questions. Within this CR informed literature review, retrodiction and retroduction are adopted as modes of inference used to build an account of the structural entities and contexts surrounding GP's determination of patient suicidality and advance an explanation

as to how GPs identify, assess and manage suicidality in primary care and how a suicidality CDSS might assist.

2.4 Results

The results of a critical realist literature review are the reviewer's attempt to unpack concepts and build theory, shaped by the reviewer's epistemological and ontological assumptions (Edgley et al., 2014). As such, the results should be treated as a tentative, deductive analysis, or theoretical redescription (Bhaskar, 2008) of the structural entities, constituent elements, and contextual conditions in which the phenomena of interest are situated (Wynn and Williams, 2012).

In this section, structural entities and contextual conditions surrounding GP's determination of patient suicidality are explored. Epidemiological perspectives and known risk factors are considered. The economic costs and current suicide prevention theories and policy frameworks are also reviewed. Together these factors highlight the background, context and need relevant to the development of a suicidality CDSS for use in primary care.

2.4.1 Epidemiology of suicide

Suicide is considered a global health concern, claiming the lives of more than 700,000 people (World Health Organisation, 2021) Epidemiological studies highlight that suicide can occur across the life-span and in all groups of people (Sinyor et al., 2017). Typically, suicide mortality is presented as suicide rates in relation to the overall population, using conventional measures of mortality and morbidity, such as the rate per 100,000 population. This convention is adopted internationally in public health approaches to allow comparison between populations of varying size and to provide incidence rates during specified time intervals. Although the highest recorded rates of suicide for men and women is consistently found in Eastern Europe, the highest actual number of suicide recorded deaths is in Asia owing

to the relative size of the population (Bertolote and Fleischmann, 2002a). The concept of prevalence is not used in relation to completed suicide, because the definition of prevalence extends to the proportion of a population who continue to have the disease or condition at a specific point in time, whereas suicide deceased no longer exist within the population (Fernández-Niño, 2016). Instead, the incidence, or suicide rate is used. Because the suicide death rates in the US and other developed countries were higher in 2010 than in 1950, suicide has been described a challenging public health problem, (Claassen et al., 2014). The increase in suicide death rates over time contrasts sharply against the overall trend of increased live expectancy and reduced mortality from myriad other causes in most countries over time (Klenk et al., 2016). In recent years, considerable work has been devoted to improving surveillance of suicide related events (Data and Surveillance Task Force of the National Action Alliance for Suicide Prevention, 2014). It is possible therefore, that the observed temporal increase in recorded suicide death rate reflects improved public health monitoring, recording and reporting practices. Nevertheless, suicide remains a significant public health problem.

Suicide deaths amount to 1.4% of all premature deaths worldwide (Bachmann, 2018) with suicide consistently among the ten leading causes of death in most countries where data is available (Bertolote and Fleischmann, 2002b). Suicide is also among the ten leading causes of loss of age standardised years of life across most of the world's continents (Naghavi, 2019).

However, the total number of suicide deaths is likely to be far larger than official estimates allow, since it has long been suspected that suicide death rates are significantly under-reported (Linsley et al., 2001). Suicide deaths may potentially be erroneously recorded as an accident (Stanistreet et al., 2001), and a narrative verdict given, rather than a determination of suicide (Hill and Cook, 2011). In the U.S., requirements for recording suicide death comprise high evidentiary standards including corroborative evidence such as a

suicide note, testimony from reliable witnesses, and history of suicide attempt or psychiatric service use (Rockett et al., 2014). In the U.K., the standard of proof for a suicide conclusion has recently been reduced from being beyond reasonable doubt, to being within the balance of probabilities (Appleby et al., 2019), reflecting a shift from a criminal to a civil standard of proof. Appleby and colleagues (2019) suggest this change will lead to higher recorded suicide rates, which some argue will more accurately reflect true numbers of suicide deaths. However, judgement of suicide within the balance of probabilities is firmly an interpretative act.

Rather than being objective, ontological facts, suicide classification will increasingly rest on the determination of the deceased person's intent, which may be shaped by coroners' perspectives and perceptions. Furthermore, the determination of suicide by a medical examiner (pathologist) or coroner seems particularly at risk of misclassification in self-poisoning cases, owing to the difficulty determining intent (Rockett et al., 2014). Coronial judgements about intent are not immune to dominant social narratives and attributional misjudgement (Tait et al., 2018). Therefore, there is the strong likelihood that the recording of suicide may be skewed as a result of errors, biases and interpretive attributions.

In addition, the way in which suicide is categorised by extant data-recording mechanisms may also misrepresent the total burden of suicide. The suicide death rate categorises suicidal acts as singular events, in the way that unforeseen injuries are categorised, however in reality suicidal behaviour is usually preceded by functional decline or a chronic recurrent process (Claassen et al., 2010). Therefore, Classen and colleagues (2010) argue suicide should be considered akin to a disease in order to more accurately account for the total burden of suicide. Adoption of this conceptualisation of suicide allows for a consideration of a far wider range of precipitating and contributory factors.

2.4.2 Global burden of suicide

A landmark series of publications, known as the global burden of disease studies, identified mental health and substance use disorders as the leading cause of years lived with disability worldwide (Whiteford et al., 2013) and the fifth largest contributor of burden of disease (Ferrari et al., 2014). These contemporary estimates of the global burden of disease sought to calculate disability adjusted life years in relation to a range of health problems, by integrating years of life lost and years of live lived with disability. However, these estimates split the burden of mental health problems from the burden of suicide and self-harm (Ferrari et al., 2014). Ferrari and colleagues (2014) argued that this split led to an incomplete estimate of the total burden of psychological distress. Whilst therefore classified separately, mental health and suicide frequently co-occur, to the extent that it has been argued by all forms of suicide can be ascribed to an underpinning mental health problem (Vigo et al., 2016). It is possible therefore that the separation of the estimated burden of mental health and suicide leads to under-appreciation of the full burden of both categories.

Furthermore, the burden of suicide usually fails to consider the full extent of self-injurious behaviour. A tendency to separate the burden of suicide from self-harm is problematic because any form of self-harm has been shown to increase risk for that person's future suicide (Hawton et al., 2015; Kapur et al., 2013). There are also conceptual problems with the separation of suicidal self-harm and non-suicidal self-injury (Kapur et al., 2013). Thus, accounting for suicide and self-harm separately is misleading. Self-harm, or self-injurious behaviour is defined as any behaviour where someone intentionally causes harm to themselves, usually to help cope with distressing or difficult thoughts and feelings (Foye et al., 2016). Common forms of self-injurious behaviour include cutting, burning or non-lethal overdoses,

but the definition may extend to any behaviour which causes self-injury and physical, psychological or emotional harm. This can include harm to the self, arising from excessive consumption of alcohol or recreational drugs, intentional mismanagement of physical health conditions, self-starvation and eating disorder, as well as body piercing and modification (National Collaborating Centre for Mental Health, 2012). Self-injurious behaviour and suicidal thoughts, feelings and behaviours often coalesce within individuals (Grandclerc et al., 2016). Estimates suggest that between forty to sixty percent of people who die by suicide have previously engaged in self-harming behaviours (Owens et al., 2002). Therefore, the separation of suicide and self-harm may lead to erroneous estimates of the burden of suicidality and confound our appreciation of the full costs and impact of suicidality on society.

Given the questionable accuracy of the estimated true burden of suicidality, underpinned by only moderately accurate epidemiological data, the actual extent of suicidality is likely under-reported and under-estimated (Bakst et al., 2016). Yet, taking into account what is known about the burden of suicidality, it is clear that suicidality remains a major public health problem worldwide and, in the U.K., leading to lives lost, impaired and profoundly altered, and exerting significant socio-economic costs.

2.4.3 Economic costs

The economic cost of suicide comprises direct costs, including cost of medical care and medicolegal expenses such as autopsies and coroners courts, as well as indirect costs, such as loss of actual and estimated earnings to premature death or permanent disability (Yang and Lester, 2007). Furthermore, numerous additional adverse consequences can result for those left behind including decreased familial economic security and relational stability, along with impaired psychological health and loss of economic productivity for the nation

(Jenkins and Singh, 2002). Each suicide death is likely to affect approximately one hundred and thirty five individuals, to a varying extent (Cerel et al., 2018). It is apparent therefore that each suicide death is likely to have significant economic concomitants.

The total cost to the UK economy for the suicide death of each working aged adult, using a full economic costing model has been estimated as £1.67 million pounds (McDaid et al., 2011). This economic model was calculated using 2009 indexed prices for the cost of health and social care, including possible A&E, hospital and emergency services costs, as well as costs attributed to coronial determination and loss of earnings. It is likely that year on year these prices may continue to rise in response to cost inflation.

Like suicide, self-harm is associated with high fiscal and societal costs, including direct costs of health service utilisation, where repeat self-harm leads to increased expense (Larkin et al., 2014), and indirect costs such as the impact on family and friends (Ferrey et al., 2016).

The annual cost of NHS hospital treatment for self-harm has been estimated as £162 million per year, taking into account presentations at A&E, psychosocial assessment costs, and treatment costs derived from hospital ward or critical care unit admissions (Tsiachristas et al., 2017). However, it has been argued that the majority of costs relating to self-harm lie outside of healthcare systems (Kinchin et al., 2017). Kinchin et al (2017) contend self-harm behaviour may lead to loss of potential years of life and productive life years, and increased disability claims, which when taken together far exceed the direct cost of healthcare treatment. Indirect costs to families, resulting from the person engaging in self-harm behaviour, have been estimated to be as much as ten percent of the total mean cost per patient, at the point of health service discharge; however, long-term follow-ups have not been undertaken and detailed cost estimates of non-fatal self-harm remain rare (McDaid, 2016).

Prevention, or delay of self-harm and suicide results in reduced costs to the economy. McDaid et al (2011) argued that even in cases ultimately ending in suicide where prevention was not realised, if health workers can potentially delay the eventual suicide of a working age-adult, they may avoid costs to the economy of £66,797.00 per year. Such an argument makes a strong case for health and social care professionals to see suicide prevention as an economically important part of their clinical activity.

A more recent economic modelling study found that training primary care staff to better identify suicide risk amongst people diagnosed with moderate to severe depression, could prevent more than 600 suicides over a 10 year period, resulting in preservation of a vast number of Quality Adjusted Life Years (QALYs), at a cost per QALY that would be considered highly cost-effective in relation to current commissioning guidance (McDaid, 2016).

In summarising the economic evidence, it has been claimed that investing one pound in suicide prevention efforts targeted at young people and adults, results in a £2.93 cost saving to society over a ten year period (Burstow et al., 2018). Suicide prevention therefore has been described as 'a best-buy' health promotion initiative likely to generate beneficial long term impact (Burstow et al., 2018).

2.4.4 Populations at risk

Research shows a very wide range of population groups are at increased risk of suicidality. The UK government's Office of National Statistics (ONS) reported 5,691 deaths registered as suicide in 2019, with the highest suicide rate in England and Wales this century (16.9 per 100,000) (Manders and Windsor-Shellard, 2020) The report produced by Manders and Windsor-Shellard (2020) presents longitudinal population level data highlighting that while overall suicide rates in the UK have been gradually declining, recent years

have seen an increased rate among certain groups, including people aged under twenty five, and in particular young women.

2.4.4.1.1 Males

Since 1950 suicide rates indicate a considerably higher rate of completed suicide in men compared to women in most countries world-wide, with the exception of China where the inverse is apparent, especially in rural areas (Bertolote and Fleischmann, 2002a). The discrepancy in China appears attributable to specific cultural factors, traditional gender and social inequalities, relative paucity of services and ready availability of means of suicide (World Health Organisation, 2009). Furthermore, worldwide it is thought that for each adult that dies by suicide, more than twenty people attempt suicide (World Health Organisation, 2014). Globally, completed suicides are three times more common in men than women, however, attempted suicides are reported more frequently for women (Bachmann, 2018). Explanations for the considerably higher rate of attempted suicide in women include higher recorded incidences of anxiety and depression, socio-economic factors, disempowerment and oppression (Vijayakumar, 2015). Experiencing sexual violence, failed fertility or loss of children also appear significant factors influencing female suicidality (Mallon et al., 2016). However, it must be considered that statistics in relation to female suicide attempts could reflect gendered role behaviours, such as women being more likely to report emotional or psychological problems to healthcare providers (Oliver et al., 2005). Conversely, males experiencing suicidal ideation are less likely to seek help or consult health service providers (Hom et al., 2015). Following from this gendered behaviour, there is the possibility that women would be more likely to attend healthcare consultations and therefore perhaps more likely to be asked about suicidal thoughts, feelings or behaviours, thus potentially contributing to the higher recorded statistics for women's suicide attempts.

2.4.4.1.2 Young people

Adolescents and young people up to the age of 25 are at elevated risk of suicide (Serafini et al., 2015). Recent years have seen a sustained increase in the suicide rate among people in the U.K aged between 10 to 24 years old, with a 30% increase among men aged 20 to 24, and highest ever recorded suicide rate for young females (the Samaritans, 2019). Similarly, self-harm rates among young people have also risen (Rodway et al., 2020). The marked increase in suicidality may reflect a range of factors including high levels of social media use entailing exposure to internet risks, economic adversity limiting economic freedoms, high thresholds to access mental health services and increasing demands for mental health support (Rodway et al., 2020). Antecedents of suicidality in young people include being classified as a looked after child, experiences of childhood abuse, witnessing domestic violence, family histories of mental health problems, previous self-harm and substance abuse (Rodway et al., 2020). Other known risk mediators in young people include academic pressures, bullying, bereavement, and physical health conditions (Rodway et al., 2016).

Women aged under 25 who go onto die by suicide are often identifiable by a distinctive risk profile comprising a personality disorder diagnosis, historical self-harm, and a tendency toward substance misuse as a coping strategy (The National Confidential Inquiry into Suicide and Safety in Mental Health, 2019). Frequently, the majority of such clinical presentations are prone to be dismissed as low suicide risk by clinical staff (The National Confidential Inquiry into Suicide and Safety in Mental Health, 2019). The apparent under-estimation of risk posed by such clinical presentations might reflect stereotypical beliefs about the 'attention seeking' and 'manipulative' characterisation of people who attract a personality disorder label (Lewis and Appleby, 1988). In particular, it has been argued that the diagnosis of Borderline Personality disorder (BPD) is a mechanism to obfuscate strategies which some women use to cope with societally

engrained oppression and abuse (Shaw and Proctor, 2005). Downplaying the significance of the experience of women who are disempowered and oppressed might lead to a BPD diagnosis, which in turn might lead to under-estimation of potential suicidality, should suicidal thoughts or behaviour be ascribed as attention seeking. Recent longitudinal data in the UK show growing suicide rates among young women, with the use of hanging an increasingly common method of suicide (Manders and Windsor-Shellard, 2020). Similar figures have been reported in Australia (Stefanac et al., 2019), with a significant increase in suicide rates in young Australian women occurring between 2004-2014. These studies highlight the need for conceptualisations of suicide risk to include young people, irrespective of sex or gender.

2.4.4.1.3 Middle-aged males and females

Of all the age groups, men of 45 to 49 years of age, and women of 45-49 years of age are reported to have the highest age-specific suicide rates (Manders and Kaur, 2019). The reasons for the peak risk in these age bands is likely to be multi-factorial, but potential explanatory factors include breakdown of interpersonal relationships, separation from children, unemployment and redundancy, loneliness, social isolation, and difficulties accessing support (Sutherland, 2018). The factors identified by Sutherland are likely to have a higher incidence within areas of social deprivation where experiences of stress, poverty, crime, substance misuse, lack of hope and diminished future prospects are commonplace (Watt, 1996).

2.4.4.1.4 Older adults

Another distinct population group which is at higher risk of suicidality is older adults aged 75 and above. This population are unlikely to be in contact with mental health services, and more likely to report depression, physical illness and bereavement (The National Confidential Inquiry into Suicide and Safety in Mental Health, 2019).

Among older adults, those who self-harm are particularly at risk, since they are more likely to have increased suicidal ideation, and a markedly higher risk of suicide death, yet a low rate of referral to mental health services (Morgan et al., 2018).

2.4.5 Risk Factors

Suicide prevention research has long recognised that there are specific risk factors associated with increased risk, and protective factors which may serve to decrease risk for some people (Chehil and Kutcher, 2012). Both risk and protective factors can occur at individual, psychosocial or societal levels (McLean et al., 2008). Risk factor research draws a demarcation between correlated factors, risk factors and causal risk factors (Offord and Kraemer, 2000). Causal risk factors are those which can be manipulated to show a changed probability of an outcome. To qualify as a causal risk factor, a variable must proceed an outcome and be associated with the outcome at a statistically significant level (Offord and Kraemer, 2000). However, statistical significance can be an artefact of sample size, and not a marker of the strength of relationship between risk factor and outcome. Many studies in the field of suicide prevention include thousands of participants and find statistically significant results, but there are no universal criteria for assessing the clinical significance of such risk factor research (Franklin et al., 2017). Many frequently considered suicidality risk factors have been conceived in this way, but without clear strength of relationship between a risk factor and outcome they are of limited use in clinical contexts and suicide prevention policy decisions (Franklin et al., 2017; Offord and Kraemer, 2000).

Over the years, many thousands of risk constructs have been proposed, ranging from sleep deprivation, chronic pain, or psychiatric disorder, through to societal fragmentation, oppression and

deprivation. Traditionally many of the risk factors studied in research have been based on psychological autopsy and expert opinion. A recent meta-analysis of fifty years of suicidality risk factors concluded that of the multitude of risk constructs that have been tested as specific risk factors, all were weak and inaccurate predictors of longitudinal risk within the methodological constraints of the research; and that overall ability to predict suicidality risk have not improved over the past fifty years (Franklin et al., 2017). The wide range of risk factors were collapsed into fifteen categories to aid analysis by Franklin and colleagues (2017) and adapted here to situate historical scope of risk factor research (Table 2-4)

Table 2-4 Broad Suicidality risk factors (adapted from Franklin et al., 2017)

Risk factor category		Example
1	Specific biological factors	Genes, hormones
2	Cognitive deficits	Intelligence, problem solving ability
3	Implicit / explicit cognitive processes	Attentional bias, identification with suicide
4	Demographic factors	Gender, marital status, employment
5	Social factors	Abuse history, family problems, isolation, adverse life experiences
6	Family History of psychopathology	First degree relative's history
7	Psychiatric treatment history	Personal psychiatric service use
8	General psychopathology	Multiple symptoms or multiple psychiatric diagnoses
9	Externalising psychopathology	Aggression, impulsivity, substance use or incarceration
10	Internalising psychopathology	Anxiety or mood disorders, hopelessness, emotional dysregulation, sleep disturbance
11	Psychosis	Positive, negative or disorganised symptoms
12	Prior self-injurious thoughts or behaviours	Self-harm, suicide attempt or ideation
13	Exposure to self-injurious thoughts and behaviour	Close relationship with someone who attempted or completed an act of suicidality
14	Physical illness / physical health characteristics	Disability, weight, height, impaired functioning and illness related quality of life
15	Personality traits	Extraversion, assertiveness, type A

In their review, Franklin et al., (2017) found that the most commonly researched risk factors have been internalising psychopathology, demographics, prior self-injurious thoughts or behaviour, and social factors (Franklin et al., 2017).

Franklin and colleagues' review (2017) draws cautionary attention to the methodological limitations of the suicidality risk factor evidence base, accounting for the weak and inaccurate predictive power of future suicidality prediction. High heterogeneity in study design and sample selection, a focus on long-term follow up rather than short term or acute suicidality risk, crossed with low base-rate predictors and low base-rate outcomes are some of these methodological limitations.

Franklin et al's (2017) findings do not mean that risk factor research is irrelevant to identifying and assessing suicidality risk, since risk factors are often based on clinical or research experience and expert consensus. However, what is highlighted is that the substantial research in this area offers only general indications of increased risk, rather than factors which definitively increase suicidality probability. This poses challenges for healthcare professionals, including GPs, to consider which specific risk factors might increase risk, and which protective factors might decrease suicidality risk for any given patient.

2.4.6 Self-harm and its relationship to suicide

Self-harm is a well-established risk factor for future suicide (House and Owens, 2020). Yet, self-harm behaviour presents challenges for clinicians assessing suicidality risk, since self-harm frequently does not involve suicidal thoughts or intent (Hawton et al., 2015).

Even when self-harming behaviours start out as coping mechanisms for distressing thoughts and feelings, there is a risk that they will become more entrenched and more severe over time (Grandclerc et al., 2016). While this may be the case for some people, other studies conclude that there are no discernible patterns of self-harm behaviours escalating in severity or risk to self over time (Witt et al., 2019). Witt et al (2019) do however go on to suggest that suicide risk should be assessed whenever non-fatal self-harm brings the

person into contact with clinical services. This is because previous self-harm related thoughts and behaviours are among the most robust predictors of future suicidal thoughts or behaviours (Ribeiro et al., 2016). Data drawn from studies reporting on suicide and self-harm rates among people who required general hospital treatment, after self-harm suggest 40 to 60% of people who die by suicide have previously engaged in self-harming behaviours (Owens et al., 2002). However, people who go on to die by suicide after self-harm, may be a specific subsection of people who self-harm, meaning the data may under-report the true extent of the association between self-harm and suicide. This is because approximately 60% of people who self-harm do not present to hospital settings (McManus et al., 2019).

Although recent years have seen improvement in the coding and reporting of self-harm presentations to emergency departments, data quality remains variable meaning estimates of the short and long-term burden of self-harm are best described as moderately accurate (The Scottish Public Health Authority, 2017).

Self-harm is a complex phenomenon requiring examination of the dynamic inter-play between multiple psychological, social and biological factors (Townsend et al., 2016). Such an approach means self-harm behaviours should not be seen an isolated event, which is commonly how research often approaches the phenomenon (Townsend et al., 2016). Consideration of the dynamic antecedents, precipitants and maintaining factors, which start and sustain self-harming behaviour, allows for fuller acknowledgement of the burden of self-harm.

Contemporary thinking in the field of suicidology recognises that the accuracy of the estimated burden of suicide and self-harm may be questioned, because the proportion of people coming into contact with clinical services because of suicidality considerably belies the relative prevalence of suicidality in the community (Hawton et al., 2012). This discrepancy has been referred to as the 'iceberg model'

because suicide deaths are analogous to the visible tip of the ice-berg, beneath which is suicidality bringing the patient into contact with clinical services, and beneath that are the hidden experiences of suicidality not resulting in clinical contact (McMahon et al., 2014). However, numerous empirical studies show a strong association between self-harm, suicide attempts and eventual suicide (Kapur et al., 2013). Therefore, it is appropriate to consider self-harm as a part of the broader definition of suicidality used in this thesis. Current prevalence estimates of self-harm in the UK suggest that 6.4% of the population engage in self-harm behaviours, and nearly one in five females aged 16-24 report self-harm behaviour (McManus et al., 2019). The frequency of self-harm presentations in primary care is reportedly increasing and between 2011-2014 there was a 68% increase in the number of adolescent girls aged 13-16 presenting with self-harm to their GP (Morgan et al., 2017). A recent large-scale review of CPRD data for the period 2001-2013, reviewed GP consultations coded in relation to self-harm and suicidality and concluded there is a temporal pattern of increasing presentations to primary-care in relation to suicidality, with females more likely to present in relation to self-harm (Carr et al., 2016). The implication of these studies suggests that presentations of suicidality and self-harm may be increasing, particularly among young women. However, it remains important that clinicians seek to understand these behaviours within the context of the individual patient and precipitating factors relevant to self-harm occurrence at the individual level.

The complexity of self-harm therefore presents specific challenges for GPs when assessing patients, since the behaviour can function as a coping strategy, and yet is strongly associated with increased risk (Bailey et al., 2017). It is suggested that GPs respond to self-harm presentations with empathy and compassion irrespective of manifest suicide intent, since self-harm behaviour is fluid and can escalate over time (Mughal et al., 2019). This is reflected in the iceberg model

(Geulayov et al., 2018), which highlights self-harm not leading to clinical contact as a significant risk factor for suicide, analogous to the submerged part of the ice-berg. Therefore even if people who self-harm describe their behaviour as a coping strategy, or as a way of signifying distress (Harris, 2000), GPs should not consider self-harm as merely low risk and transient episodic behaviour (Bailey et al., 2017).

2.4.7 Exposure and contagion

Another specific risk factor gaining increasing attention in the literature is exposure to suicidality, which is increasingly recognised as more pervasive than previous estimates (Cerel et al., 2016). Exposure can be through personal awareness of suicidality related behaviour among family or friends (Franklin et al., 2017), and through media content (Gould and Shaffer, 1986), news coverage (Lutter et al., 2020) or internet content (Kirtley and O'Connor, 2020). Exposure to suicidality has been associated with emotional distress and impaired mental health (Feigelman et al., 2018), and some studies have demonstrated association with an increased likelihood of a future suicide attempt (Burke et al., 2010). An imitative or contagious conceptualisation of suicidality has existed for many years (Bohanna, 2013). Exposure to suicidality may make the exposed person more aware of suicidality, and its potential use of as a more valid way of coping with, or escaping emotional distress (Miklin et al., 2019). Increased suicidal desire, increased pain tolerance and reduced fear of death, collectively described as acquired capability for suicide, have been suggested as important determinants of suicidality (Van Orden et al., 2010). It is possible that for some, exposure results in suicidality being incorporated into the expose's repertoire of potential responses to future stressors, whilst for others it may reduce subsequent capacity for future suicidality (Miklin et al., 2019). Cognitive appraisal and sense-making appear to be important

mediators in this regard. However, for some people the risk of suicide contagion or imitation may exist.

Media guidelines have been produced in attempt to curb possible imitation since sensationalist reporting has been suggested as a contributory factor leading to increased exposure and spreading risk (Marchant et al., 2020). However, the effectiveness of media guidelines in reducing suicidality risk is under-researched and unclear (Stack, 2020). Nevertheless, this area of research is salient to primary care, since within the literature (the Samaritans, 2020), there are documented cases of increased incidence of suicidality among peers, or defined communities, following awareness of acts of suicidality. Moreover, a recent systematic review suggests reporting of celebrity suicide deaths can lead to increased suicide attempts and imitation of the method of death, whereas the impact of media reporting of non-celebrity suicide deaths is unclear (Niederkrotenthaler et al., 2020). However, exposure to suicide through media, or inter-personal networks, can lead to a social transmission of suicidal thoughts, feelings or behaviours, which can transcend traditional risk factors, potentially leading to multiple suicide among people with shared social links (Hill et al., 2020).

Suicide cluster is the term given to situations in which a greater than expected occurrence of suicide takes place across time or location, with at least three or more deaths (Hawton et al., 2020). Traditionally, a distinction has been made between mass and point clusters, with the former referring to suicides occurring in temporal proximity, and the later contained within time and geographic proximity (Niedzwiedz et al., 2014). A third type are echo clusters, where a recurrence of suicide is noted within a geographic space, but separated by time (Robinson et al., 2016). In attempt to explain clusters, numerous explanatory mechanisms have been proposed, with little credible empirical evidence, including social modelling, imitation, priming, and homophily (Haw et al., 2013). Homophily has been defined as affiliation with others with similar attitudes and

behavioural tendencies, where these features can become more enmeshed over time (Brechwald and Prinstein, 2011). However, the exact precipitants and causative agents underpinning clusters remain unclear. It is likely that multiple mechanisms occur and are activated at different times and in different settings, confounding attempts at understanding the clustering phenomena (Haw et al., 2013; Hawton et al., 2020).

2.4.7.1 Suicidality Bereavement

A particular form of suicidality exposure, associated with increased contagion and suicide clusters, is bereavement by suicide. Suicide bereavement impacts a significant proportion of the public, but remains a relatively hidden experience due to the stigma surrounding suicide death (Evans and Abrahamson, 2020). Though contested, some studies have demonstrated increased risk of suicidality following exposure to suicide bereavement (Bohanna, 2013). Suicide bereaved parents and mothers in particular, appear at risk of developing physical and mental health problems, using psychiatric services, and future suicidality (Pitman et al., 2014; Pitman et al., 2016). Meaning searching, and sense making can be a protracted experience after suicide death of a first degree relative due to the cognitive, emotional and relational loss (Silven Hagstrom, 2019). Experiences of stigma and shame, along with feelings of guilt and responsibility are common among suicide bereaved family and friends of the deceased, which potentially contribute to impaired mental health among those left behind (Wainwright et al., 2020). Responses to suicide bereavement, which could be described as prolonged or complex grief, have been suggested as a key mediator of future suicidality risk, and appear associated with lifetime depression risk, self-blaming thoughts and impaired social and occupational functioning (Tal et al., 2017). People bereaved by suicide report receiving less social support than other types of sudden bereavement (Azorina et al., 2019). Primary care can offer a vital support to suicide bereaved, with GPs having a key role in delivering

psychological and physical healthcare, signposting to key agencies, and providing emotional support post-suicidality bereavement (Wainwright et al., 2020). However, GPs have described feeling under-prepared to work with suicide bereaved (Foggin et al., 2016). Nevertheless, pro-active contact from GP practices to acknowledge the death, extend compassion, and signpost the bereaved to suicide bereavement groups can be experienced as helpful (Wainwright et al., 2020).

2.4.8 Socio-economic risk

There is a large amount of evidence, which serves to highlight associations between suicidality, social fragmentation and socio-economic deprivation (Platt et al., 2017). A general trend appears to exist between lower rates of suicidality and higher socio-economic areas when data is examined at the local neighbourhood level (Rehkopf and Buka, 2006). Similarly, higher area level deprivation is associated with higher suicidality rates (Platt, 2016). However, Platt (2016) cautions that significant methodological heterogeneity limits claims about the impact of social deprivation on suicidality. Therefore, there appears to be an inferred association between socio-economic deprivation and suicidality at the area level, but the strength of the association is inconclusive.

There is growing evidence that suicidality risk increases within certain occupational groups (Hawton et al., 2011). Within the U.K., manual occupations, such as labourers, construction workers, coal miners and welders have been associated with significant and increasing suicidality risk over time (Roberts et al., 2013). Other occupational groups with low employment security and uncertain career prospects including bar staff, musicians, artists and care workers have also been shown to be at increased risk (Windsor-Shellard and Gunnell, 2019). Windsor-Shellard and Gunnell's review (2019), however did not substantiate previously long-held beleifs about increased

suicidality rates among doctors and farmers in the UK, but their study only examined data over a four year period, meaning wider extrapolation is limited. In contrast, a range of previous studies suggest certain specific highly educated population groups are historically associated with high suicidality risk, including doctors, veterinarians, nurses, teachers and managerial professionals (Agerbo et al., 2007; Hawton et al., 2011; Hawton et al., 2004; Hawton et al., 2002). Access to lethal means and specialist knowledge of methods of suicidality might elevate risk within these specific occupations, as might persistent occupational stress and the relative prevalence of psychiatric disorders within these groups.

Long term unemployment and economic recission have also been highlighted as specific risk factors for suicidality (Barr et al., 2012). Widening financial, educational and employment inequalities exacerbated by economic recession have been associated with increased prevelance of mental health problems, anti-depressant prescription and suicide rates among men and less educated people (Barr et al., 2015). The impact of unemployment and recession on suicidality may be indirect, but likely to cause intermediary problems such as, defaulted mortgages, house repossesions and personal debt (Coope et al., 2014). Greater personal unsecured debt appears stronlgy associated with suicide completion and substance misuse (Richardson et al., 2013), and the more sources of debt which someone has, the more likely the risk of the person developing a mental disorder (Jenkins et al., 2008).

The importance of the realtionship between socio-economic factors and suicidality is particularly relevant currently, due to the impact of the Covid-19 coronavirus pandemic on economic stress and inequalities (Reger et al., 2020). The implication is that GPs should carefully consider the socio-economic circusmtances of patients, due to the association with suicidality risk.

2.4.9 Mental-health problems

Another population who have substantially increased risk of suicidality are people living with mental health problems. Increased risk is demonstrated across all psychiatric diagnoses, and particularly within the first few months of diagnosis (Bolton et al., 2015). While increased risk is associated with all psychiatric diagnoses, most suicides occur among people with mood disorders, psychosis and substance use, although people with psychological trauma histories, anxiety, personality, or organic psychiatric disorders are also at increased risk of suicidality (Brådvik, 2018). Beyond the immediate risk after receiving a diagnosis, other high-risk periods within the psychiatric population include during, and within 1 year of psychiatric inpatient treatment, particularly the initial weeks and months post-discharge (Large et al., 2011a; The National Confidential Inquiry into Suicide and Homicide by People with Mental Illness, 2017).

International surveys suggest approximately 50% of people who experienced serious suicidal ideation, planned an attempt and made a previous suicide attempt, have a previously diagnosed mental disorder (Nock et al., 2009). In addition, it has been argued that the strongest predictor of suicide attempts in developed countries such as the U.K. are mood disorders, PTSD, conduct disorder and substance misuse disorders (Nock et al., 2009).

it has been suggested repeatedly in the literature that unrecognised or undiagnosed mental disorder or substance use problems under pin most suicides (Ferrari et al., 2014). Such claims are usually based on psychological autopsy studies which have been described as a vital research method in understanding completed suicide (Isometsä, 2001). Traditionally psychological autopsy studies find mental disorders, whether diagnosed or suspected have the strongest associations with suicide, attributing up to 90% of suicide to mental disorder (Cavanagh et al., 2003). Other psychological autopsy studies suggest that the impact of adverse life events within 12 months of death were critical factors in the deceased persons eventual suicide

(Foster, 2011). However, the reliability and findings of psychological autopsy studies are open to question, since they have suffered from significant methodological shortcomings, including a lack of standardised procedure (Pouliot and De Leo, 2006). The lack of defined and reproducible methodology, and frequent use of non-standardised diagnostic instruments means there is wide scope for researcher or respondent biases to distort findings (Hjelmeland et al., 2012). Furthermore, it has been argued that the dominant medicalised approach underpinning autopsy studies leads to researchers inevitably considering suicide as a consequence of mental health problems (Pouliot and De Leo, 2006). Bias in clinical judgement has long been recognised since diagnosis involves recourse to interpretation of qualitive criteria (Horvath, 1964). There are a range of cognitive distortions which can interfere with physicians and researchers interpretations, including confirmation, availability and anchoring biases (Wellbery, 2011). It is highly possible that such biases could influence psychological autopsy research, particularly in the case of interviewing informants where emotional responses can bias responses (Hjelmeland et al., 2012). Bereaved others perform complex reconstruction of their narratives of causation after a suicide death, in attempt to make sense of the events that have happened (Owens et al., 2007). Such a process is also open to bias as grieving and possibly traumatised people seek to repair damage to their sense of moral identity. Furthermore, contemporary thinking in suicidology recognises that while mental health problems may exacerbate risk, suicidality is primarily a trans diagnostic consideration and not tied to any particular mental health disorder (The British Psychological Society, 2017). Nock and colleagues (2009) go on to point out that diagnosis in itself is insufficient to determine who is likely to act on suicidality related thoughts and instead suggest transdiagnostic phenomena such as impulsiveness, aggressiveness or agitation may mediate suicidality risk among people carrying a psychiatric label. It is likely therefore

that receiving a psychiatric diagnosis or treatment is correlated with increased risk but is neither causative nor predictive of the level of risk, meaning the utility of a mental health diagnostic label in targeting suicide prevention efforts is limited.

2.4.10 Criminal justice involvement

People under the care of the criminal justice services are also a group known to be at higher risk, with suicide often the leading cause of death among prisoner populations (Konrad et al., 2007). Prisoner suicide is commonly reported internationally, and studies suggest male prisoners in England are at 5 to 6 times more likely to die by suicide than members of the general population (Fazel et al., 2005). Self-harm is common among male and female inmates in English prisons and other custodial settings, with high rates of repetition and associated increased risk of suicide, particularly among male prisoners (Hawton et al., 2014). Discharge from prison is also associated with increased risk, attributed to the stress of community reintegration (Jones and Maynard, 2013). A range of historical, interpersonal, clinical and prison specific risk factors have been associated with high-risk suicide attempts (Marzano et al., 2016), including personal and familial history, offending history, comorbid mental health disorders, and specific factors within the prison, such as staffing provision or specific programmes offered. Risk is likely to arise due to a complex interaction between these individual level and contextual factors, suggesting a multidisciplinary approach would be required to manage suicidality risk among the criminal justice population (Fazel et al., 2017). Offenders serving probation are also considered a very high-risk group, and nearly 9 times more likely to die by suicide than the general population and have significantly higher suicide rates than incarcerated prisoners (Phillips et al., 2018; Sirdifield et al., 2020).

2.4.11 Societal wide distribution of risk factors

In summation, the UK statistics and the studies reviewed reflect wider epidemiological findings, that suicide can occur across the life-span and in all groups of people (Sinyor et al., 2017). This is an especially relevant finding for primary care, since in the U.K. over 90% of healthcare and the majority of patient contact with health services is provided in primary care (Stephenson, 2011). However, the accuracy of our knowledge as to whom is at risk of suicidality is however not complete. Several factors are likely to influence accurate detection and prevention of suicide, including societal stigma leading to secrecy and avoidance of clinical contact along with wide variation in knowledge and awareness of suicidality among health professionals (Chehil and Kutcher, 2012). What is apparent though is that there are broad groups who are most at risk for suicidality including men, young people, middle-aged people, people who are divorced, older adults, people living in less affluent areas, and people in the care of institutional organisations such as mental health services or the criminal justice system.

It is clear from the scope of literature reviewed that a key task in suicidality prevention is to determine whom might be most at risk, but this remains academically unanswered and clinically uncertain. Arising from this level of uncertainty, a wide range of theoretical explanations have been proposed for understanding and conceptualising suicide and suicidality.

2.4.12 Protective factors

Over the years, there have been various attempts to understand the operation and effectiveness of protective factors . Influential work in this area includes Linehans' Reasons for Living (Linehan et al., 1983). However to date most protective factors research has been inconsistent, methodologically limited, concentrated in general or clinical samples rather than people with specific experiences of

suicidality, and generated weak effect sizes (Franklin et al., 2017). Nevertheless, some studies have reported that the presence of protective factors such as spirituality or religion, close family ties, or moral objection to suicidality may mitigate against suicidality (Malone et al., 2000). More recent work has focused on using online recovery stories and narratives of people with lived experience in attempt to bolster people's protective factors (Kirkpatrick et al., 2017; Stage, 2019). Such approaches hold promise, as they are based in qualitative research exploring the lived experiences of individuals (Chan et al., 2017). Furthermore, exploration of patient protective factors are a well-known aspect of psychiatric clinical case formulation, derived from Engel's work on the biopsychosocial model (Bolton, 2014). Primary care clinicians are likely to be familiar with the concept of exploring patients' protective factors, since GPs possess experience working with patients, or their carers, to help identify factors which help keep them safe and signs which suggest they need further medical help (Edwards et al., 2019).

2.4.13 Theoretical constructs and models for understanding suicide and suicidality

A number of theories across different disciplines (e.g. psychology, sociology) have been proposed for understanding the development and maintenance of suicidal behaviour. An early influential attempt at understanding suicidality was Durkheim's seminal typology originally published in 1897 (Durkheim, 2002), in which it was argued social structures and social integration mediate suicide risk. However, a key limitation of Durkheim's work concerns the proposition that studying suicide rates at a population level enables understanding of individual behaviour (Mueller et al., 2021). In recognition that population level data can only provide limited guidance as to individual's suicide risk, subsequent work sought to identify specific individual psychological constructs thought to be associated with risk such as psychache or mental-pain (Shneidman, 1998), hopelessness (Beck et al., 1985;

Beck et al., 1974b), impulsivity (Corruble et al., 1999), and experiences of entrapment, (perception of inability to escape, or be rescued from a problem leading to psychological defeat) (O'Connor, 2003). However, such psychological constructs, like other attempts at risk-prediction based on risk-factors (section 2.3) are inaccurate and weak predictors of suicide risk (Franklin et al., 2017). In response to these known limitations, contemporary theoretical models of suicide and suicidal behaviour have been developed, which attempt to incorporate greater attention to individual differences, personality and cognitive factors, and the impact of negative life events or social circumstances (O'Connor and Nock, 2014). In this section, 3 of the most relevant contemporary theoretical frameworks are presented and critically appraised in relation to their contribution in the assessment and management of suicide risk.

2.4.13.1 The Interpersonal Theory of Suicide (Joiner, 2005)

Joiners' Interpersonal theory of suicide (Joiner, 2005), suggests suicidality results when the person perceives they cause burden for their significant others, and experience a low sense of social belonging, along with desire to die which outweighs fear of suicidality and reasons to live. The accumulation of emotional pain, leading to desire to die, along with acquiring capability to enact suicidality has been suggested as critical in the distinction between ideation and enactment (Van Orden et al., 2010).

However, Joiners' theory has been criticised as seeking to reduce the complexity of suicidality to linear causal thinking, since the constructs of perceived burden, thwarted belonging and acquired capability for suicide seek to provide universal explanation, yet are contested and pay scant attention to individual variation in meaning making or context (Hjelmeland and Loa Knizek, 2020).

2.4.13.2 The Integrated Volitional Model (O'Connor and Kirtley, 2018)

An alternative contemporary model of suicidality which seeks to explain suicidality within an ideation to enactment framework is the

integrated motivational volitional model of suicidality (IVM) (O'Connor and Kirtley, 2018). A strength of the IVM is that it seeks to synthesise a breadth of knowledge about suicidality into a cohesive theoretical framework. It seeks to account for the different processes leading to development of suicidal ideation, as well as those precipitating or facilitating an act of suicidality. The IVM incorporates insights from stress-diathesis, theory of planned behaviour and the cry of pain theory of suicidality. Stress-vulnerability, defeat, entrapment, motivational and volitional variables, such as access to means, exposure to suicidality, and suicide rehearsal, are drawn together as elements in the pathway towards suicidality. The IVM therefore offers a theoretically rich model to explain the transition from stress diathesis to acts of suicidality. The underpinning evidence supporting the model is broad and persuasive, albeit like all knowledge of suicidality, open to question. A recent study designed to show the strength of factors within the model found that a relationship exists between suicidal ideation and defeat, but suicidality was not mediated through feelings of being trapped (Tucker et al., 2016). To date there remains no direct evidence of a causal relationship between the construct of entrapment and suicidality (O'Connor and Portzky, 2018). Furthermore, whilst the IVM offers a state-of-the-art ideation to enactment model, underpinned by decades of psychological research, it may be perceived as too abstract to inform routine clinical practice in primary care. It is however highly relevant to this thesis in bringing together a conceptualisation of the psychological processes and pathway which individuals move through, before an act of suicidality. The IVM also re-emphasises the complexity of suicidality and suicide prevention.

2.4.13.3 The 3-Step theory (Klonsky and May, 2015)

Building on the insights of previous ideation to enactment frameworks, the 3-step theory has been proposed (Klonsky and May,

2015). This theory suggests suicidality is explained by four factors; pain, hopelessness, connectedness and suicidality capacity, which occur over 3 stages. The 3 stages of the pathway to enactment are described as the development of suicidal ideation, reduced sense of perceived purpose or meaning (termed disrupted connectedness), and suicidality capacity. Empirical evidence for the 3-step theory is growing (Dhingra et al., 2019; Klonsky et al., 2018). However, the theory is open to critique, as like other attempts at parsimonious explanations for suicidality, the theory may miss the vital nuances of individual experience. Instead of attempting to build over-arching explanation, it has been argued that suicidality research could be more helpful were it to focus on understanding the differences in people's pathways to suicidality (Hjelmeland, 2016).

2.4.14 Summative and inter-actional risk assessment

It is apparent from the literature reviewed that suicidality is complex, and the challenge of determining which patients are most at risk is not something which can be simply answered. Assessment of suicidality is therefore a process which requires examination of individual circumstances, as well as consideration of existing theories and knowledge (Williams, 2014). It is likely that the known clinical and demographic risk factors are mediated by multiple interacting biological, psychological, social, and contextual factors (Wasserman, 2016). This confluence of risk factors and individual circumstances makes accurate prediction difficult, and is likely to require clinical assessment taking the complexity and multifactorial nature of suicidality into account (McClure, 2000).

An assessment of suicidality within a patient consultation, also needs to consider that the extent of risk attached to an individual is likely to fluctuate over the course of time (Morriss et al., 2013). This fluctuation is driven by and responds to the interaction and counteraction of under-pinning risk, protective and contextual factors.

It has been suggested that suicidality risk assessment, and risk formulation, are discrete but linked activities, which should consider static risk factors and patient's individual thoughts, motivations, intent, planning and behaviours regarding suicidality (Silverman and Berman, 2014).

A clinically useful model of suicidality risk formulation has been suggested by Pisani and colleagues (2016), incorporating patient specific clinical risk information composed of enduring and dynamic factors, such as past suicidality and current stressors, balanced against judgement of risk, relative to population norms and current patient status, available risk mitigating resources, and foreseeable changes (Pisani et al., 2016). Pisani and colleague's model moves away from categorisation of risk as low, moderate or high, and instead focuses on patient specific risk formulation with reference to the known population, demographic and biopsychosocial risk factors. The model is clinically focused, adaptable to different practice contexts, and explicitly acknowledges that temporal changes in risk are possible. It has clear utility in clinical practice and education. However, the main limitation of the model is that it has not been subject to empirical evaluation, and its impact on clinical consultations and clinical decision making is unclear. Creating a detailed risk formulation may be difficult within the primary care context, due to the significant time pressures and variation in GPs experience, knowledge and willingness to discuss suicidality with patients. In addition, some might consider the key goal within primary care is to identify which patients should be referred to specialist services (Sequeira et al., 2019). From such a perspective, detailed risk formulations might appear the preserve of psychological and psychiatric specialists, whereas the task in primary care might be assessment of the individual patient's risk profile, rather than risk formulation.

A clinically useful way to conceptualise differing risk profiles is to distinguish between a range of distal risk factors and proximal

warning signs during assessment (Rudd et al., 2006) Risk factors are often static (e.g. male gender, psychiatric history, historical suicide attempt, etc.), whereas warning signs are more acute, transient, and dynamic, such as feelings of hopelessness, social withdrawal, increased anxiety and stress (McDowell et al., 2011). Warning signs can be helpfully explored during assessment and may well be amenable to brief clinical interventions. The risk factor and warning signs approach could help inform GPs' perceptions of risk and their clinical decision making. The approach also serves as a nascent form of risk formulation, whilst meeting the goal of a rudimentary risk assessment. Therefore, a multifactorial assessment model, distinguishing distal risk factors and proximal warning signs may provide clinical utility and help guide and inform suicide assessments and GPs clinical decision-making processes.

The dynamic, complex and unpredictable nature of suicidality risk identification and assessment has been carefully considered and reviewed in this chapter. Suicidality should be seen as individual and multifactorial. Suicidality may be considered resultant from personal crisis, with a range of social and individual risk factors implicated (Nordentoft et al., 2020) and completed suicide, as a final act of behaviour resulting from a range of factors, difficulties and distress (Gvion and Apter, 2012). However, the accumulated clinical and research evidence does not allow us to accurately identify who is most at risk and serves as a general indication only. Vast swathes of the population possess at least one, if not multiple risk factors, and many people could be on the pathway to suicidality unbeknownst to clinical services. It is clear, therefore, that suicidality remains a major public health problem and there is considerable need for improved suicidality prevention efforts.

2.4.15 Suicidality prevention frameworks and policies

Internationally, nation states are being encouraged to develop country wide, comprehensive suicide prevention strategies, to improve prevention within their local contexts (World Health Organisation, 2014). National suicide prevention strategies may help to identify vulnerable groups, enhance surveillance and reporting, increase awareness and contribute to risk reduction by promoting environmental and personal protective factors.

Traditionally, effective suicide prevention strategies are either population level or targeted at specific populations or groups (Chehil and Kutcher, 2012). However, it is increasingly recognised that multi-component approaches may be more effective. Such approaches might encompass improved education, awareness and gatekeeper training, screening for at risk individuals, improving access to treatment for psychiatric disorders and assertive follow up care for people carrying out acts of suicidality, restricting access to lethal means, and working with the media to ensure non sensationalist reporting of suicidality (Mann et al., 2005; Mann and Currier, 2011)

Established multi-component models exist such as Optimising Suicide Prevention Programs and their Implementation in Europe (OPSI-Europe). OPSI Europe incorporates four principal levels, including separate training for GPs and community gatekeepers, public education and awareness campaigns, and facilitating self-help groups and informational resources (Hegerl, 2016). Such approaches appear to have merit, with the number of completed and attempted suicides recorded reducing by 24% over a 12-month period in one German city (Hegerl, 2016). A synergisitc nature between the different aspects of multi-component programmes has been suggested, but to date there is no firm evidence that multi-component approaches are more effective than their strongest indivudal compoents (van der Feltz-Cornelis et al., 2011). In their systematic review van der Feltz-Cornelis and colleagues (2011) identified 6 key aspects of mult-component suicidality preventions. These were training GPs, public

awareness campaings, training gatekeepers, imporving care pathways for suicide attempters, training journalists to improve media reporting and restricting public access to lethal means. Whilst the cumulative and synergisitc aspect of the multi-compontent programmes is unclear, the individual components are not unreasonable.

Another much heralded multi-component approach is the zero suicide movement, stemming from the perfect depression initiative in Detroit, USA. The perfect depression care sought to improve patient safety, eliminate suicides and improve patient satisfaction with their clinical care, by instigating culture change at orgnasiational and individual profesisonal levels within healthcare systems (Coffey, 2015). Strategies to reduce suicide rates included means restriction, training for healthcare providers, patient follow up after routine appointments and facilliating access to peer support (Hogan and Grumet, 2016). The zero suicide programme focuses on the assessment and management of suicide risk in healthcare settings, through a process of organisational culture change and widespread use of standardised risk screening, targeted intervnetions and improved care pathways (National Action Alliance for Suicide Prevention Clinical Care and Intervention Task Force, 2012). Empirical support for the zero suicide model is however questionalbe. Preliminary evaluations have been conducted in localised areas by healthcare delivery orgnasiations with pecuniary interests. Furthermore, without large scale, metodologically complex controlled evaluation it is impossible to casually relate reduction in suicidality to any specific suicidality prevention effort (Labouliere et al., 2018).

However, the zero suicide model is gaining popularity among UK policy makers, and is being trialled in a small number of UK health services (Matthews-King, 2018). Concerningly, since zero suicide considers every patient suicide death as entirely preventable, each occurrence of patient suicide may be framed as a culpable failure on the part of health professionals (Sisti and Joffe, 2018). Some health

professionals, including GPs, already consider suicidality "a bag of worms issue" (Bajaj et al., 2008). The implicit connotation of blame attached to suicide within the zero programme may dissuade health workers from opening up conversations about risk with patients, due to fear they might be exposed to additional professional risk (McGowan, 2017). Fortunately, zero suicide is not yet part of the English national suicide prevention strategy.

2.4.16 England's national suicide prevention strategy

The national suicide prevention strategy for England (Department of Health, 2012), emphasised improved suicide prevention at both the general population level and specific targeted population groups. Specific groups identified at risk included children and young people, survivors of abuse and violence, military veterans, people living with long term health conditions, people in financial precarity, people with substance misuse, people with suspected but undiagnosed mental health problems, people from black and minority ethnic groups and asylum seekers and people who identify with non-normative sexual orientations. The third annual review of the strategy added people who self-harm as another at risk group (Department of Health and Social Care, 2017). The national strategy therefore described a vast swath of the population as potentially being at risk, but offered little guidance for identifying who may be at acute risk in the short-term. Primary care is identified numerous times throughout the national strategy as a key context for improving suicide prevention efforts. This is because GPs routinely work with patients who have many known risk factors, are key gatekeepers to specialist services and are often the first point of healthcare contact for people in psychological distress (Department of Health, 2012). More recently, the NHS five year forward view for mental health (NHS England, 2016b), and the NHS Long Term Plan (NHS England, 2019b) have continued to emphasise reduction in suicidality as a key concern. Primary care has therefore continued to be identified as an area for improved suicidality prevention efforts. The NHS Long Term Plan (2019) also

specifically identified the need for a suicidality specific clinical decision support system to enhance GPs ability to deliver personalised care to people at suicidality risk (Michail et al., 2020). It is clear then that England's suicide prevention strategy places explicit emphasis on GPs working as part of a multi-component and multi-agency approach, and because of their unique position GPs are well placed to identify, assess and care plan for people at risk of suicidality.

2.4.17 Prevention between public-health and primary-care

National suicide prevention strategies are typically led by public health approaches and the English national strategy is no exception. Public health preventative models typically target whole sections of the community and are not focused on individual cases. An established model of preventative healthcare is Caplan's model of primary, secondary, and tertiary prevention (Caplan, 1964; Caplan and Caplan, 2000).

Elaboration of Caplan's principles has led to national suicide prevention strategies commonly including a mixture of indirect and direct suicide prevention processes (Jenkins and Singh, 2002). Indirect processes are defined as attempts to reduce background factors such as access and availability of means of suicide, whereas direct processes are targeted interventions aimed at individuals more likely to be at risk (Jenkins and Singh, 2002).

Evidence suggests that strong collaboration between primary care and public health services is likely to improve population health (Institute of Medicine, 2012; Valaitis et al., 2012). It has been suggested the two specialities should be considered as the cornerstone of affordable, efficient and equitable healthcare systems (White, 2015). However, a tension exists between primary care, with its focus on individuals within the context of their families and immediate communities, and public health approaches, which focus on whole populations (Thomas and Gnani, 2012). This tension may be heightened by the English governments strategy to give

responsibility for funding, developing and innovating public health to GP consortia, as local NHS commissioners, whilst also creating Public Health England, an executive agency of the department of health and social care, tasked with over-seeing health promotion and preventative care (Department of Health, 2010). These changes have placed renewed emphasis on GPs working to reduce health inequalities and maximise population health (Royal College of General Practitioners, 2010). However, healthcare professionals report tension between patient and population level care, with skewed resource allocation towards population level targets rather than the need of individual patients. This leads to practitioners having to introduce organisational public health priorities into the consultation which may been incongruous to patient priorities (Greenway et al., 2013). This intersection of public health policy and individualised care means that within the time boundary of the consultation GPs are asked to respond to patients presenting symptoms, detect other problems, safely prescribe medication, coordinate secondary care referrals, communicate risks, opportunistically promote health, and engage patients in shared decision making (Silverman and Kinnersley, 2012). The challenge posed of reconciling state agendas and patient-centred care, is considerable for GPs. This may be particularly apparent in the case of suicidality, given its contested conceptualisation and limited utility of decades of risk factor research, amidst the significant time and resource pressures which GPs work under.

2.5 Conclusion

This chapter has underlined the global burden of suicide and the need for improved suicide prevention efforts in the UK, whilst outlining relevant policy and clinical practice contexts. The limitations of risk-factor research and clinicians' inability to accurately predict patient suicidality has been highlighted, and key theoretical models of suicidality have been reviewed. Despite extensive prior research, the existing literature only offers indications of which patients might be at risk, leaving GPs unsupported in their determination of risk and their

clinical decisions regarding patient suicidality. The need for a CDSS to help improve suicidality prevention in primary care is apparent, and the next chapter will review potential generative mechanisms relevant to GPs identification, assessment and clinical management of suicidality and potential use of a suicidality CDSS.

Chapter 3: Generative mechanisms influencing GPs' identification, assessment and clinical management of suicidality: A critical realist literature review.

3.1 Introduction

This chapter explores the generative mechanisms most likely to influence GP's identification, assessment and clinical management of suicidality and GPs' potential use of a suicidality CDSS in primary care. The findings of the literature review help to highlight factors pertinent to GP's identification of suicidality and factors which mediate their response to patients, and which might mediate GP's use of a suicidality CDSS.

3.2 Method

The method for the literature review presented in chapter 2 (section 2.3) was continued. However, within this half of the literature review a more nuanced emphasis was placed on GPs' context, normative practices in primary care in relation to suicidality presentations and risk assessment, and the roles and functions of CDSSs within primary care.

3.3 Results

Within these results presented in this section, the importance of primary care in suicide prevention and high rates of contact prior to patient's suicide death is narrated. 8 candidate generative mechanisms are presented which exert potential to mediate GPs' response to patient suicidality and their prospective use of the CDSS.

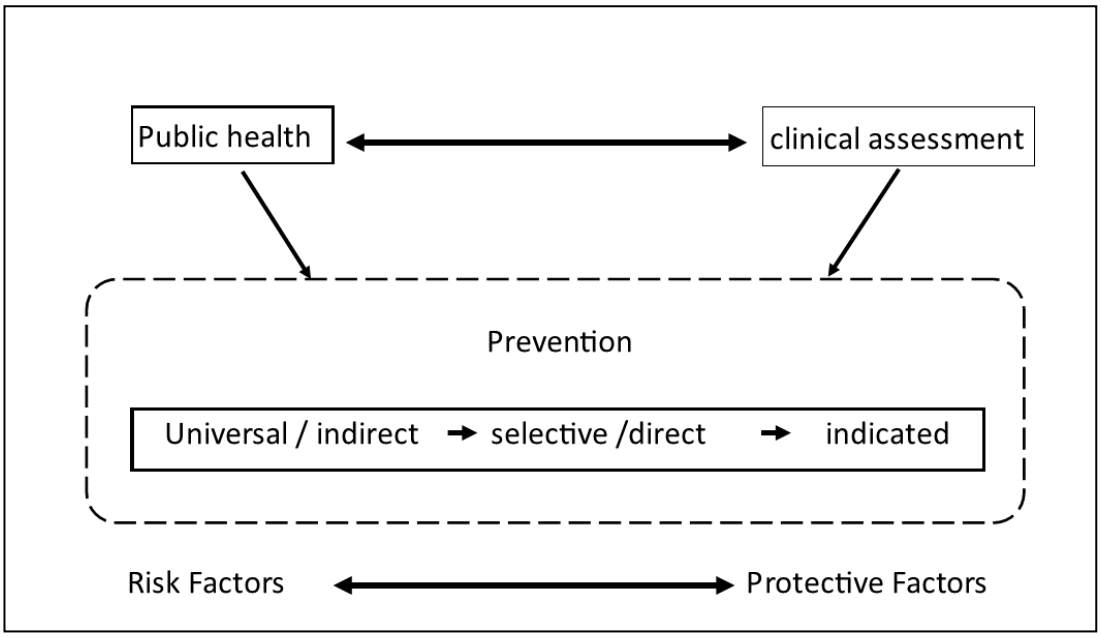
3.3.1 The importance of primary care

Bronfenbrenner's Ecological Systems Theory (Bronfenbrenner, 1979), proposed society as comprised of a range of interconnected cultural, social and structural components which come together to form a macrosystem (defined as an environment enabling human

development and behaviour). Macro-systems reflect the manifestation of overarching patterns of ideology and the organisation of societal institutions. Underpinning the development of macro-systems are interconnected entities, functioning as building blocks, including culture, sub-cultures, societal institutions, social networks, social roles, interpersonal interactions and individual behaviour. Drawing on Bronfenbrenner (1979), it is possible to consider a socio-ecological macro-system of care for suicidality, comprised of a range of cultural, social and structurally interconnected components, including ethical and moral concerns, socio-economic considerations and public health or preventative agendas.

The responsibility for leading suicidality prevention and care sits somewhere between public health and clinical specialities, particularly psychiatry given the degree of association between mental disorder and suicidality (Bertolote, 2004). Bertolote (2004) articulates a model for suicidality prevention, highlighting the interplay of public health perspectives, clinical assessment and preventative approaches. Clinical assessment requires consideration of risk factors offset by protective factors. Conceptual categories of preventative interventions are proposed as universal, selective or indicated. Selection of preventative interventions therefore could be matched to specific patient presentation. This model broadly corresponds to Indirect and Direct suicidality prevention (Jenkins and Singh, 2002), but has the added utility of locating clinical assessment within larger structural and contextual suicidality prevention.

Figure 3-1: suicidality prevention, public health and clinical assessment perspectives, (adapted from Bertolote 2004, and Jenkins and Singh, 2002)



However, Bertolote's identification of psychiatry as the key clinical speciality in suicidality care may be misguided, since contemporary understandings of suicidality, such as the iceberg model (Geulayov et al., 2018) recognise prevalence in the community far exceeds that in specialist mental health services. As reviewed in chapter two, primary care is the speciality most likely to be in contact with the full range of at-risk groups and populations. Primary care is consequently a key part of the suicidality care provision macro-system. Bertolote's model (2004) serves as an adaptable conceptualisation for the schematic importance of suicidality prevention in primary care, and potential use of a suicidality CDSS as a selective or indicated preventative tool.

Primary care has long been considered an appropriate context to develop suicidality prevention initiatives (Mann et al., 2005; Milton et al., 1999), and the speciality is repeatedly singled out in key suicide prevention frameworks reviewed in chapter two.

3.3.2 Pre-suicidality contact with primary care

Primary care is usually the first point of entry to healthcare systems for people who die by suicide, and often their last healthcare contact (Bryan and Rudd, 2011). Psychological autopsy and medical record review studies suggest 45% of people who die by suicide consult a primary care professional in the month before suicide death (Luoma et al., 2002) and nearly 20% of people consult within one week of their suicide death (Pirkis and Burgess, 1998). A recent systematic review suggests, across a 12 month period, the percentage of suicide deceased consulting at least once in primary care is higher than 80% (Stene-Larsen and Reneflot, 2019). This degree of contact pre-suicide serves to further highlight the importance of improving suicidality prevention efforts in primary care. Moreover, Stene-Larsen and Reneflot's (2019) systematic review incorporates large registry-based studies, covering whole populations, rather than being limited to small sample sizes and specific geographic locations as normally found within psychological autopsy or medical record review studies. Studies of both UK based registers, and case-series reported high rates of contact with primary care before suicide. Case series data drawn from the UKs series of studies known as the 'National confidential inquiry into suicide and safety in mental health' (NCISH) suggests more than 90% of people who die by suicide consult in primary-care within 12 months of suicide, 47% within 1 month, and 16% within 1 week (Pearson et al., 2009).

Findings drawn from the UK Clinical Practice Research Datalink (CPRD), a large scale primary care register in the UK incorporating data from GP practices using Vision or EMIS electronic software systems, suggests that there is likely to be a pattern of increasing number and frequency of GP contacts prior to patient suicide (The National Confidential Inquiry into Suicide and Homicide by People with Mental Illness, 2014). The report also indicates across a 10 year period, each GP practice in England is likely to have a median of 6 patient suicide deaths. Whilst this suggests that patient suicide death

remains a low frequency event in primary care, it is important to remain cognisant of the widespread consequences emanating from acts of suicidality as reviewed in chapter two. In addition, the high proportion of unrecognised risk likely to be found among typical primary care caseloads is important to consider, offering potential opportunity for preventative efforts. Variations in recording processes surrounding suicidality might also suggest estimates are under-reported. Additionally, suicide and self-harm maybe inaccurately-reported within the CPRD, since suicidality may not be assigned appropriate clinical codes (known as Read codes) in routine primary care records (Thomas et al., 2013). Further compounding the complexity of estimating the true frequency with which suicidality might be discussed in primary care consultations, some studies suggest suicidality is not always appropriately identified, discussed or care-planned for despite clear risk markers (Bajaj et al., 2008; Feldman et al., 2007; Hooper et al., 2012).

Simulated patient studies suggest that when faced with presenting problems associated with major depression, qualified primary care doctors infrequently and inconsistently enquire about patient suicidality, asking explicitly about suicide in just 36 percent of consultations (Feldman et al., 2007; Hooper et al., 2012). Physician factors such as age, gender, experience, and attitudes towards suicidality have been suggested as important determinants, with more recently qualified, male doctors of white ethnicity, appearing more likely to conduct suicide risk assessment (Hooper et al., 2012).

In some studies, GPs have stated that asking patients about suicidality makes them feel uncomfortable, uncertain and under-skilled (Bajaj et al., 2008; Michail and Tait, 2016). This is not surprising, since working with patient suicidality is acknowledged to be a stressful and demanding aspect of clinical practice, even for practitioners who frequently encounter suicidality (Chehil and Kutcher, 2012).

Additional potential barriers to discussing suicidality include time constraints, language barriers, perceptions of cultural appropriateness and concerns about precipitating future acts of suicidality (Bajaj et al., 2008). GPs also describe complexities in relation to their communication with and referral pathways to mental health services, challenges of working with bereaved families after a patient suicide, and the personal and professional impact of a patient suicide (Leavey et al., 2017). There is a range of generative mechanisms influencing GPs' practice in this area. However, it is likely that there are also important structural and contextual factors, interacting with these potential generative mechanisms, to determine if, how and when GPs might ask patients about suicidality, and GPs potential use of a suicidality CDSS.

3.3.3 Candidate Generative mechanisms

This section synthesises the literature to present identified candidate generative mechanisms of interest. These candidate mechanisms are considered pertinent to both research questions, influencing GPs' identification, assessment and care-planning for suicidality, as well as GPs' prospective use of a suicidality CDSS.

3.3.3.1 Structural and systemic contextual pressure in primary care

Primary care is characterised by the centrality of a doctor-patient consultation, initiated by the patient, within which GPs have the potential to understand the patient's presentation inside the wider context of the patient's life (Stephenson, 2011). This contextual view is referred to as 'whole person medicine' by Stephenson. GPs' ability to know their patient's contexts and circumstances has stemmed from the personal continuity of care between a patient and their GP, which has been a defining characteristic of primary care since the nineteen fifties. Continuity of care is viewed by GPs as most helpful when patients have multiple or complex problems (Guthrie and Wyke, 2006). However, in recent years, primary care has also begun to be defined by increased patient demand, workforce shortages, reduced

resources and escalating bureaucracy (Hobbs et al., 2016; Riley et al., 2018). In the modern context, primary care has been described as a continuous exposure to human illness and sickness, set against busy clinical sessions, vast amounts of administrative chores, and constant task interruption (Riasat, 2013). Amidst these contextual pressures, significant tensions between continuity of care and improving patient access exist. As a consequence of these contextual pressures many GPs report feeling stressed, experiencing low morale and considering leaving the profession (Croxson et al., 2017). At the same time as these increasing workload pressures, and diminishing resources, primary care in England has been experiencing significant recruitment and retention problems (Marchand and Peckham, 2017). Recruitment difficulties have been linked to GP perceptions of adverse conditions including high workflow, time pressures, limited control over work and organisational culture (Linzer et al., 2009). Collectively, these problems have been described as amounting to a crisis placing the future of general practice in jeopardy (Wilkinson, 2014). In response, the UK government announced a range of additional funding and other measures in attempt to bolster the resilience of general practice (NHS England, 2016a). These additional resources were released at time of where more than 400 GP practices had closed in recent years (Wickware, 2018). Furthermore, estimates suggest an additional 1 in 10 GP practices could be forced to close by 2022 (Cook, 2018). It is therefore apparent that primary care is experiencing significant systemic pressures. Within context of these pressures, high workload, and impact on morale, GPs are striving to provide quality professional care to their patients. However negative consequences of this interplay of high workload, systemic stress, and diminishing resources are likely to ensue, including diminution of GPs ability to offer 'whole person medicine' and decreased continuity of care.

A further consequence is that GP clinics often run late because of the mismatch between expectations of what GPs can cover in ten to

twelve minutes per patient, and the reality of what might be considered acceptably safe practice (McCartney, 2017). Significantly, primary care remains funded to provide consultations in 10-minute slots per patient. Within their allotted slot, patients are expected to raise one major complaint as the reason for seeking the consultation. However, research suggests on average patients raise 2.1 concerns per consultation (Stuart et al., 2019), yet the system remains configured to support a singular problem based consultation. This is particularly relevant, since if GPs are struggling to make up time after longer consultations, there could be temptation to provide some patients with a more cursory and inappropriately shorter consultation (Silverman and Kinnersley, 2012). These problems are compounded by the pressures of full patient waiting rooms and waiting lists (Leavey et al., 2017).

Patient perception of these systemic problems and time pressures may negatively influence patient's willingness to open up complex problems during a consultation (Pollock et al., 2002). Some patients such as those experiencing depression or a sense of worthlessness and hopelessness may feel that they do not deserve to take up much of the doctors time (Gask et al., 2003). In addition, some patients may proactively curtail their disclosures of psychological distress, in order to reduce the consultation time, to relive the burden which they perceive their GP to be experiencing (Pollock et al., 2002).

Amidst the significant contextual pressures within which they operate in, GPs report the biggest stressor they experience is the emotional aspect of their work (Riley et al., 2018). Many NHS staff report stress, exhaustion and burnt-out due to a system facing unprecedently high workloads at a time of significant financial strain (Wilkinson, 2015). The impact of government austerity programmes has led to cuts in health-services, impacting current provision and future capacity, while giving rise to low morale and increased sick absence (Robertson et al., 2017).

Against this organisational backdrop a culture of blame and fear has become apparent, in which NHS services and managers react defensively, harshly and sometimes punitively (Wilkinson, 2015). In this highly pressured healthcare system, stress can trigger a defensive, inward focus amongst staff and loss of connection to job role and purpose whilst increasing employee's appraisal of the emotional labour required to do their job (George, 2016). Emotional labour has been defined as context specific rules governing the type and extent of emotions which employees may be allowed to express, or suppress, in relation to their role within organisations (Brotheridge and Lee, 2003).

The extent to which healthcare structures allow staff to appropriately express and manage the emotional strain of their role can promote emotional harmony or emotional dissonance in relation to the difficult situations healthcare staff find themselves in (Mann, 2005). The dissonance between how GPs staff feel in their role, and what they are able or required to do and show, may contribute to experiences of moral distress. Moral distress has been defined as the psychological conflict that arises when organisational constraints make ethically appropriate action difficult (Austin et al., 2017). Austin and colleagues (2017) argue moral distress can be experienced among physicians in primary-care and may led to negative emotions, compassion fatigue and the possibility of reduced quality of care. Moral distress is likely to occur when health workers such as GPs have to make clinical decisions involving conflicting ethical decisions and principles in relation to patients autonomy, within organisational climates which may not be conducive to resolving ethical problems (Lützén et al., 2010). Because GPs are more likely than most clinicians to have long-standing relationships with patients and their families, it is possible that they may experience moral distress in relation to suicidality consultations, as both a cognitive and social interpersonal process, potentially contributing to emotional fatigue and experience of contextual pressure.

Practical responses to these contextual pressures identified in the literature include GPs spreading the consultation over a number of different meetings, or deliberately extending individual appointment durations despite awareness of the limitations of the ten minute slot and impact on workload (Pollock and Grime, 2003). Additional strategies GPs report to manage the contextual pressures include placing increasing emphasis on patient self-management, attempting to reduce consultation complexity by restricting focus to a limited number of clinical problems per consultation, and trying to stay within proximity to the ten minute appointment time (Fisher et al., 2017).

There is therefore a complex situation faced by GPs seeking to help their patients amidst the contextual pressures of primary care. This involves GPs needing to reconcile the medicalisation of psychological distress, with frequent social causation and individual patient responsibility (agency) for seeking help (McPherson and Armstrong, 2012), along with the organisational and structural factors impacting their work. These contextual pressures and factors likely mediate GPs approach to patient's psychological distress and may significantly contribute to GPs' ability and willingness to identify, assess and manage suicidality. However, GPs' capacity for working with suicidality will also be shaped by topic specific knowledge and awareness.

3.3.3.2 GP knowledge*, skills and characteristics*

The professional training curriculum for GPs, states in its topic guide relating to the care of people with mental health problems, that GPs should be able to risk assess and manage patients who disclose suicidal thoughts, and co-create a safety-plan with patients to reduce risk (Royal College of General Practitioners, 2020). The curriculum also states that in general, GPs should use a structured approach to decision making within the consultation and recommended that GPs clinical decisions should include exploration of physical, psychological, social and cultural factors. This wider view of patient's presentation should then allow GPs to interpret patients' narrative with reference

to the individual's clinical record and biographical data (Royal College of General Practitioners, 2016). Successfully carrying out such a consultation regarding suicidality, appears a detailed and intricate process requiring well-developed inter-personal, communication and consultation skills on the part of the GP, to gather and synthesise a complex array of information, whilst creating an atmosphere which enables patients to disclose their concerns and suicidality. The curriculum offers no further guidance on how the GP should structure their decision-making process regarding patient suicidality risk.

Historically within England, there have been no mandatory psychiatric or mental-health rotations within GP training schemes, (House of Commons Health Committee, 2017); and many GPs have little formal training in working with mental health problems, or working with suicidality (Sudak et al., 2007) . Historically, fewer than half of GPs have reported receiving any formal training on working with suicidality (Bajaj et al., 2008). Therefore, it is apparent that GPs maybe approaching a complex task, with individual variation in topic specific knowledge, and little to inform their structured decision-making processes.

GPs' own characteristics may have a bearing on their responses to patients communicated suicidality within the consultation. Research suggests that white, early career and male GPs are more likely to ask patients about suicidality (Hooper et al., 2012). In another study, male GPs reported higher levels of self-perceived competency in working with suicidality than their female colleagues (Graham et al., 2011). Self-perceived competency did not mean that women doctors in the study were less willing to assess or treat suicidality, but may reflect broader lack of self-confidence among female doctors (Graham et al., 2011). Medicine has been described by some as "a boy's club" replete with subtle and overt gender bias in favour of male doctors (Khullar, 2017). It is possible therefore that female doctor's lower reported confidence ratings reflect these structural factors within medicine. The apparent increased willingness of newly qualified

doctors to discuss suicidality with patients may reflect the increasing priority of suicide prevention in national policies and inclusion of some suicidality training in medical training.

The extant literature highlights that attitudes and social (or professional) norms shape intention and eventual behavioural actions (Montaño and Kasprzyk, 2008). Therefore, GPs' attitudes about the appropriateness, and effectiveness of suicide prevention efforts is likely to be an important variable influencing their approach. It has been suggested that GPs' attitudes towards suicidality maybe partially shaped through the provision of tailored suicide prevention training (Tait and Michail, 2014).

Recent years have seen calls for improved suicidality and mental health training in medical curricula (House of Commons Health Committee, 2017; McDaid et al., 2011; Public Health England, 2019). Such calls represent an important development in the field and suicidality prevention experts now argue that every GP should have training in suicide awareness, risk assessment and ability to explore suicidality related thoughts or feelings within a ten minute GP appointment (Bear et al., 2019).

Particular attention within academic and practice literature has focused on GP recognition, screening and treatment of depression as an aspect of preventing suicidality (Hawton et al., 2013a). Provision of GP training in recognising, treating and referring depressed patients judged to be at risk of suicide has been a key aspect of multi-level depression care and suicide prevention approaches (Coffey, 2015; Hegerl et al., 2013). Whilst depression is estimated to be the most common psychiatric disorder among people who die by suicide (Hawton et al., 2013b), the majority of people who experience depression do not carry out acts of suicidality. Moreover, there are many other identified risk factors for suicidality beyond depression, as seen in chapter 2. Therefore, restricting suicidality training to

working with depressed patients is insufficient for suicidality prevention in primary care.

Primary care studies highlight many GPs feel like they need enhanced training in suicide risk assessment and working with patient suicidality across diagnostic presentations (Bajaj et al., 2008; Saini et al., 2015). Some GPs have candidly confessed that they lack adequate knowledge and skills to effectively work with suicidality, and some GPs reported that they thought patient suicide may be an unpreventable outcome (Michail and Tait, 2016). Similarly, GPs have reported difficulties trying to determine who might be at increased risk versus who might be presenting as a manifestation of distress requiring attention and support (Saini et al., 2015). In particular, GPs have highlighted young people as a population where GPs experience uncertainty and feel they need indicated assessment questions and consultation guidance (Michail and Tait, 2016). In contrast, other GPs report feeling relatively competent working with suicidality in young people, and demonstrate good awareness of distal risk factors but variable awareness of proximal warning signs (Michail et al., 2017).

Historically where GP suicidality training has existed, it has usually been organised at a local level, in a relatively uncoordinated way, and not been subjected to rigorous evaluation, with a few notable exceptions.

Skills-Based Training On Risk Management (STORM) is an educational intervention aimed at front line health professionals, including GPs (Morriss et al., 1999). STORM incorporates focused training on suicidality assessment, enhancing patient's problem-solving skills, crisis management and prevention. Completing STORM training has been shown to lead to improvement in clinicians confidence and ability to enhance patients problem solving skills, when working with patient suicidality (Morriss et al., 1999).

Applied Suicide Intervention Skills Training (ASIST) is another suicidality training package subjected to empirical evaluation. ASIST

combines a standardised training programme for assessing and responding to suicidality, including listening skills practice, role-plays and simulated patient consultations (McAuliffe and Perry, 2007). Clinicians participating in ASIST training have been shown to report improved knowledge, awareness and confidence when working with suicidality (Smith et al., 2014).

Whilst training programmes such as ASIST or STORM have demonstrated sustained improvements in clinician's knowledge, skills, and attitudes (Morriss et al., 1999; Smith et al., 2014) , the enduring impact of such training on clinicians' micro skills of interviewing patients expressing suicidality is less clear.

The effectiveness of such programmes is hard to evaluate, and the nature of cohorts in the studies are typically multi-disciplinary in nature as the training has been delivered across healthcare professionals at population levels, rather than targeting GPs in primary care. Usually only a selection of GPs are able to participate in such suicidality training initiatives and there are known difficulties releasing GPs from practice in order to attend training (Appleby et al., 2000). Moreover, GPs attending suicidality training maybe self-selecting due to topic interest, and these may not be the GPs who most need suicidality skills training (Morriss et al., 2005).

Despite the calls for improved suicidality training for GPs, the empirical evidence highlights that previous primary care suicidality training programmes demonstrate little positive impact on suicide attempts or deaths, or incidence of repeated self-harm (Milner et al., 2017). Milner and colleagues (2017) point out that whilst some studies suggest GP suicidality training might relate to reduction in recorded suicide attempts, the literature in this area is characterised by high variation in results and weakened by high heterogeneity in design and methodology. Therefore, large scale GP suicide prevention training is not recommended on the basis of current evidence which

shows little treatment effect on suicide deaths or repetition of self-harm in controlled studies (Milner et al., 2017).

Whilst GP training may seem a logical intervention, more methodologically sophisticated research appears indicated to over-come the limitations identified by Milner and colleagues (2017). Such a programme of work has not yet been undertaken. Therefore, at present, GPs are likely to continue to report high variation in knowledge and skills, interacting with their own characteristics and attitudes.

GP's willingness to explore patient suicidality may also reflect their own bias and perspectives, for example GPs concerns in relation to the cultural inappropriateness of asking about suicide has been reported in the literature (Bajaj et al., 2008). GPs' individual moral and ethical views may also influence their response to patient suicidality. Many people in western societies see suicide as morally wrong (Rottman et al., 2014), yet consider physician assisted suicide as potentially acceptable in cases of terminal illness and irretrievable suffering (Davis, 2019). The apparent schism in attitudes towards suicidality highlighted by Davis (2019) may reflect a functional pragmatism, that beyond a certain tipping point, many people may consider suicidality an appropriate outcome. Discrepancy may occur between ethics and values, leading to moral and flexible justifications for suicidality (Danaher, 2014).

GPs are subject to social and professional influences and cultural norms, and may find their personal views and attitudes challenged when working with patient suicidality. As a patient driven behaviour, suicidality is in immediate conflict with doctors primary axiological stance enshrined within the Hippocratic oath (Abbasi, 2019). The patient as an autonomous agent is entirely absent from the Hippocratic oath (Walton and Kerridge, 2014), and the oath to do no harm is immediately challenged by potential conflict with patient's posing harm to themselves. Each presentation of suicidality therefore

embodies a potential ethical conflict for GPs. Studies highlight that working with patient suicidality can evoke a moral and ethical dilemma for medical professionals due to conflict between physicians role as preservers and maintainers of life and patient's suicidality (Anderson et al., 2003). Working with suicidality places the medical practitioner, in a negotiation between patient life and death, which may precipitate practitioner feelings of hopelessness or anger, as well as the desire to preserve life and hope (David et al., 2010).

It has been suggested that working with suicidality therefore evokes a response between competing moralistic (suicidality is wrong) and libertarian views (that individuals have the right to decide to live or die) (Mishara and Weisstub, 2005). It is vital therefore, that GPs reflect on their attitudes, beliefs and skills in relation to working with suicidality. GPs, like other health workers may hold diverse views regarding the legitimacy of patient's suicidality, with some considering patients who have adequate mental capacity able to enact their free-will, whilst others may consider suicidality as necessarily pathological and requiring investigation of an individual's capacity to make decisions about treatment (Kapur et al., 2010).

Neighbour (1987) reminds GPs that when making decisions about patient's needs and treatment options, GPs must reflexively consider how far they will allow their own values to influence patient decisions, and how far they will allow patient's values or choices to influence their own actions (Neighbour, 1987).

Complicating GP's sense making of their position with regard to patient suicidality is the merging of suicidality and psychopathology (Marsh, 2015) which reformulates suicidality as primarily a medical, rather than social concern. The medical practitioner must therefore reconcile with each presentation, the degree to which they suspect a mental health presentation is influencing the mental capacity of the person considering or engaging in suicidality.

The emergent picture is of an extremely complex clinical presentation, and a work force with no standardised approach and high variation in attitudes, prior training, suicidality knowledge and skills. When coupled with the structural and contextual pressures in primary-care, it is likely that some, if not many, GPs will experience patient suicidality consultations as "a bag of worms" issue (Bajaj et al., 2008 p232) and potentially stressful and anxiety provoking.

3.3.3.3 Uncertainty, Implicit threat and clinician anxiety

Primary care medical practice is characterised by uncertainty of understanding patient presentation, due to multimorbidity, evolving signs and symptoms, and culturally nuanced interpretations and patient presentations (Malterud et al., 2017). Correspondingly, the context necessarily involves nuances of risk management in the broadest sense, as physicians' technical, personal and conceptual resources are tested within a culturally constructed meeting in which certainty is expected (Evans and Trotter, 2009). Being able to make rapid decisions about unclearly defined problems, whilst tolerating high amounts of uncertainty and ambiguity are core features of primary care practice (Green and Holden, 2003). Managing the inherent uncertainty and unpredictability is described as an essential skill for doctors working in primary care (O'Riordan et al., 2011). The degree to which doctors can tolerate uncertainty appears to partially mediate risk aversion and risk tolerance (Lawton et al., 2019). GP tolerance of uncertainty might be mediated by personal epistemological style, with propensity towards biopsychosocial epistemology associated with less stress in the face of uncertainty, than GP colleagues adhering to more staunchly biomedical perspectives (Evans and Trotter, 2009). GPs who do not readily engage with biopsychosocial concepts may therefore find uncertainty a demanding aspect of practice.

Suicidality is arguably one of the most uncertain areas of primary-care practice, since working with patients expressing suicidality involves uncertainty and ambiguity (Paterson et al., 2007). This ambiguity may lead to underestimation of suicidality risk (Manley and Beezhold, 2011), or inappropriate escalation of risk management and risk aversive practice. Although suicidality remains a low-frequency event at a primary care population level, surveys suggest that across their career, 80% of doctors have experience of a patient case ending in suicide (Poma et al., 2011). Whilst subject experts describe working with patient suicidality as a stressful and demanding aspect of clinical practice, (Chehil and Kutcher, 2012), comparatively few papers or documents identify clinician stress and uncertainty as significant aspects of GPs practice in relation to patient suicidality.

Instead, GPs' experiences of working with suicidality are more frequently framed in the literature as training needs, rather than experiences of stress or uncertainty (Michail and Tait, 2016; Moriarty et al., 2020; Saini et al., 2015). This may be a consequence of GPs need to preserve perceived technical, personal and conceptual competence as buffers against the uncertainty and stressors of the context in which they work (Evans and Trotter, 2009). It may also result from the deeply ingrained acculturation and socialisation commencing in medical school, that doctors should present themselves as possessing competence, alongside every-day familiarity with uncertainty and the possibility of patient death as features which pervade medical training and practice (Montgomery, 2006).

To manage the peculiarities of primary care consultations, GP training and practice frequently incorporates insights from consultation models, such as Neighbours 'Inner Consultation', where the GP seeks to balance enabling patient disclosure, gathering information, jointly agreeing next steps, mitigating against risk, and preserving self for the next patient (Neighbour, 1987). GP self-care and maintenance of self-awareness of emotional responses to patient presentation is

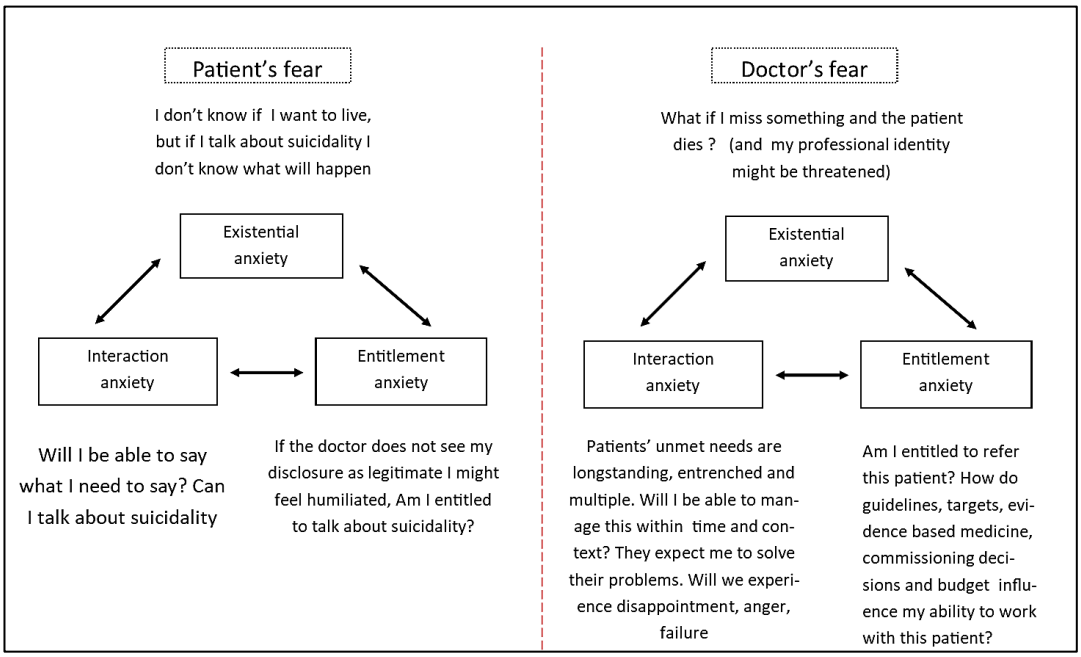
essential to GPs protecting their fitness to practice, and ensuring that their own values and beliefs due not unduly prejudice their clinical work (Papanikitas, 2017). Consultation models such as Neighbours' framework are therefore vital in this regard and such models are likely to be helpful for the majority of clinical presentations GPs encounter. However, working with suicidality may pose challenges testing the effectiveness of GPs consultation models and styles.

Suicidality consultations possess the potential for GPs to be drawn into a complex, time-consuming conversation, replete with uncertain outcome, as the proverbial 'bag of worms', interacting with GPs experiences of contextual time-pressures, stress and strain. Suicidality consultations therefore are a potential confluence of contextual pressures, uncertainty, increased stress and implicit threat to GPs wellbeing.

In contrast to the portrayal of doctors as composed, component and technically proficient in managing their consultation, an alternative view of the primary-care consultation has been proposed, in which fear is the primary driver of the doctor-patient dynamic (Fischer and Ereaut, 2012) (figure 3-2)

Fischer and Ereaut (2012) suggest both doctors and patients can experience fear within the GP consultation, occurring across 3 domains. These are Existential (questions about meaning of life and personal identity), Interactional (being able to raise needs, or constrain the scope of the consultation) and Entitlement (credibility and legitimacy). These proposed simultaneous dyadic experiences of anxiety suggests that both GPs and patients may experience significant anxiety during suicidality consultations.

Figure 3-2: Interacting systems of anxiety withing consultations (Adapted from Fischer & Ereaut, 2012)



Although rarely acknowledged, sometimes patient interactions which are experienced as anxiety provoking, invoke powerful and unhelpful responses in doctors, such as frustration, anger, disgust or horror, (Inui and Frankel, 2006). Furthermore, GPs are not immune to psychological projection of their own fears, vulnerabilities or thoughts on to patients.

Moreover, GPs are not immune to suicidality, or feeling stressed, or trapped in an extremely demanding work context. Therefore, the possibility exists that suicidality consultations might be characterised by dyadic anxiety, precipitating stress and sometimes powerful or unhelpful reactions.

To pre-empt these powerful potential responses, the GP should strive to maintain empathy and intimacy within the consultation, and focus on patient subjective need, and avoid adopting a mechanistic approach which reduces the patient to an object in order to enhance controllability and practitioner safety (Shapiro, 2008). Ability to offer consultations longer than 10 minutes and regular participation in reflective activities such as Balint groups have been associated with higher levels of GP empathy (Lelorain et al., 2013). However, the

stress and strain of medical practice can reduce empathy over-time, perhaps partly due to unrelenting and intensifying, professional and bureaucratic demand to present equanimity (Smajdor et al., 2011).

In contrast with the cultivated image of the technically skilful, rational and emotionally detached doctor (Kerasidou and Horn, 2016), suicidality consultations therefore represent something messier and more anxiety provoking than is usually admitted.

Rarely mentioned in the literature is the implicit threat to professional well-being that working with suicidality can pose. GPs are likely to have awareness of the possibility that working with risky presentations can end in bad outcomes for patients, and doctors. There is likelihood that during their career, each doctor will have to produce at least one coroner's report, or be called to coroners court as a witness (Derby and Derbyshire Local Medical Committee, 2016; The Medical Defence Union, 2018). A summon to coroners court can be daunting for even experienced GPs (Edrich, 2013). Furthermore the scrutiny of professional practice during a coroner's inquest after a suicide can precipitate complaints, clinical negligence allegations, internal NHS investigations, disciplinary action and sometimes General Medical Council (GMC) regulatory investigation into doctors ability to continue to practice safely (Ward, 2017). This aspect of suicidality posing a threat to GPs pecuniary and professional wellbeing is seldom voiced in the literature, although it is possible that GPs will have some awareness in this regard.

Moreover, GPs may also have awareness of the emotional and psychological consequences that working with suicidality risks, including perhaps awareness of colleagues who have lost patients to suicidality.

The likelihood of experiencing a patient suicide has been described as an occupational hazard in routine mental health work (Plakun and Tillman, 2005), yet the impact on clinicians well-being and psychological health can be significant. Losing a patient to suicide can

be one of the most profoundly disturbing events in a professional's career (Farberow, 2005). The severity of impact on GPs' wellbeing may-be even greater, if they have worked with the patient, and their family or close friends for some time. The impact of patient suicide on GPs can be significant, with depression, anxiety, insomnia and suicidal ideation reported by GPs who have lost patients to suicide (Halligan and Corcoran, 2001). Feelings of professional failure and guilt may dominate GPs emotional reactions, and the experience of losing a patient to suicide can become 'engraved' on GPs minds (Davidsen, 2011). At such times, GPs may require access to informal support provided by peers and colleagues as well as access to formal support services (Saini et al., 2016). However, frequently patient suicides are treated as 'critical case', subject to review at practice, CCG and regulatory levels of management. The impact of such a process may lead practitioners to feel subject to numerous concurrent invasive examinations of their clinical practice, a process described as akin to 'multiple jeopardy' and 'death by a thousand arrows' (Horsfall, 2014). This investigatory process after patient suicide inevitably leads to continued and increasing scrutiny over the GPs clinical practice, and the team or setting in which they work. This has been described as an inflationary spiral of surveillance and control demanding closer monitoring of patients and their potential level of risk, and increased scrutiny over the GPs practice (Kendall and Wiles, 2010).

Furthermore, being subject to formal professional investigation may heighten GPs own risks of suicidality (Horsfall, 2014). Meanwhile, doctors are likely to know that they are a professional group with elevated risk of suicidality themselves, and will have knowledge of colleagues who have died by suicide (Gerada, 2018). Therefore, there is the possibility that suicidality conversations with patients evoke a whole range of powerful and emotive reactions in the doctor.

Finally, whilst the legal position in the U.K. remains that it is not illegal to commit suicide, it is illegal to assist someone else's suicide

death, at the discretion of the Director of Public Prosecutions (DPP) (Qiu, 2009). The law and derived GP regulatory guidance, adopt a traditional and conservative view of patient suicidality, with the statutory regulator the General Medical Council (GMC) reminding GPs that it is a criminal offence to aid or assist a suicide attempt (General Medical Council, 2015). When it comes to suicidality, both the GMC and the British Medical Association (the medical trade body), are unequivocal that doctor's role is to reduce suffering through the art of medicine in order to make people better, and that respect for patient's autonomy of decision making cannot justify any action which might be considered illegal action on the part of the medical practitioner legal (Qiu, 2009). Should the doctor do or say anything that could be remotely construed as aiding or assisting suicide, the GP may expose themselves to the prospect of criminal punishment and professional sanction. All this is implicitly raised when suicidality is disclosed in consultations.

This uncomfortable reality may not sit well with doctors, having to manage a stressful job and their own mental health and wellbeing, then being confronted with the difficult presentation of suicidality, imbued with uncertain risk, uncertain prognosis, and uncertain notions of blame and accountability. At some level, patient disclosure of suicidality poses an existential, professional and personal threat to doctors' sense of safety and wellbeing. It has been argued that clinicians' anticipatory anxiety of patient confirmation of suicidality risk may be a major factor in some clinicians reluctance to open up conversations about suicidality (Quinnett, 2019). Uncertainty, fear and experiences of anxiety then may be important generative mechanisms influencing GPs within suicidality consultations.

3.3.3.4 Limitations of suicidality risk assessment instruments

Potential anxiety GPs might experience in suicidality consultations may be heightened due to the limited ability of risk prediction

research in the field of suicide to inform decisions about immediate clinical risk (Cole-King and Platt, 2017). Historically, many attempts to identity universal regularities in the pathway towards suicidality have been made, with most suicidality risk prediction focused on static risk-factors such as demographics, or transient risk factors such as reported suicidal ideation (Franklin et al., 2017). These attempts have been relatively unsuccessful, and risk prediction research has failed to translate to clinically meaningful information to inform clinician's judgement of patient risk (Kessler et al., 2019). Despite decades of research investigating suicidality risk factors, no single risk factor accurately predicts suicidality much beyond chance (Franklin et al., 2017). Because of the poor predictive power of known risk factors, a definitive way to consistently and accurately identify patients at immediate to short-term risk remains inconclusive (Ryan and Large, 2013). The limitations of risk-factor based approaches to suicide prevention occur partly because statistical significance in a research study does not necessarily translate to clinical significance (Linthicum et al., 2018). However, risk factor research is derived from clinical and topic expertise, therefore retaining a degree of cogency. From this clinical and expert perspective, a plethora of suicidality risk assessment instruments have been developed; such instruments are attempts to predict suicidality, largely based on risk-factor research, and many are widely used in healthcare contexts.

Well-known examples include rating scales, such as the Beck Scale for Suicidal Ideation (BSSI); (Beck et al., 1979), the Beck Suicidal Intent Scale (BSIS) (Beck et al., 1974a) and Beck Hopelessness Scale (BHS) (Beck et al., 1974b), deriving from work undertaken developing psychological treatment for people who had attempted suicide and people with depression. Given the substantial historical association of depression and suicidality, a range of depression rating scales have also been used to investigate suicidality risk, including the Hamilton Rating Scale for Depression (HSRD) (Hamilton, 1960),

the Beck Depression Inventory (BDI) (Beck et al., 1996; Beck et al., 1961), and the patient health questionnaire (PHQ-9) (Kroenke et al., 2001), even though these scales contain just one item each specifically in relation to suicidality.

Other well-known instruments, designed to inform clinicians suicidality risk assessment and treatment decisions, are suicidality prediction instruments, such as the SADPERSONS mnemonic (Patterson et al., 1983), the Manchester self-harm rule (MSHR) (Cooper et al., 2006) and the ReACT self-harm rule (Steeg et al., 2012). These instruments were all created in attempt to predict future suicidality among individuals attending hospital emergency departments after suicidality. In their initial validation studies, the MSHR and ReACT demonstrated good sensitivity, but poor specificity and weak positive predictive value. The largest study using the SADPERSONS, involving a sample of over 5,000 patients presenting to emergency departments after self-harm also found the mnemonic had poor predictive ability for future suicidality (Katz et al., 2017). Between the three instruments, clinician attention is directed toward a range of static and dynamic risk factors (table 3-4 below)

Such suicidality prediction instruments may be useful to clinicians by providing important areas to ask patients about during assessment. However, as can be seen there are significant differences between the instruments regarding the underpinning risk-factors considered most salient. This potentially creates confusion and reduced clarity of which factors clinicians should be most concerned about at the point of patient assessment.

Table 3-1: Suicidality prediction instruments

SAD PERSONS (Patterson et al., 1983, Katz et al. 2017)	Manchester Self Harm Rule (Cooper et al., 2006)	ReACT (Steeg et al., 2012)
Sensitivity: 48.8% Specificity: 60.1% PPV: 0.9% NPV: 99.3%	**Sensitivity: 94% Specificity: 25% PPV: 20% NPV: 95%**	**Sensitivity: 95% Specificity: 21% PPV: 30% NPV: 91%**
Sex (male)	History of Self Harm	Recent self-harm (past year)
Age < 19 or > 45	Previous Psychiatric Treatment	Alone or homeless (living status)
Depression or hopelessness	Benzodiazepine use in current overdose	Cutting used as a method of self-harm
Previous attempts or previous psychiatric history	Any current psychiatric treatment	Treatment for a current psychiatric disorder
Excessive alcohol or drug use		
Rational thinking loss		
Separated, divorced, or widowed		
Organised or serious attempt		
No social support		
Stated future intent		

A more recent tool, designed to over-come the high variability of terminology and differing emphasis placed upon disparate risk-factors in previous instruments is the Columbia–Suicide Severity Rating Scale (C-SSRS) (Posner et al., 2011). The C-SSRS seeks to aid clinicians and patients to distinguish suicidality related thoughts from behaviours in attempt to aid assessment and inform treatment approaches. The C-SSRS aims to ensure clinicians pose questions about suicidality in a standardised way and unlike many other suicidality instruments, functions as an interviewing guide and risk assessment scale.

Despite the promise posed by suicidality risk assessment instruments, a string of recent high-quality systematic reviews highlight suicidality risk instrument literature is replete with methodological limitations and high heterogeneity in study design and quality, and frequently employing long duration of follow-up to increase prevalence, and perhaps increase Positive Predictive Value (PPV) (Carter et al., 2017; Chan et al., 2016; National Collaborating Centre for Mental Health, 2012; Quinlivan et al., 2016; Runeson et al., 2017). The studies included in these reviews report wide variation in instruments' sensitivity, specificity and PPV. Instruments typically demonstrate moderate sensitivity but lower specificity, and the PPV of all suicidality risk assessment instruments has consistently been shown to be relatively low.

As a result, all instruments struggled to correctly distinguish people at risk from those who are not. Because of these limitations. the NICE self-harm guidelines review conducted by the National Collaborating Centre for Mental Health (2012) stated suicidality risk assessment instruments should not be used to predict future suicide or repetition of self-harm, and should not be used to determine treatment or discharge decisions. However, the reviewers also stated that risk instruments may retain utility informing, helping to structure, and adding detail to clinicians' psychosocial assessments. The CSSRS may have particular value in this regard due to its nature as both risk assessment scale and interview guide, however to date there have been too few studies using the CSSRS to justify inclusion in systematic reviews (Runeson et al., 2017).

Further limiting the applicability of most suicidality instrument research for use in primary care are study sampling decisions. The majority of risk instrument studies involved samples of psychiatric inpatients, or people presenting at ED after self-harm. Whilst such populations are seen in primary care, they are at higher-risk and are not reflective of the overall population served by GPs, raising doubts

about external validity of the scales, and suitability for use in primary care.

Systematic reviews of risk-instrument studies conducted with more typical primary-care populations found only four studies reporting diagnostic accuracy, and just two studies using suicidality risk assessment instruments assessed against validated reference tests (Gaynes et al., 2004; O'Connor et al., 2013). O'Connor et al., (2013) concluded whilst further research was needed, there was minimal evidence that routine use of suicidality risk assessment instruments would improve suicidality prevention efforts in primary care.

Furthermore, the use of complex, time-consuming suicidality risk assessment instruments may be an awkward fit with contextual demands in primary care. Time required to administrator instruments and interpret patient scores is a major potential barrier to use of suicidality instruments in primary-care (Boudreaux and Horowitz, 2014). Moreover, based on this author's experience of trying to implement routine use of psychometric tools in primary-care contexts, licensing fees, and suspicions about instruments' external validity, or relevance of the reference population used in instrument development may disincentivise use.

To overcome some of these limitations, electronic versions of suicidality instruments have been developed, including an electronic version of the C-SRRS (Mundt et al., 2010). It has been suggested that electronic instruments are more likely to be completed than paper based alternatives, (Greist et al., 2014). Furthermore, some studies have claimed use of the electronic C-SSRS facilitates greater disclosure of suicidality than clinician interview (Mundt et al., 2013). Despite being increasingly used in zero-suicide programmes in the USA and elsewhere, there remains insufficient high-quality evidence to recommend use of the electronic C-SRRS in primary care.

Nevertheless, recent developments in suicidality prevention, such as the Zero Suicide movement continue to call for universal suicidality screening (Labouliere et al., 2018; National Action Alliance for Suicide Prevention Clinical Care and Intervention Task Force, 2012). Electronic versions of instruments such as the PHQ-9 and CSSRS are increasingly being used in this regard (Viguera et al., 2015).

Electronic suicidality assessment instruments represent an important area for future research, since technological approaches to suicidality prevention are possible and may help to overcome potential barriers (Luxton et al., 2011). Effectively harnessing the potential offered by technology based approaches to suicide prevention could confer opportunity to proactively intervene in the pathway towards suicidality (Christensen et al., 2014). However, to maximise the likelihood that GPs could use them, instruments intended to screen or assess psychosocial and emotional wellbeing must be integrated into GPs electronic health records (EHR) (Glasgow et al., 2012). Similarly, Boudreaux and Horowitz (2014) echoed that suicidality screening or assessment tools should be designed with prospective integration into EHRs in mind. The relative ease or difficulty with which instruments can be integrated into EHRs, post-development, could present additional potential barriers to use.

Continued call for whole population screening, such as in Zero Suicide, using suicidality risk instruments, is peculiar, since although such instruments generate some useful information about future suicidality, they are known to have limited PPV (National Collaborating Centre for Mental Health, 2012) and continually generate high false positives whilst missing many people who will enact suicidality (Large, 2018).

Furthermore, the ability of risk instruments to inform clinical decision-making in relation to the level of risk is also extremely limited. Attempts to stratify risk using scales is problematic due to the limited

accuracy of scales (Carter and Spittal, 2018). Studies suggest the majority of people who die by suicide were considered low risk in relation to established population level risk factors (Large et al., 2011b), Therefore the validity of the risk-assessment and prediction paradigm is limited, due to the poor predictive power of suicidality risk assessment instruments. Attempts at assessment and prediction are confounded by the high distribution of risk-factors among the population at large, whilst suicide is a low frequency event (Schwartz-Lifshitz et al., 2012). This poses substantial difficulties reconciling sensitivity and specificity, this has long been suggested likely renders any suicide risk assessment and prediction instrument practically useless (Rosen, 1954). It has been hypothesised that even an instrument with maximum sensitivity and specificity would struggle with moderate PPV and generate high numbers of false positives (Pokorny, 1983). The PPV and negative predictive value (NPV) of risk instruments is limited by the relative prevalence in the population, meaning low frequency outcomes such as suicide are unlikely to be predicted with accuracy, because of the relationship between prevalence and PPV (Carter et al., 2017). Due to these limitations, suicidality risk-assessment cannot serve as the sole basis for clinical decision-making and interventions to reduce suicide (Nielssen et al., 2017). Despite recent and historical attempts at improving suicidality assessment and prediction, and the potential to leverage machine learning (Franklin et al., 2017), De Leo's 2002 summation of the state of suicidality assessment and prediction research endures:

"*suicide prevention remains an area full of hopes and potential, but not of certainties*" (De Leo, 2002), p373.

Attempts to categorise people as high or low risk is misleading, usually inaccurate and serves to detract from meaningful assessment of people's circumstances and clinical need. (Quinlivan et al., 2016). Instead of focusing on identification and prediction of risk, it has been argued that a more meaningful approach is to consider individual needs assessment whilst seeking to identify modifiable risk factors

and use indicated interventions (Carter and Spittal, 2018). Such an approach would mean looking at the individual within their social context, exploring factors which could medicate the person's suicidality risk (Mulder et al., 2016), and remembering that suicidality does not occur in a vacuum, but occurs in dynamic social, cultural, historical and interpersonal contexts (White, 2016). Such a shift moves clinical decisions about risk beyond static risk factors, or warning signs, to incorporate a contextual view of patient need and circumstances.

However, it is likely that the limited ability of risk-factor research and risk-instruments, coupled with the high variation in knowledge and experience among GPs, contextual pressures, and the uncertainty or implicit threat contained within suicidality consultations, will lead to many GPs developing idiosyncratic ways of working with suicidality. Such practice is likely to rely on mental schemata, or heuristics for working with patient's suicidality.

3.3.3.5 Heuristics and Biases

The very nature of medical practice is replete with uncertainty arising from doctors' need to reconcile clinical experience, empirical data, patient histories and narratives with physical signs and symptoms. This process is an interpretive practice, reliant on clinical reasoning and tacit knowledge (Malterud, 2001). Infrequently encountered clinical presentations may be a source of difficulty for physicians, taxing their knowledge store and interpretative ability, whilst evoking the possibility of misrecognition and misjudgement, leading to the risk of embarrassment for the physician or impoverished care for the patient (Montgomery, 2006).

Gaining increased familiarity with differing clinical presentations, and experiencing non-routine patient cases is important to allow medics to reformulate their clinical knowledge with regard to complex consultations (Mylopoulos et al., 2011). This allows development of problem solving heuristics, or illness scripts, which are mental models

of knowledge organisation, containing information relating to specific clinical presentations, possible consequences, and the context or circumstance in which the clinical presentation might develop (Schmidt et al., 1990). Such mental models might be based on a particular case as an example of an instance previously encountered, or a more general and abstract model, based on a variety of clinical features, diagnostic categories, and clinical experiences (Elstein and Schwarz, 2002). Acquisition of such mental models has been described as developing pattern recognition skills, derived from experiential and situational understanding, which is learnt, rather than taught (Hays, 2006).

It appears that GPs often rely on pattern recognition as key aspect of clinical reasoning, describing their approach as thinking about patterns in presentation, rather than diagnoses (Goyder et al., 2015). Pattern recognition is usually triggered early in a consultation, when GPs unconsciously recognize particular signs or symptoms associated with a diagnosis or particular presentation, based on their prior experiences (Heneghan et al., 2009). The use of such heuristics has been described by GPs as enabling rapid assessment of problems potentially requiring emergency action, such as discerning when chest pain might require hospital care, as well as separating psychosocial from physical concerns (Borgquist et al., 2003). Whilst pattern recognition might be a form of extremely rapid clinical reasoning, the possibility of neglecting to assess important information exists (Yazdani et al., 2017). Furthermore, the elusive and transdiagnostic nature of suicidality, coupled with its comparatively low base rate among the primary-care population means some GPs may infrequently assess suicidality, and gain less experience of interpreting the associated signs, symptoms, and features. There is therefore possibility that GPs who infrequently encounter patients presenting with suicide risk, may have under-developed or poor suicidality pattern-recognition. It is also possible to infer GPs might have incomplete suicidality mental-models or patterns, as GPs appear

more readily primed to enquire about suicidality in certain presentations than others. Studies show GPs acknowledge they are more likely to investigate suicidality risk in people with significant depressive symptoms, yet potentially less likely if patients present with anxiety disorders, substance use problems, historical self-harm, or impaired occupational or social functioning (Bajaj et al., 2008; Bono and Amendola, 2015).

In contrast to the pattern recognition model of clinical-reasoning, medical training has traditionally emphasised hypothesis generation and evaluation as cornerstones of diagnostic and clinical reasoning within the hypothetico-deductive model of clinical reasoning (Yazdani et al., 2017) Hypothesis generation can be built upon time intensive inductive approaches, entailing full patient work-up and extensive clinical investigation, or hypotheticodeductive methods, in which educated guesses are subject to verification by selected tests (Arocha et al., 1993).

However, it is argued that neither pattern-recognition, nor hypothetico-deduction accurately describes the process of clinical assessment and diagnosis in primary care, due to the huge spectrum of conditions that can be encountered (Donner-Banzhoff, 2018). Instead, GPs engage their patients in assessment using a rapid problem solving approach, to deal efficiently with the scope and variation in possible presentations (Hays, 2006). In reality GPs clinical reasoning is likely therefore to involve a more sophisticated process than simplistic reliance on pattern recognition, yet it may not be adequately explained by adherence to the hypothetico-deductive approach. Instead, it has been suggested that expert medical reasoning relies on a combination of pattern recognition initially, followed by hypothesis generation and testing should pattern recognition fail (Elstein et al., 1990).

An influential contemporary theory, also suggests clinical judgement is a synthesis of approaches (Croskerry, 2009),underpinned by dual

process theories of cognitive reasoning and judgement (Evans, 2008). Dual process models propose different cognitive processes leading to rapid, automatic, unconscious and low cognitive load decision making, contrasted against decision-making, which is slow, conscious, deliberate and cognitively taxing. These are referred to as system one, associated with heuristic based rapid reasoning, and system two, associated with analytic reasoning (Kahneman and Frederick, 2002). Kahneman and Frederick (2002) identify that traditionally these systems may have been thought of as intuition and reason. Both intuition and reason combine in clinical decision-making, as GPs interweave clinical experience, generalisable research derived knowledge, heuristics, and contextual patient information (Greenhalgh, 2002). Intuitive and analytical processing, working in parallel, have been suggested as central to doctors resolution of uncertainty and partial, but evolving recognition of presenting problems, in highly time pressured, busy clinical contexts (Adams et al., 2016). Such an approach appears relevant to suicidality consultations, since clinical judgment in relation to patient suicidality is likely to involve a mixture of 'gut' hunches, or intuition, and reasoned clinical judgement (Simon, 2011), evoking the application of dual process theory.

However, within Croskerry's (2003) model of clinical and diagnostic reasoning, the primary mode of operation remains pattern recognition, meaning patterns associated with patient presentation may be misidentified or mistaken for other problems. This is more likely in cases like suicidality, where patient presentations may seem vague, ambiguous, or ensuing from a wide range of potential precipitants. Furthermore, type one thinking such as pattern recognition may be subject to a wide range of known biases which can influence clinical decision making, including anchoring, availability and confirmation bias (Croskerry, 2003). Deliberate activation of type two thinking, referred to as cognitive forcing, or debiasing, may mitigate against these biases. Croskerry (2003) makes the point that

effective use of debiasing strategies requires high levels of meta-cognitive awareness, for doctors to question their own decision-making process. Maintaining metacognitive awareness is difficult in conditions of cognitive and task overload. It is possible therefore that GPs do continue to rely primarily on system one thinking during the initial stages of patient consultation, and may have fluctuating capacity to debias and shift to system two based assessment. Reliance on system one, as a form of cognitive shortcut employed by GPs could therefore prove to problematic, especially if GPs allow their use of cognitive shortcuts to become automatic and unconscious, potentially leading to missing important patient or contextual information, and leading to poor patient experience of the consultation (Groopman, 2007). Over-reliance on system one thinking is therefore especially problematic to suicidality consultations, given the high stakes, and potential difficulties faced by patients and doctors in talking about suicidality.

3.3.3.6 Difficulties communicating about suicidality

The process of talking about suicidality is complex, for both patients and doctors, and complicated by the mechanisms reviewed so-far including contextual pressures in primary-care, variation in GP knowledge and skills, characteristics of patients and doctors, the culture blame and accountability and the limitations of the risk assessment and prediction paradigm.

The difficulties talking about suicidality may commence with difficulties in the process of help-seeking, since patients know they may have to talk about suicidality. For patients, seeking help at a time of distress may be incredibly difficult. There are known barriers to help seeking from GPs for emotional or psychological problems, including perceptions of societal stigma, embarrassment, low feelings of self-worth, or low expectations for help, coupled with awareness of time-pressures and brevity of consultations in primary-care (Dew et al., 2005; Farr et al., 2021; Gask et al., 2003; Kadam et al., 2001; Pollock et al., 2002).

Patient disclosure of psychological and emotional problems, results from an active decision-making process on the part of patient (Tait, 2009). The typical primary care patient possesses adequate capacity to be an active-agent who can exercise a choice, to help make GPs aware of their experiences of psychological, or emotional distress and suicidality, or to conceal their experiences. Principle reasons for patients not disclosing imminent threats to self-wellbeing, such as suicidality, include attempt to avert embarrassment, fear of being negatively judged or admonished by the doctor, and avoidance of having to deal with difficult problems (Levy et al., 2019). Men in particular may seek to avoid disclosing such vulnerabilities in consultation, and are generally thought to be less likely to seek help from healthcare providers for emotional and psychological problems, and more likely to drop-out from treatment interventions (Brown et al., 2019)

In general, many adult and older adult patients may choose to present their distress as somatic rather than emotional, or have a tendency to overly 'normalise', and not frame their experiences as significant psychological distress (Tait, 2009). This is probably in attempt to preserve legitimacy and avoid stigma associated with psychological problems. It is possible that people may be more likely to disclose suicidality after previous positive experiences of mental health support (Cukrowicz et al., 2014), perhaps reflecting a socialisation that is acceptable to voice vulnerability and suicidality in consultations.

Nonetheless studies suggest that even when explicitly asked about suicidality 20-50% of patients who go on to die by suicide, chose not to voice thoughts or plans regarding suicidality when asked by physicians (Schulberg et al., 2004). This concealment of risk can occur for a range of reasons, not least of which might be if the person is at an advanced stage of the pathway to suicidality, and reasons for living maybe perceived as insufficient and outweighed by desire for death.

Furthermore, when people are experiencing suicidality, they may already be thinking life is not worth living, or considering ending their life. Some people may then start to frame GP consultations and possible health service interventions as obstacles to their freedom to engage in suicidality, and expect confrontation between their experiences of suicidality and doctors roles as preservers of life (Resnick, 2002).

Evidence suggests that most people experiencing suicidality do not seek help due to a range of factors including stigmatising attitudes towards suicidality and mental health, pejorative attitudes towards seeking professional help, and not perceiving that they might need, or could access treatment (Han et al., 2018). Patients and family who have lived through suicidality have remarked that being able to openly discuss suicidality during regular contacts with professionals who provide them space to discuss problems, ventilate emotional reactions and provide practical guidance on managing suicidality triggers is helpful (Player et al., 2015).

However, patients often struggle to put suicidality concerns into words, perhaps particularly in the early stages of a suicidality episode. When patients do talk about suicidality, they are more likely to describe suicidality in natural language, using euphemism such as 'Doing myself in', 'stopping it all', and 'finding a way out' (Reeves et al., 2004)p65. Young people may describe experiences of suicidality as something they '"deserve", and self-harm as a form of "self-punishment", or something giving a "sense of relief", which can become habitual and escalate in frequency or severity (Wadman et al., 2016)p.5-7

Young people may be particularly likely to find it hard to communicate suicidality distress to adults in positions of authority, such as GPs, (Owens et al., 2011), partly due to a sense that they should keep suicidality private and hidden (Wadman et al., 2016). Instead, young people maybe more likely to try to cope alone or

confide in friends (Coggan et al., 1997). Underpinning young people's reluctance to disclose emotional and psychological problems appears a perception that GPs are not a valid or appropriate source of help for psychological distress (Biddle et al., 2006). It is considered that young people may be reluctant to express suicidality within the consultation and less likely to endorse suicidality if explicitly asked (Younes et al., 2013). Furthermore, young males may be particularly unlikely to seek-help before an act of suicidality (Stanistreet et al., 2004). This reluctance to seek-help and disclose suicidality appears particularly nuanced among young-people (Farr et al., 2021). It is therefore especially important that GPs attune to the reasons that patients have attended consultation.

Understanding that manifest reasons for the consultation might not be the real reasons that patients have presented is part of the art of primary-care practice. It is not uncommon for patients to present with a hidden agenda of problems that are difficult to voice, masked by other presenting problems (Silverman, 2005). Reading through patients' narrative to see what else might be clinically important, or the actual reason for the consultation, requires highly developed interpersonal skills, self-awareness, and reflexivity on the part of the GP (Davidsen, 2009).

GPs' ability to listen carefully to patient's manifest reasons for the consultation, as well as being able to notice any hidden agenda, and to probe for underling concerns about suicidality may depend on the language used. At times doctors and patients may converse in markedly different linguistic voices, in which they may struggle to understand and make sense of one-another. Habermas' theory of communicative action (Habermas, 1985), proposed society is simultaneously composed of the lifeworld and systemworld. The concept of Lifeworld describes the everyday world of natural social interaction, where culture, social integration and personality are produced, whereas the systemworld corresponds to the economy and political nation state (Scambler, 2001) These two systems are seen

as interdependent, and reproduced through human action. However, the systemworld has a tendency to colonise, or distort the lifeworld. State provided healthcare institutions are products of the interaction of these systems. Correspondingly patients can be seen as presenting using the voice of the lifeworld, whereas doctors may consult in the voice of medicine, a linguistic register of the systems world, reflecting the indirect colonisation of medical care and the lifeworld (Mishler, 1984). The voice of medicine exerts the potential to dominate or control an encounter and to decontextualise and depersonalise events, distancing personal or social meanings and causation. Hence extreme sadness, elicited by events in the patient's lifeworld, such as bereavement, may be recoded as depression, or other illness. Modern medicine frequently substitutes technological intimacy for personal closeness, where understanding and assistance are translated to become diagnosis, prognosis, treatment and intervention (Shapiro, 2008). This subversion of patients experience behind technical rationality is a product of the systems world.

GP interactions take place at the crossroads of the lifeworld and systemworld (Greenhalgh, 2014), requiring doctors to be fluent in both the voice of the lifeworld and the voice of medicine. However, due to multiple demands operating in primary care, including task saturation, sometimes doctors may be so immersed in their medical world that they struggle to switch registers. Furthermore, many patients are not able to express their concerns in the voice of medicine. This separation between lifeworld and systemworld languages leads to patients potentially being misheard, misunderstood and less able to articulate their needs (Woods, 2006). To remedy this potential negative outcome, it has been suggested that doctors should know the person, before constructing the person as a patient (Launer, 2017). The Doctors job at the point of clinical contact is therefore, to translate patients experiences into the voice of medicine, whilst hearing and responding to patient's narrative. This

process is referred to as balancing narrative and normative realities in the consultation (Launer, 2019).

Because GPs are often juggling multiple demands on their personal, cognitive and emotional capacities, engaging patients as people may infrequently happen. Instead it has been argued that GPs are likely to adopt one of four broad patterns of communication in consultations termed; mutual lifeworld, lifeworld ignored, lifeworld blocked and strictly medicine (Barry et al., 2001). These communication patterns corresponded to the extent which doctors and patients were able to engage in genuinely patient centred communication. Studies of patient and health professional's experiences of suicidality consultations support the typology put forward by Barry et al., (2001) with patients attempts to communicate their emotional pain described as voiced and heard, unspoken yet still heard, spoken but unheard, or unspoken and unheard (Dunkley et al., 2017).

Complicating this potential is the reality that modern day GP consultations also feature a third mediator of communication, the voice of technology (Greenhalgh, 2014). Technology affords enhanced opportunity to engage in cased based reasoning, given the potential volume of information about a patient's lifeworld that exists within EHRs. However the increasing and ubiquitous use of technology in consultations means patients and GPs must become skilled at working with and working around the voice of technology (Greenhalgh, 2014). The degree to which a suicidality CDSS facilitates, or serves as a barrier, to GPs and patients engaging in conversation about suicidality, and lifeworld-based understandings of patients' emotional pain or distress is therefore particularly salient. In order to promote enhanced case-based decision making, and to enable discussion about suicidality risk the CDSS must strike a balance between the competing voices within the consultation.

A range of papers exist advising GPs on the best ways to conduct the consultation and engage patients in conversations about suicidality

(Bono and Amendola, 2015; Bryan et al., 2009; Carrigan and Lynch, 2003; McDowell et al., 2011; Morriss et al., 2013; Oravecz and Moore, 2006; Sinclair and Leach, 2017).

Many of these papers suggest ways in which GPs might ask patients about suicidality, including a mixture of risk-oriented questions aligned to systemworld concerns, and personal, contextualising questions, aligned to the lifeworld. Suggested questions excerpted from Bryan et al. (2009) highlight the difference between focus on clinical concerns or risk prediction, balanced against understanding the nuances of the patient's life and circumstance.

Table 3-2: Suicidality questions aligned to Systemworld and Lifeworld concerns

Systemsworld concern	How many times have you tried to kill yourself? So, you've never cut yourself, burned yourself, held a gun to your head, taken more pills than you should, or tried to kill yourself in any other way?
Lifeworld concern	Let's talk about what's going on right now. You said you've been thinking about [content]. What is keeping you alive right now?

Such suggested phrases and questions are not unproblematic. The extent to which busy clinicians operating in primary-care can or do use such suggested questions is unclear. Furthermore, how such phrasing might be received by patients is also unknown, and the degree to which such questions might result in patients feeling heard and their concerns validated is also unknown. The extent to which GPs can incorporate such questions into their consultation style is also unclear, and the extent to which GPs are able to straddle lifeworld and systems world registers using such questions is unknown. How suggested questions interact with the impact and voice of technology on the consultation is also unknown. Furthermore, should patients perceive clinicians impersonally working through a pre-determined list of questions, some patients may

selectively conceal suicidality risk in an act of defiance (Ganzini et al., 2013).

Moreover, studies of GPs naturalistic clinical practice suggest the way in which questions about suicidality are phrased and posed to patients can differ significantly from recommended questions and phrases in the GP literature. Sometimes GPs responses may convey messages to patients which serve to reinforce patients reticence to disclose suicidality risk information (Vannoy et al., 2010). Asking questions about suicidality without contextualising the enquiry may inhibit patient's responses. At times GPs may also construct questions about suicidality in a way that leads the patient towards a preferred answer and not another potential response. Such questions are characterised by wording like "you're not thinking of hurting yourself or anything like that?". This type of sentence construction has been described in the field of linguistics as possessing negative polarity, potentially conveying to the patient the GPs preference for a negative response to the question (Vannoy and Robins, 2011). Video recordings of routine consultations in secondary care mental-health and GP practices suggests that 75 percent of the time suicidality questions posed to patients are phrased with negative polarity (McCabe et al., 2017). Furthermore, McCabe et al. (2017) reported that patients were significantly more likely to refute suicidality risk when questions were phrased with negative polarity, which served to preclude further disclosure of suicidality risk.

The implicit function of negative polarity in suicidality questions may be to convey to the patient "if you actually are suicidal, please deny it now" as an invitation to a form of tacit collusion to avoid having to engage in emotively charged, complex conversations about the unpleasant clinical reality, that some patients do kill themselves (Quinnett, 2019).

How suicidality is conceptually and linguistically approached in the consultation is therefore vital. The relative ease with which suicidality

can be voiced between patients and doctors clearly may exert a significant bearing on the nature and extent of risk information that might be disclosed, shaping GPs ability to care-plan for patients' risk. The GPs task is complex and multifaceted, requiring attention to the patient's lifeworld and narrative, balanced against their role as servants to the systemsworld and normative practices, to make sense of the level of risk and to try to protect their patient from suicidality. A task made even more difficult by the relative professional isolation in which GPs work.

3.3.3.7 Managing suicidality in relative isolation

The model of primary care delivery in the UK has been referred to as the independent GP model, conferring significant autonomy, as well as professional isolation (Kennedy, 2014). As a consequence of their high workload, GPs maybe more likely to spend time with patients than colleagues or other health professionals. Recent data suggests currently GPs might record more than 40 patient contacts per day (Gregory, 2018). As GPs run their clinics, juggling telephone and in-surgery contacts they frequently encounter signs and symptoms of low mood, and the need to assess depression and suicidality is not uncommon. Part of GPs' responses to patient disclosure of suicidality is to act as a gate-keeper for secondary care mental-health provision, such as community mental health teams (CMHT) and crisis resolution and home treatment (CRHT) services (Saini et al., 2015).

However, GPs have to conduct this decision-making process with little support and in relative professional isolation. A important theme in the literature relates to complexities accessing secondary care mental health services for patients who have disclosed suicidality (Michail and Tait, 2016; Saini et al., 2015). GPs report that after patient disclosures, their decision-making regarding patient referral to mental health services is constrained by inflexible acceptance criteria set by those services, rather than patient need. This leaves GPs feeling isolated, and in the middle between the patient and the services (Saini et al., 2015). GPs may then feel that they have to push CRHTs

to consider assessing the risk among patients whom the GP has already identified as high risk (Michail and Tait, 2016). This process is experienced by GPs as frustrating and intensified by local variation in service availability, configuration, and commissioning. Decisions to tolerate the frustration of the referral pathway are probably mediated by GPs perceptions of significant risk to the patient, or identified need for specialist treatment (Telford et al., 2002). However these difficulties accessing specialist mental health services means GPs frequently end up managing complex patients, with a degree of risk, in relative isolation (Saini et al., 2015). GPs are then required to work with the uncertainty of suicidality with little emotional, professional or practical support at the point of consultation.

3.3.3.8 Perceived utility and benefit of CDSS systems

The use of computers within primary care is well established, with every GP practice in the UK utilising a clinical computer system by 2003 (Kontopantelis et al., 2018). The clinical computer systems are known as Electronic Health Records (EHR). The functions of EHRs include patient administration, recording patients' health information, ordering tests or medication, creating illness registers, enabling public health reporting, generating patient education materials and supporting clinical decision-making (Huang et al., 2018). Many primary-care providers consider EHR systems have potential to improve clinical productivity, patient safety and quality of care (O'Donnell et al., 2018). EHRs used in English primary-care incorporate the use of a clinical classification and coding system known as Read codes (de Lusignan and Chan, 2008). Read codes provide a thesaurus of clinical terms and procedures along with a standardised vocabulary to record patients' health problems (NHS Digital, 2020). Accurate read coding and use of EHR systems has been shown to be associated with improved ambulatory care, across a range of clinical conditions such as hypertension, coronary-heart

disease and diabetes (Robson et al., 2020). It has been argued that one of the key ways EHRs can be used to improve patient safety and clinical decision-making is through CDSS embedded within EHRs, to provide real-time decision support to clinicians at the point of patent contact (Sittig et al., 2006). Whilst many CDSS tool have been developed so that they are integrated within EHRs, some function as stand-alone platforms or internet-based tools, leading to CDSS being defined as:

> *"any electronic system designed to aid directly in clinical decision making, in which characteristics of individual patients are used to generate patient specific assessments or recommendations that are then presented to clinicians for consideration".*
>
> (Kawatmoto et al., 2005, p.765-766)

CDSS tools which deliver the best available information to clinicians at the point of clinical-decision making have been described as a practical necessity for improving care in the continually evolving healthcare context, given the ever expanding clinical evidence base (Tcheng et al., 2017). Early CDSS systems often were not available at individual clinical workstations or not well integrated into EHRs, however modern CDSS tools, increasingly integrated into EHRs have been described as facilitating information management, focusing clinician attention, and providing patient specific recommendations (Musen et al., 2014).

A systematic review by Bright and colleagues (Bright et al., 2012), identified three main types of decision support tools. These include classic CDSS (alerts, reminders, or prompts with regard to specific actions such as medication prescription, or ordering specific clinical investigations), information retrieval tools (to aid in the search and retrieval of clinical information based on patient specific information), and knowledge resources which provide a summary of the evidence base with regard to distinctive clinical issues pertinent to a specific care situation. Their review found that CDSSs had a favourable effect

on clinicians' preventative care decisions, ordering of further clinical assessments and medication prescription, but variable evidence that CDSS tools can positively impact on clinician workload and efficiency, and sparse evidence for their economic or global clinical outcomes (Bright et al., 2012).

CDSSs can be experienced by GPs as introducing distraction into the consultation through the need for ongoing data-entry (Launer, 2017) and some GPs report use of CDSS and EHRs as not fitting well with the fluid, and dynamic ways in which GPs make sense of patients problems (O'Donnell et al., 2018). It has been suggested that if computerised systems do not fit with the flow of a primary-care consultation, they can become a de-facto third party in the consultation, impacting GPs' and patients' patterns of reciprocal communication and negatively effecting patients' experience of personalised care (Pearce et al., 2011). The now ubiquitous use of CDSS and EHRs within primary-care, means such health-technologies can be seen as a third element within the consultation, in addition to medical practice and patient interaction, and which must be manged to take account of their potential benefits and limitations (Greenhalgh, 2014).

Despite some clinicians concerns about the impact of CDSSs within consultations, and the variable evidence base concerning their benefits for clinical care, clinician efficiency and workload, CDSSs retain the potential to provide clinicians, patients and carers with intelligently filtered knowledge and personalised information, presented at appropriate times to enhance healthcare delivery (Berner, 2009).

Contemporary CDSSs, are moving towards what Berner (2009) refers to as "knowledge based CDSS" (p5) because they include layered clinical knowledge, providing expert consultation advice to the clinician at the point of use, and may include generic condition management guidance, specific care-planning guidelines for a given

condition, or individualised suggestions taking into account patients' unique clinical presentation (Berner, 2009).

This integration of functions found in the knowledge based CDSS is something of an amalgamation of the three types identified in Bright et al.'s review (2012) and represents what has been termed as the 'next generation of clinical decision support', which seeks intentionally to link evidence to best practice (Wu et al., 2002). It has been claimed that if realised, such systems hold the potential to advance the field towards the goal of 'precision medicine' (Middleton et al., 2016) whereby patient care could be tailored to the individual's presentation in correlation with their broader context and biopsychosocial circumstances.

Presently CDSSs are being developed and evaluated in secondary mental health service contexts in attempt to help clinicians with global risk assessment, depression case management, help seeking for self-harm, and satisfaction with clinical decision making (Buckingham, 2007; Rowe et al., 2018; Slade et al., 2014) . However a recent systematic review of CDSS tools concluded that, there was a clear need for new, accessible CDSS tools which promote evidence based practice in frontline clinical environments (Koposov et al., 2017).

The attraction of CDSSs for primary care may include the extensive use of computers in primary care coupled with the function of primary care to diagnose undifferentiated problems and provide continuing care for chronic disease (Delaney et al., 1999).

Indeed, numerous specific CDSSs exist for use in primary care, including tools to support screening and diagnosis in relation to symptoms frequently correlated with various disorders. Such symptoms include chest pain and shortness of breath (Kostopoulou et al., 2017), hypertension (Montgomery et al., 2000) and respiratory tract infection (McGinn et al., 2013a). CDSSs have also been developed to aid clinicians with depression care management

(Fortney et al., 2010), and the application of clinical guidelines in cardiovascular disease presentations (Kessler et al., 2017). CDSSs have also been developed to aid GPs conceptualisation of patient risk for various conditions including future cardiovascular risk (Hippisley-Cox et al., 2007) (Peiris et al., 2009), future osteoporotic or hip fracture (Hippisley-Cox and Coupland, 2009) and future risk of medication prescription error (Avery et al., 2012). In addition, CDSSs have been developed to help clinicians and service users to record concerns about risk of vulnerability, neglect, and harm to self or others. However, there is currently no empirically supported, or policy recommended CDSS tool to help clinicians determine the level of a patient's risk to self, including suicidality risk.

Historically the potential benefit of a technological solution to improve GPs ability to work with suicidality has been recognised. Attempts have been made to help scaffold clinicians impression of suicidality risk, including computer based interview prompts (Griest et al., 1973), and highlighting specific risk factors within the EHR (Berg et al., 2018). Whilst these tools have represented an important step forward in using health technologies to improve primary-care capacity to work with patient suicidality, at present there is still no extant, empirically evaluated knowledge-based suicidality CDSS.

The need for improved technology based suicidality prevention tools has been recognised by policy makers at a national level, with the NHS Long-Term Plan specifying decision support tools and machine learning are required to augment clinicians ability to deliver personalised care and mitigate against future self-harm or suicide (NHS England, 2019b) (p72).

The potential of such a tool to inform and guide GPs clinical-decisions is apparent, and GP's have expressed a CDSS would be of use to support their work with patient suicidality (Michail and Tait, 2016). Currently, without such a tool to inform clinical decisions about

suicidality, GPs have to continue to make the best decision they can. Doing so requires reconciliation of multi-layered information pertinent to suicidality risk, including knowledge from psychiatric, social, patient specific, and population level datasets to arrive at an approximation of risk. This process could be described as an evaluative clinical decision (Adams, 1990), where a decision is made geared towards the identification, assessment and clinical management of suicidality.

It has been suggested that CDSS tools can enhance clinical decision-making, while enhancing ambulatory and preventative care (Bright et al., 2012). The association between CDSS use and higher quality care may be strongest with regard to activities which require minimal data entry, and which are cognitively simpler for GPs decision making (Jaspers et al., 2011). Conversely decisions about patient suicidality are necessarily complex and multifaceted. When making complex decision, use of CDSSs may help doctors to guard against cognitive error and bias inherent in fast and implicit cognition (Segal, 2007). Debiasing errors in clinical reasoning is a key strategy to improving clinical decision making (Croskerry, 2003). CDSS tools can be designed to possess a cognitive forcing function, allowing GPs to double check their thinking for cognitive errors (Mitchell and de Wet, 2014), and forcing the override from system one thinking (pattern matching) to system two thinking (detailed analysis of patients presentation) (Croskerry, 2009).

Literature suggests CDSS tools are often poorly regarded by practitioners who use them, particularly if they are experienced as exerting a burdensome impact on clinician's time (Shanafelt et al., 2016). It is likely that a CDSS tool requiring considerable data entry by clinicians will be negatively perceived and less likely to be used in practice (Shiffman et al., 1999). Therefore, potential development of a suicidality CDSS must pay attention to clinician time-pressures, ease of use, cognitive load on GPs, integration with existing IT infrastructure and perceived relevance to suicidality prevention. If

these considerations can be met, the premise of CDSS to enhance GPs decision-making in suicidality consultations could be achieved.

However, there is a marked lack of evidence-base in relation to the potential for a CDSS to assist GPs with the identification, assessment, and care-planning of patients who may be at risk of suicidality. Furthermore, there is no existing suicidality specific CDSS which has been co-produced with GPs and people with lived experience and subject to a degree of empirical evaluation.

Therefore, the premise of suicidality specific knowledge based CDSS system remains hitherto unrealised. Such a CDSS may be able to help GPs to more precisely think about experiences within the life and circumstance of the individual patient and factors mediating suicidality, to assess the degree of suicide risk and to collaboratively plan care with patients as required.

3.4 Discussion

It is clear from the candidate generative mechanisms, and review of structural entities and contextual conditions, that a range of implicit and explicit factors potentially influence GPs' identification, assessment, and clinical management of patient suicidality. The task facing GPs in this regard is complex, multi-faceted and fluid, as suicidality is neither static nor predictable. In order to assist with this complexity, GPs have stated a decision-making support tool would be useful (Michail and Tait, 2016). Such a CDSS could provide a way of guiding exploration of suicidality risk, documenting the consultation and improving the variability of suicidality data recording in primary care (Michail and Tait, 2016).

8 key generative mechanisms have been proposed which are central to the prospective use of a suicidality CDSS, and which may act interdependently and independently to influence GPs during a suicidality consultation. The generative mechanisms must be considered when designing a CDSS that is able to fit with clinical and

contextual reality in primary care, GPs ways of working with suicidality and health-technologies, and the capabilities of EHRs and CDSSs. The potential of the CDSS to mediate the impact of these generative mechanisms is unclear; however, the CDSS could be designed to take into account these generative mechanisms, and the way in which they might influence GPs approach to suicidality and GP's use of the CDSS:

Table 3-3: Key generative mechanisms and potential mediation by a suicidality CDSS

Key generative mechanisms	Aspect of suicidality prevention which could be mediated by the CDSS		
	Identification	Assessment	Care-planning
Structural pressure	✓	✓	✓
GP knowledge skills and attitudes	✓	✓	✓
Uncertainty, implicit threat and anxiety	✓	✓	✓
Limitations of suicidality risk assessment	✓	✓	✓
GP use of heuristics and biases	✓	✓	✓
Difficulties communicating about suicidality	✓	✓	✓
Managing suicidality in isolation	✓	✓	✓
Perceived utility of a CDSS	✓	✓	✓

Creation of a multi-function, knowledge-based suicidality CDSS could provide expert guidance at the point of consultation, guide GPs' decision-making, improve data recording and potentially improve GPs' and patients' experiences of suicidality consultations. If the CDSS can be designed to mediate the impact of the identified generative mechanisms, it is possible that the CDSS might make an important contribution to improving suicidality prevention in primary care.

3.5 Conclusion

This chapter has described the process and findings of a literature review, informed by CR to explore and identify generative mechanisms, considered most likely to influence GPs identification, assessment and clinical management of suicidality and GPs' potential use of a suicidality CDSS in primary care. The use of a CR informed approach to literature review entailed clarifying the structures and context pertinent to suicidality prevention in primary care, and the use of abductive reasoning across a broad range of literature, to identify generative mechanisms and to build theory pertaining to the design and use of the CDSS. In the following chapter, the philosophical underpinnings and methodology of this thesis will be discussed.

Chapter 4: Philosophical underpinnings and methodology

4.1 Introduction

This chapter provides an outline of the philosophical underpinnings of this thesis, and elaborates the methodology and methods employed to generate data with regard to the thesis' aims and objectives. Critical Realism (CR) will be introduced and an overview provided of the application of CR in the thesis. The methodological propositions associated with CR and several key assumptions of the approach will be considered. Finally, the implications of an under-pinning CR stance for the current thesis are discussed.

4.2 Methodology

The methodology for the thesis, will combine published evidence with stakeholder perspectives and experiences. Such a combination, has been referred to as the application of top-down and bottom-up methods, designed to integrate theoretical underpinnings, key cultural issues and the perspectives of healthcare providers and service-users (Bradshaw et al., 2012).

4.3 Philosophical underpinning

Within this thesis, CR is adopted as the philosophical position underpinning the conceptual framework, shaping epistemological and ontological assumptions. Epistemology has been described as one's theory of knowledge (Barker et al., 2016), and ontology described as the view of what is real, the meaning of reality and its nature (Everest, 2014). CR has a distinctive view of epistemology and ontology, which is often seen as situated in a middle-ground between positivism and intepretivism, affording a nuanced perspective for research without uncritically following traditionally established research paradigms (Zachariadis et al., 2013).

4.3.1 Critical realism

CR has been described as a post-positivist research paradigm (Lincoln and Guba, 2000). CR recognises the importance of empirical observation and measurement in advancing understandings and explanations for observed events but rejects the positivist assumption that knowledge can be subject to the principle of verification. In keeping with Popper's falsifiability premise (Popper, 2002) post-positivist standpoints see theories as never truly verifiable, but can be subject to falsification, meaning knowledge claims must always be seen as tentative (Crook and Garrat, 2005). Post-positivism therefore is primarily an epistemological position, yet implicitly incorporates an ontological stance regarding the desirability, but non obtainability, of absolute truth and universal explanation (Fox, 2012).

Moreover, CR like other post-positivist approaches rejects the assumptions of interpretivism and social constructivism regarding multiple, and purely socially constructed realities. Yet, CR may be described as retaining a weak constructivist stance since the approach accepts that social structures shape people's experiences (Joffe, 2012) and accumulated knowledge is a social product (Yucel, 2018). The particular position CR adopts therefore is between strong positivism and strong constructivism.

However, CR can be differentiated from both positivism and constructivism in important ways. Positivism seeks to test theory against data, whereas constructivism seeks to build theory grounded in the data. CR takes a "third path" in research, providing an account for the area of study and data obtained, with reference to ideas implicated in causation and social structures or mechanisms by which causal factors may be activated (Danermark et al., 2002). In this way CR argues that observed phenomena are caused by objects, entities and structures giving rise to the observed phenomena, even if these causative factors, or generative mechanisms, cannot be observed (Mingers, 2006).

The focus of CR informed work is to provide a context for imagining how perceived events might be understood, by using ideas to clarify, simplify and explain that which can be observed. Such an approach moves beyond a concern with measuring, to explore what might be of relevance in bringing about the observed factors. In this way the role of research is explanatory rather than predictive (Bhaskar, 2008).

CR therefore shifts the focus away from the epistemological commitments in positivism (the search for universal laws and prediction of events) and constructivism (that all knowledge is relative) to provide an explanation for observed events in relation to mechanisms or general tendencies which may or may not be observable. Central to this endeavour is the view that research should involve a switch of emphasis from epistemology to ontology, and within ontology less emphasis on describing events and increased efforts to identify possible explanatory mechanisms (Danermark et al., 2002). The ontological re-emphasis, involves commitment to ontological reality.

4.3.2 Ontological realism

Ontological realism, is a perspective which can be applied to theories that hold a view that reality exists, independently of human knowledge (Drummond, 2012). Within the field of CR, Bhaskar drew a demarcation between what he described as transitive and intransitive dimensions of knowledge and reality (Bhaskar, 2008). The transitive-domain refers to man-made, cumulatively established knowledge, which is used to generate new knowledge. The intransitive-domain refers to real structures, objects and mechanisms existing independently of human activity and current knowledge production capacities. This demarcation between the transitive and intransitive domains allows for a fundamental distinction between ontology and epistemology (Yucel, 2018). This separation of ontology and epistemology occurs, since the body of knowledge humans have

is part of reality, yet knowledge can never supplant reality, which is seen as mind-independent and evolving. The basic tenant of critical realism is therefore that the world and reality exist independently of cognitive processes and human knowledge, with three overlapping domains of reality proposed, referred to as a stratified ontology (Bhaskar, 2008)

4.3.2.1 A stratified ontology

Bhaskar's stratified ontology proposes reality is comprised of that which can be observed ('the empirical'), that which is occurring and which influences what is observed ('the actual'), and the factor of factors, giving rise to the empirical and the actual ('the real') (Bhaskar, 2008).

Sayer (2000) sought to operationalise these concepts further, referring to the empirical as the domain of experience and observation, the actual as events which happens when structures or powers are activated, and the real as potential structures or powers existing irrespective of human conceptualisation (Sayer, 2000). CR sees the proposed structures and powers as real yet distinct from events which they may generate, and events are real and distinct from human experiencing and noticing of them (Bhaskar, 2008). These extant structures or powers have a general tendency to behave in certain ways when activated to exert causative power.

The differentiation between the domains of stratified reality and their constituent elements is represented in figure 4-1:

Figure 4-1: Overlapping domains of reality, adapted from Bhaskar, 2008, page 47

	Domains of the stratified ontology		
	Empirical	Actual	Real
Experiences	☑	☑	☑
Events		☑	☑
Mechanisms			☑

The powers or structures existing in the real, which can give rise to events and experiences when activated are termed 'generative mechanisms'. These mechanisms cannot be directly observed, but can be been inferred as having been activated to produce specific observed effects. The purpose of CR informed research therefore becomes a search for the prospective structures or generative mechanisms associated with the real (Sayer, 2000). Identification of plausible generative mechanisms occurs through accounting for what is observed and experienced (Walsh and Evans, 2014), in relation to an inferred interaction between structural entities, and specific contextual conditions combining to activate hypothesised generative mechanisms underpinning particular events (Wynn and Williams, 2012). There is no established methodology by which generative mechanisms can be consistently identified resulting from the usually unobservable nature of such mechanisms (Bygstad and Munkvold, 2011). Furthermore the activation of generative mechanisms occurs in the context of interaction between human agency and social structures, since humans can re-produce or transform social normative behaviours, functions and structures (Archer, 1998a). Research therefore ought to take note of structures providing the broad conditions shaping people's lives, and human agency shaping that which actually takes place in society, since only human beings can act (Danermark et al., 2002). The search for mechanisms and

structures is therefore a complex process concerned with the interaction of context, human agency, possible social structures and hypothesised generative mechanisms. This is an abstract process involving theoretical description, retroduction to possible causes, elimination of alternative competing mechanisms, selection of identified generative mechanisms, and correction of previously suggested findings in light on the new proposed explanation (Archer et al., 1998; Bhaskar et al., 2010).

Such a focus on the fundamental onotological components of research including structure, agency, culture, and the necessary interaction between these constituent elements, means CR research is focused at the level of underlying philosophy (Porpora, 2013). Consideration of this broad scope of factors means that CR research frequently includes mixed-methods designs incorporating different sorts of data, in attempt to provide a multi-level description of the research topic (O'Mahoney and Vincent, 2014)

4.3.3 Epistemological relativism

The abstract process of searching for mechanisms, with reference to previously hypothesised mechanisms and theoretical constructs, whilst remaining open to emergent information, requires a pluralistic approach to research methods. Such an approach requires deliberate application of research methods to answer specific research questions situated within a conceptual framework supporting mixed-method designs. CR research enables this through a pragmatic approach to methodology and methods (Haigh et al., 2019). The methods employed must be 'practically adequate' balancing appropriateness to the object of research study, and the purpose and expectation of research inquiry (Sayer, 1992). Practical adequacy therefore leads to selection of research methods relevant to the research question and intention along with pragmatic choice of methods most likely to illuminate structures and mechanisms influencing that which can be observed. From this perspective, observational data cannot be

treated as signifying constant conjunction of events or proof of causality, but may highlight partial generalities (Danermark et al., 2002). This partial co-occurrence of events and outcome has been termed "demi-regularity" (Lawson, 1997), as opposed to strict regularity and predictable outcome. CR holds that it is necessary to consider research findings tentatively in light of demi-regularity, since it is always possible that generative mechanisms and causal powers may exist without being activated, or exercised (O'Mahoney and Vincent, 2014). Therefore, CR embraces the concept of epistemological relativism, meaning understandings of the world described in research, must be contextualised by time and place since understandings are personally and collectively construed (Bhaskar, 2008; Pilgrim, 2018). This temporally situated aspect of explanations put forward in research is important since researchers' understandings of the world and their retroductive processes in attempt to identify generative mechanisms, are mediated by cultural and historical standpoints (Al-Amoudi and Willmott, 2011). As knowledge of reality progresses historically situated explanations may be replaced by newer or adapted theory.

4.3.4 Judgemental rationality

A third important aspect of CR research is the concept of judgmental rationality. CR research remains cognisant of the tentative nature of explanations that can be put forward, shaped by the notion of demi-regularity and epistemological relativism. Yet it is still possible to evaluate and compare the explanatory power of different research findings and theoretical explanations (Price and Martin, 2018). This is because some theories approximate reality better than others. There are rational ways to evaluate the explanatory power of research, including checking the coherence of explanations with participants, explicitly seeking feedback from informants and stakeholders during a study, and evaluating which explanation appears most strongly

related to empirical evidence (Bygstad and Munkvold, 2011). CR research therefore requires rational judgement to compare and prioritise attempts to understand the world (Scambler, 2017). Prioritisation of attempts at explanation may be made on the basis of their critical potential to expose implicit assumptions within dominant systems of thought or their emancipatory potential, to supplant or remove less helpful explanations (Danermark et al., 2002).

CR therefore goes beyond a correspondence theory of truth, to include consensus and coherence criteria, and requires the researcher to be explicit about choices in data collection and analysis to aid replicability of the research. It requires the researcher to approach the topic of interest using different research methods to provide the most complete explanation in relation to the chosen area of investigation (Barker et al., 2016).

4.3.5 Critique of critical realism

CR research may be critiqued on a number of bases, including utility, application and coherence. As CR research often involves a theoretical description of phenomena and proposed generative mechanisms, necessarily involving value based judgements in relation to empirical evidence, it has been suggested that CR research possess an evaluative and prescriptive character (Hammersley, 2009). Explanations put forth from a CR perspective may not meet other researchers' evaluative consensus and coherence judgements. Furthermore, some researchers, particularly those opposed to CRs' ontological and epistemic commitments may seek definitive answers and find CR leaves unanswered questions. It has been described as meaningless to pursue descriptions of reality beyond that which can be experienced (Magill, 1994), since any claim to reality is provisional, contestable and probably only partially accurate. Curiously Magill's critique actually echoes CRs' description of transient and intransient domains of reality, one the central concerns of CR

philosophy. Advocates of the CR perspective are clear however, that the approach is a meta-theoretical position, which in and of itself does not predict, or offer definitive explanations, for anything (Archer et al., 2016).

Furthermore, the abstract and conceptual nature of CR may seem far removed from applied health research. CR's commitment to meta-physical realism, stratified ontology and emergent generative mechanisms may seem overly philosophical and anathema to the pragmatic nature of primary care practice. In response to such criticism, it has been suggested that researchers use CR's conceptual underpinning as meta-theoretical toolkit to guide research, and to inform the development of contextually specific theories (Cruickshank, 2003). Cruickshank (2003) refers to these more focused applications of CR as 'domain-specific meta-theory'. Construction of domain-specific meta-theory should seek to account for the relationship between structure and human agency (Raduescu and Vessey, 2009). Despite attempts to separate the impact of agency and structure, CR has been accused of recurrently privileging structures over agency, since structures are seen as possessing causal power to shape, elaborate and transform human behaviour (Contu and Willmott, 2005). Nevertheless, CR provides a meta-theoretical lens for examining both human agency and social structures. The relative extent to which these elements might be highlighted may depend on the research design used. A demarcation has been drawn between intensive or extensive design (Danermark et al., 2002). The former is primarily concerned with qualitatively explaining how a process works in a small number of cases in specific contexts, and the later affording greater scope to consider quantitative measurement of demi-regularity and representative samples. Danermark et al., (2002) caution that both extensive and intensive designs are useful approaches in the search for generative mechanisms, although they seek to answer different questions. Arguably intensive designs offer greater scope to investigate how a

mechanism may work in a defined and limited context, yet may provide limited generalisable information regarding the frequency with which a phenomenon may occur or likely empirical patterns that might be expected in other contexts. In attempt to overcome these limitations CR informed research should therefore seek to include the impact of structural entities, constituent elements, and contextual conditions in which the phenomena of interest is situated, according to the researcher's own perspective (Wynn and Williams, 2012).

Despite the critiques which may be made, CR retains strong potential to provide an internally consistent and philosophically developed framework for research seeking to avoid the limitations of positivism and constructivism as the dominant competing methodological positions (Gorski, 2013). In contrast, CR offers a guiding meta-theory which, can be employed flexibly in attempt to identify and describe healthcare systems, processes, and generative mechanisms pertinent to healthcare delivery. CR therefore is a metatheoretical approach, providing a general theoretical and philosophical starting point for research, without being prescriptive of research design, or method (Edwards et al., 2014).

4.3.6 Critical realism and implementation science

Development and implementation of new healthcare interventions, technologies or ways of delivering services is acknowledged as a complex field. In his influential review of applied healthcare research implementation Cooksey (2006) identified two primary knowledge translation gaps. The first 'gap' relates to the translation of research and findings into clinically applicable systems or products, whereas the second 'gap' relates to the introduction of those ideas and products into routine clinical practice (Cooksey, 2006). In response, a range of theoretical propositions and an entire field of research referred to as implementation science has evolved. Implementation

science has been defined as attempts to improve healthcare quality and effectiveness by encouraging systematic uptake of research findings and evidence-based practice (Eccles and Mittman, 2006). However, in contrast to commonly used models of healthcare intervention development, such as the MRC framework for developing complex interventions, (Craig et al., 2008), implementation science focuses beyond patient-level service provision, to also incorporate provider, organisational and policy levels of healthcare (Bauer et al., 2015). Whilst recent iterations of the MRC framework have sought to provide a greater account of context through process evaluation (Moore et al., 2015), such models of intervention development have been criticised as insufficiently accounting for the complexity of healthcare systems (Shiell et al., 2008). Sheill and colleagues (2008) highlight healthcare systems retain capacity to adapt and behave in non-linear ways. This complexity and changeability reflects Bhaskar's (2008) notion of open-systems ontology, which is insufficiently accounted for within the MRC framework.

Furthermore, the MRC framework also inadequately accounts for the interaction of structure and agency, as it tends to confuse the two concepts. In contrast, a CR informed perspective allows consideration of 'interventions' as temporally situated events within a healthcare system, shaped by the context, as well as social structures and networks which connect patients and providers to the setting (Hawe et al., 2009). Moreover, the language of 'intervention' is also problematic, since all healthcare interactions may constitute an intervention but the term lacks precision and obfuscates explicit connection between underpinning theory, mechanisms and healthcare delivery (Forbes, 2009).

In addition to the numerous existing intervention development theories, a range of implementation-based theories exist to guide the establishment and up-take of healthcare technologies, systems or processes.

A typology of implementation theories has been proposed. Nilsen (2015) demarcates between process models which seek to translate research into practice, determinant theories which aim to highlight or explain factors which might influence implementation outcomes, and evaluation frameworks which specify certain aspects of implementation which may be evaluated to determine implementation success (Nilsen, 2015). Accordingly a range of existing theoretical models can be found including Normalisation Process Theory (NPT) (May et al., 2007), Realist evaluation (Pawson and Tilley, 1997) the Unified Theory of Acceptance and Use of Technology (UTAUT) (Venkatesh et al., 2016) and the Non-Adoption, Abandonment, Scale-up, Spread and Sustainability framework (NASSS) (Greenhalgh and Abimbola, 2019). These theoretical models have relevance for evaluating implementation of healthcare technologies or systems. However, they are designed to support the evaluation of existing technologies rather than guiding the creation and implementation of technology. Furthermore, they offer only partial clues as to possible relevant generative mechanisms relevant to the use and adoption of a suicidality CDSS.

However, instead of conceptualising a suicidality CDSS as an intervention, or stand-alone technology such as medical device in its own right, CDSS are considered as a healthcare technology supporting clinicians decision-making (Kawamoto et al., 2005). Making appropriate clinical decisions is part of clinical care-planning, which is a key element of the patient-safety paradigm. Patient safety focused work has broadened from focusing on patient level interventions and risk management, to recognition that meaningful improvements can be gained by considering the interaction between patient care, environmental circumstances and organisational culture (Quinlivan et al., 2020). Such a wider view allows for consideration of agency, structure, culture, constituent elements of a CDSS and the contextual conditions in which use of a CDSS is situated.

Another key conceptualisation of a CDSS pertains to its quality improvement potential. Quality Improvement (QI) in healthcare has been defined as enhancing clinical effectiveness, patient safety and patient experience (Darzi, 2008). Furthermore it has been suggested that effective QI benefits patients, NHS staff and provider organisations by improving care, and potentially decreasing long and short-term economic costs (Swensen et al., 2013).

A methodology for mapping QI development has been provided consisting of best generalisable scientific knowledge, comprehension of particular context, measuring changes created by the QI initiative, familiarity with change methods, ability to execute planned changes, and awareness of the flow of power within a system in order to make lasting change (Batalden and Davidoff, 2007). Such a framework is commensurate with a CR informed perspective and will be adopted as part of the conceptual framework guiding this thesis. However, it is also necessary to consider that the organisation and delivery of care goes beyond the individual level of patients and clinicians to include contextual drivers derived from multiple sources, including systems level and service level factors. The autonomy of GPs as actors, to reproduce or diverge from normative conditions, at various levels means that despite broad utility, most implementation theories have limited potential to concretise mechanisms pertinent to development, use and implementation of a suicidality CDSS. A helpful theory in this regard maybe the Consolidated Framework for Implementation Research (CFIR) (Damschroder et al., 2009). The CFIR highlights multiple implementation constructs across five domains considered to be influential moderators or mediators of implementation outcome (Bauer et al., 2015). The five domains highlighted in the CFIR are characteristics of the intervention, the outer setting (the economic, political, and social context pertinent to the target organisation for the proposed intervention), the inner setting (features of structural, political, and cultural contexts internal to the organisation through which the implementation process will proceed), the characteristics of

individuals involved, and lastly factors specific to the implementation process as a discrete process of change (Damschroder et al., 2009). According to Nilsen's typology (2015), the CFIR is a determinant framework which seeks to concretise conceptual constructs likely to influence implementation outcomes (Damschroder, 2020). A key strength of the CFIR is its breadth, which seeks to account for both the influence and actions of individual actors, as well as organisational, and cultural values and wider social structures. This breadth of scope is in keeping with CR perspectives of the necessity to capture the impact of structure and agency in order to guide effective implementation, since human actions and systems are both interdependent and independent. Furthermore, the CFIR tallies closely with known factors influencing changes to primary-care delivery and practice. These known factors include the necessity of an enabling external policy context, organisational culture and readiness for change, professionals autonomy and decision-making capabilities, and the nature and characteristics of the proposed change (Lau et al., 2016).

Primary care has a particular research and implementation culture, where any proposed practice change must be seen as acceptable to GPs (Lau et al., 2014). Primary care culture therefore demands that any proposed change must pay attention to factors concerning its acceptability, compatibility, compliance and delivery. Contemporary approaches to implementation research highlight this complexity, and suggest that overcoming the multiple barriers to implementation of practice-change requires skill and situational judgement, and approached as a science informed practice, rather than a procedural process to be unquestioningly followed (Greenhalgh, 2017). In this way, neither the abstract propositions of the CR meta-theoretical framework, nor the relative specificity of implementation frameworks such as the CFIR hold all the answers required. However, in combination they offer complementary strengths, and will guide the

thesis and the empirical studies designed to create and provide initial evaluation of a suicidality CDSS.

4.4 Method and implication for this thesis

CR informed perspectives will allow for the integration of underpinning theory, whilst accounting for proposed generative mechanisms and prospective use of the suicidality CDSS in primary-care suicidality prevention.

The content for a suicidality CDSS will be developed and evaluated through a pragmatic application of top-down and bottom-up methods, combining published evidence with stakeholder perspectives and experiences (Bradshaw et al., 2012). This will allow synthesis of theoretical underpinnings, key contextual issues and the perspectives of healthcare providers and service-users. Methodological triangulation, or the use of different kinds of method to answer the thesis' research questions, will be sought. Key benefits of methodological triangulation include greater data completeness, enhanced retroductive explanatory power, and clarification of results from different view-points (Risjord et al., 2001). Methodological triangulation is relevant to CR informed research since clarification and completeness provide detailed observations, which in turn may illuminate generative mechanisms (McEvoy and Richards, 2006). Methodological triangulation will be sought through the pragmatic use of top-down and bottom-up approaches, to investigate the potential content, format and use of a suicidality CDSS.

To shape the proposed CDSS, so that it fits with the demands of the primary care context, existing methodological frameworks for the development of CDSS will be incorporated. CDSS are most likely to be successful when there is a clinically identified opportunity for actionable clinical-decision support (Damberg et al., 2012). This opportunity is apparent since GPs have previously expressed a suicidality CDSS would aid their clinical practice, decision-making and

primary-care suicidality prevention efforts (Michail and Tait, 2016). Furthermore the external policy context as reviewed in chapter two also supports the development of a suicidality CDSS, since the need for such a tool has been highlighted in the NHS Long Term Plan (NHS England, 2019b).

In keeping with the integration of top-down and bottom-up perspectives, (Bradshaw et al., 2012), the empirical studies within this thesis are undertaken to explore the impact of structures and context on GPs approach to working with patient suicidality, and GPs prospective use of the CDSS.

The first empirical study (chapter 5) and the second empirical study (chapter 6) report qualitative studies undertaken with primary care GPs and patients to incorporate their views as prospective end-users of a suicidality consultation in which the CDSS could be used. Individual interviews were conducted with GPs to gain their perspective of possible generative mechanisms, which may influence their inquiry of patient suicidality in consultations; and views on content of the CDSS and mechanisms which might help or hinder its utilisation. The perspective of patients as people with lived-experience of disclosing suicidality in GP consultations is also vital to data completeness. Two small groups of patients were brought together to provide embedded consultation to the research and a lived-experience perspective in service-user advisory groups. Group members were asked to provide their perspectives of suicidality consultations, CDSS content, and views regarding potential generative mechanisms influencing use of the tool in consultation.

The third empirical study (chapter 7) reports on 3 co-production workshops conducted with key stakeholders, featuring a modified Delphi technique used to refine the content of the CDSS, and to further elucidate potential generative mechanisms influencing its use.

Delphi surveys are a group facilitation technique designed to obtain experts consensus in relation to specific topics (Felicity et al., 2000). Incorporating the insights of experts in primary care, suicidality prevention and health-service implementation supported completeness, clarification and retroductive explanation regarding possible use of the CDSS.

The fourth empirical study (chapter 8) provides an account of the initial prototype development and usability testing. Iterative development of the CDSS took place in relation to the explanations elaborated through chapters 3-7 and directly informed by methodological triangulation. Usability testing of the prototype involved evaluation with reference to an established framework for developing CDSS tools, (Kannry et al., 2015), combining actionable decision-support, multiple rounds of usability development, and usability testing. The usability testing sought feedback from GPs on the ease of use of the tool, its integration with existing IT systems and practices (workflow) and its overall relevance to suicidality consultations.

Overall, this pragmatic application of a mixed-method, intensive design, allows methodological triangulation, within the over-arching meta-framework of CR, and adds to the development of domain-specific theory regarding the use of a suicidality CDSS. The philosophical and theoretical frameworks guiding this work are set out below:

Figure 4-2: Philosophical and theoretical frameworks

Meta-philosophical framework	Critical Realism (Bhaskar, 2008) • Ontological Realism • Epistemological Relativism • Judgemental Rationality
Theoretical frameworks	CFIR (Damschroeder et al., 2009) Achieving Change in Primary-Care (Lau et al., 2016) Healthcare QI transformation (Batalden & Davidoff, 2007)
Proposed generative-mechanisms & domain specific theory	Contextual pressures GP knowledge, skills, & characteristics Uncertainty & implicit threat Limitations of risk prediction Heuristics & biases / Dual Process Theory (Croskerry) Difficulties communicating about suicidality in primarycare GP isolation Perceived benefit of a suicidality CDSS

To aid conceptual clarity, the theoretical components of the CFIR (Damschroeder et al., 2009), the Achieving Change in Primary-Care (ACiPC) (Lau et al., 2016) and the Quality Improvement Change model (QIC) (Batalden & Davidoff, 2007) can be grouped into four focused areas. These are broadly described as:

- CDSS characteristics and GP autonomy
- Primary-care context and culture
- Wider structural drivers
- Change sustainment

These four key focal areas will be investigated through the methods employed, with expected nuances to be found in different

methodological components of the thesis. This subtle variation is estimated, because in CR informed research different stake-holders are anticipated to be able to articulate information pertaining to potential generative mechanisms to varying degrees depending on their awareness and experiences of the research topic (Manzano, 2016). Anticipated areas of greater nuance are depicted by shaded areas below.

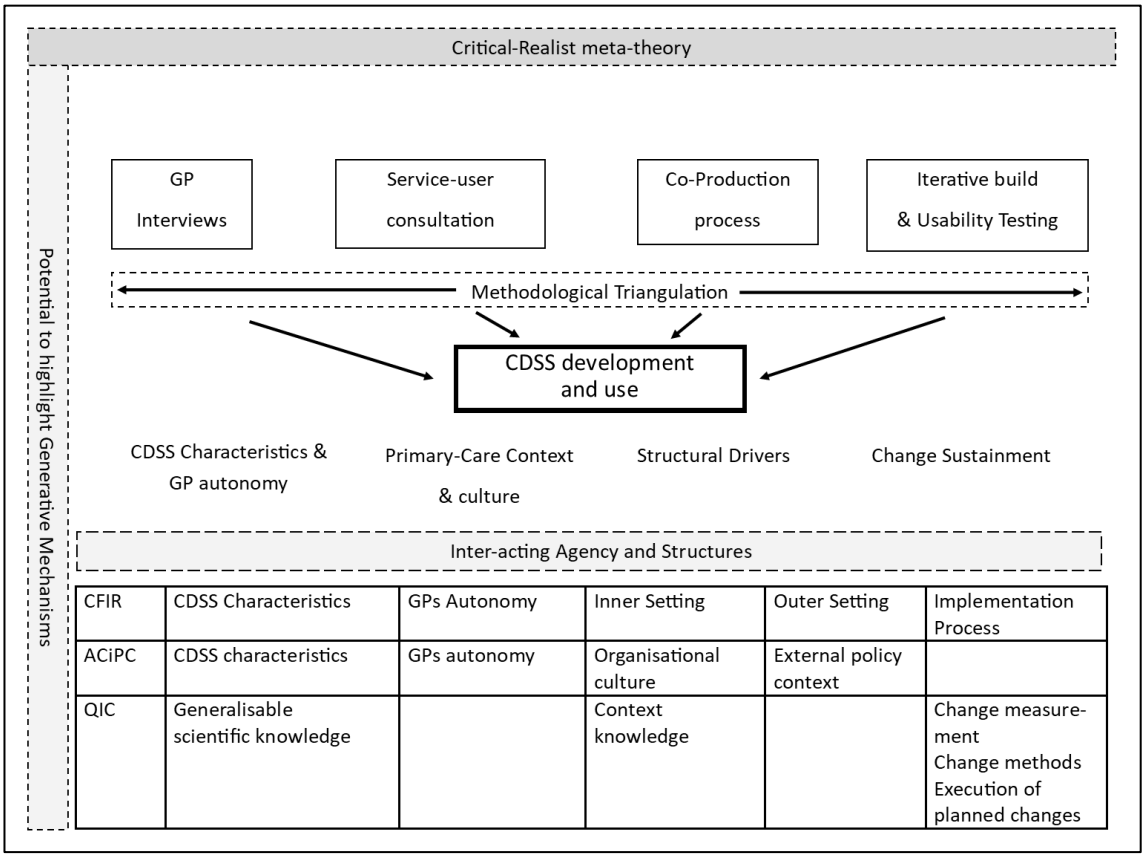
Table 4-1: Key focal areas by methodological component

Theoretical consideration	GP interviews	Patients embedded consultation	Co-Production	Iterative build and usability testing
CDSS characteristics & GP Autonomy	✓	✓	✓	✓
Primary care context	✓	✓	✓	✓
Wider Structural drivers	✓	✓	✓	✓
Change Sustainability	✓	✓	✓	✓

CR meta-theory offers a theoretically rich guiding framework to inform the development of domain specific theory, whilst enabling a mixed-method design without the problems of paradigm switching (McEvoy and Richards, 2006). This design will allow for the incorporation of a quantitative strand within a broader intensive, qualitative design, allowing for triangulation and more complete description of the development and usability of the CDSS. Such mixed-methods designs are sometimes referred to as either an embedded, or nested concurrent design where partial mixing of qualitative and quantitative data occurs, although one data type may be considered of greater relevance to the specific research question (Doyle et al., 2009). This methodological approach, and the specific methods used will enable triangulation and completeness of data to

inform development and guide initial usability evaluation of the suicidality CDSS.

Figure 4-3: An intensive study design for the development of a suicidality CDSS



CFIR	CDSS Characteristics	GPs Autonomy	Inner Setting	Outer Setting	Implementation Process
ACiPC	CDSS characteristics	GPs autonomy	Organisational culture	External policy context	
QIC	Generalisable scientific knowledge		Context knowledge		Change measure-ment Change methods Execution of planned changes

The intensive design adopted will develop an explanation, based on a small number of cases in a specific context, taking into consideration structural entities and contextual conditions influencing GPs response to patient suicidality and allow investigation of mechanisms pertinent to GPs ways of working with patient suicidality and prospective use of the CDSS. The information gained from the intensive approach will iteratively shape the development of the CDSS, whilst laying the ground-work for future extensive research. The design therefore seeks to integrate theoretical underpinnings, along with emergent information regarding key contextual issues and the perspectives of GPs and patients.

4.5 Aims and objectives

4.5.1.1 Overall Aim

To develop an electronic Clinical-decision Support System (CDSS), grounded in general practitioner experience and informed by stakeholder expertise and research evidence, to improve primary care suicidality consultations, by assisting GPs with the identification, assessment and clinical management of suicidality in primary care consultations.

4.5.1.2 Aim 1: Explore GPs' perspectives

To explore GP's perspectives on the format, content and use of a suicidality CDSS and generative mechanisms which might influence their practice in this regard.

4.5.1.2.1 Objective 1: Interviewing GPs, to explore:

i) How do GPs identify, assess and manage patient suicidality in primary care, and what do GPs think influences their practice and clinical decision making in this regard.

ii) What are GP's perspectives on the format, content and use of a suicidality CDSS, and how could a CDSS assist GPs to identify, assess, and manage suicidality in primary care.

4.5.1.3 Aim 2: Explore patient's perspectives

To explore primary care patient's perspectives on the format, content and use of a suicidality CDSS and generative mechanisms which might influence suicidality consultations with a GP.

4.5.1.3.1 Objective 2; to facilitate patient advisory groups to explore:

i) How do primary care patients with lived experience of suicidality understand and experience GP consultations in relation to suicidality including how GPs identify, assess and manage suicide risk in primary care.

ii) What are the views of primary care patients with lived experience of suicidality on the content, format and use of a CDSS for suicidality.

4.5.1.4 Aim 3: Developing the content for the CDSS

To bring together multiple stakeholders (GPs, patients, topic specific experts) to agree and refine the content of the CDSS so that it is clinically appropriate to the needs of GPs' and the primary care context and feasible to be used within primary care suicidality consultations.

4.5.1.4.1 Objective 3: to facilitate consensus workshops to:

i) Conduct a modified Delphi expert consensus exercise to achieve consensus agreement on a short list of items or prompts.

ii) Agree and refine the content of the CDSS, explore barriers and facilitators towards implementation and elucidate potentially relevant generative mechanisms influencing the use and implementation of the CDSS.

4.5.1.5 Aim *4: To build and evaluate a prototype suicidality CDSS*

4.5.1.5.1 Objective 4: To build the CDSS prototype by synthesising findings from the previous stages of the study and liaising with primary care health informatics specialists to refine final content.

4.5.1.5.2 Objective 5: To conduct usability testing, guided by an established theoretical and methodological framework (Kannry et al., 2015) to provide an initial evaluation of the CDSS in practice.

Chapter 5: General Practitioners' perspectives

5.1 Introduction

This chapter follows on from the key considerations highlighted in the literature review and the potential candidate generative mechanisms of relevance to GPs identification, assessment and management of suicidality risk, and use of a CDSS to help with this task. The chapter reports an empirical study conducted with GPs to explore their perspectives on the format, content and use of a suicidality CDSS and generative mechanisms which might influence their practice in this regard.

5.2 Method

5.2.1 Setting

The study took place in the catchment areas of the Nottingham City and Nottinghamshire county NHS Clinical Commissioning Groups (CCGs), now merged under the umbrella of NHS Nottingham and Nottinghamshire CCG, responsible for the healthcare of a population of 1,096,640 people (Nottingham and Nottinghamshire Clinical Commissioning Group 2020). CCGs are NHS organisations set up by the Health and Social Care Act 2012 to organise the delivery of NHS services in England.

5.2.2 Study design

A qualitative research design was adopted to explore GP's perspectives and to inform the shortlist of items and prompts within the CDSS.

5.2.3 The purpose of the method

In-depth interviews were conducted on a one to one basis, to understand GP's perspectives regarding the format, content and use of a suicidality CDSS, as well as potential generative mechanisms influencing GPs use of the CDSS. 2 research questions underpinned the method:

i) How do GPs identify, assess and manage patient suicidality in primary care, and what do GPs think influences their practice in this regard.

ii) What are GP's perspectives on the format, content and use of a suicidality CDSS, and how could a CDSS assist GPs to identify, assess, and manage suicidality in primary care.

5.2.4 Methods of data collection

Semi-structured interviews were used to interview GPs, to understand GPs' perspectives. A single interview lasting up to 60 minutes took place, either over the phone or face-to-face between the research student and each participating GP. Face to face interviews took place in locations and at times that were convenient to GPs, so as to not detract from their clinical responsibilities. Typically, this involved meeting in their practice after clinic, or in appropriate non clinical settings. All interviews took place between November 2017 and April 2018.

A CR informed approach to interviewing was adopted highlighting participants' views regarding the interactions between their actions in context, specific contextual factors, possible generative mechanisms and resulting outcomes (Pawson, 1996). The CR informed approach to interviewing is situated between positivist and constructivist positions. An interpretivist stance is taken is so far as qualitative research interviews offer the chance to engage participants in co-constructed meaning-making, rather than merely functioning as a conduit to distribute information to researchers (DiCicco-Bloom and Crabtree, 2006). However, CR informed research interviews also seek to highlight that human behaviour takes place in context where pre-existing social structures and generative mechanisms may both constrain or facilitate human action, without fully determining them (Smith and Elger, 2012). The interview process is active, rather than passive, because both the researcher and the interviewee contribute

resources and perspectives on reality to the interview, whilst elaborating the researcher's theory ("theory-driven" interviewing) (Smith and Elger, 2014). The interview retains a semi-structured nature, with the interviewer asking key questions in broadly the same way with each participant yet probing for further information (Arthur and Nazroo, 2003). A semi-structured interview approach was therefore used to facilitate intensive data collection of GPs perspectives and experiences, and gauge GPs reaction to the researcher's initial theories as identified during the literature review.

5.2.4.1 Interview topic guide

An interview topic-guide (Appendix D) was developed, to allow the interview to test the researcher's theories against the participant's insights regarding the candidate generative mechanisms identified in the literature review as first order theories, relevant contextual factors, and possible outcomes (Manzano, 2016). The topic-guide was piloted during 3 practice interviews undertaken with nursing and psychiatric colleagues with suicide prevention expertise whom the research student works with in his clinical role, on the understanding that no data would be retained, but insights from the pilot interviews might shape the research student's developing theories. Colleagues taking part in a pilot interview included two consultant psychiatrists, and a nurse consultant. The topic-guide sought to explore the 2 research questions (page 126).

As such, the topic guide was intended to enable exploration of GPs perspectives of the candidate generative mechanisms situated against key corresponding theoretical conceptualisations, (CDSS characteristics and GP autonomy, primary care context and culture, wider structural drivers and change sustainability).

5.2.5 Methods of data analysis

Interviews were recorded using a digital audio recorder and transcribed using a verbatim approach. 6 interviews (20% of the

sample) were transcribed by the research student, with the remaining interviews transcribed by a professional transcription agency. An industry standard non-disclosure agreement was incorporated to protect interviewee confidentiality. Verbatim transcripts were redacted by the researcher to remove any remaining personal identifiable data.

All transcripts were coded by the research student and data were analysed by the research student using DeDoose (version 8.3.17).

Additionally, 6 of the 30 transcripts (20%) were independently coded by the primary academic supervisor or a volunteer research assistant. Such dual coding is considered good practice in Content Analysis to gauge the consistency of understanding of codes and their reproducibility or intercoder reliability (Weber, 1990).

A layered qualitative data analytic strategy was adopted, to provide an overview of GPs accounts of the format, content and use of a suicidality CDSS, and potential generative mechanisms influencing their use of the proposed CDSS. The strategy sought to include insights provided by Content Analysis (CA) (Hsieh and Shannon, 2005) and Critical Realist qualitative analysis (CRQA) (Fletcher, 2016). Combining insights from different qualitative analytic strategies in such a way is possible and allows for analysis of the breadth and depth of data to produce a multi layered understanding of participant's accounts (Spiers and Riley, 2018). CA was applied to identify GPs most commonly occurring responses to interview questions, whilst CRQA was applied to gain insights into specific contextual factors and possible generative mechanisms occurring in the interaction of agency and structure.

5.2.5.1 Content analysis (CA)

CA is a general term used to describe a number of different strategies used to analyse text, which employ a systematic coding and categorising approach to examine trends, patterns and frequencies of

word use (Vaismoradi et al., 2013). A key concern within CA is categorising data according to a coding scheme, and consistency in applying the scheme in order to condense large quantities of text into much fewer content categories (Weber, 1990). Variations of CA exist including conventional, deductive, summative (Hsieh and Shannon, 2005) which place varying emphasis on reporting numerical trends within the data, or grouping responses into themes, reflecting manifest or latent content (Erlingsson and Brysiewicz, 2017).

Because of the importance of prior theory in CR research, in this thesis an adapted from of Deductive CA (DCA) was used in accordance with established procedure (Hsieh and Shannon, 2005). DCA commenced with using key concepts, such as assessing suicidal ideation and plans, or variables such as referring to Crisis Resolution Home Treatment teams (CRHT), as initial coding categories. Passages of text were coded for interest corresponding to these initial pre-determined categories. Text that could not be categorised within the initial coding scheme were allocated a new code. Codes and Categories were then revised iteratively to account for the spread of all codes and collapse similar codes into a smaller number of categories. The rank order frequency of codes and category use were calculated to reflect GPs manifest views on the respective importance of the corresponding theoretical construct or variable. Latent analysis (Hsieh and Shannon, 2005) was then also undertaken by grouping the categories into over-arching themes. Themes reported through DCA retain close proximity to their composite categories, rather than a higher degree of interpretation as is commonly applied in thematic-analysis studies (Vaismoradi et al., 2013). Themes, sub-categories, number, and percentage of statements in each category are reported to show the spread of the data and the relative magnitude of participants' concerns (Liem, 2019). DCA, therefore, provides a descriptive account of the data and manifest content including quantitative count of the codes used, with initial latent analysis and

interpretative content leading to creation of themes within the data (Graneheim et al., 2017).

5.2.5.2 Critical realist qualitative analysis (CRQA)

In order to ensure theoretical consistency with a CR informed approach, the CRQA approach (Fletcher; 2016) was adopted. This method extends Content Analysis (CA) by incorporating another layer of analysis, informed by CR, in order to identify possible generative mechanisms (Fletcher, 2016). Fletcher's method is important since the literature on applied CR is often vague regarding data-handling and analytical processes. CRQA followed the DCA process, but then additionally added a cycle of re-coding the data into CR informed categories of Structure and Agency. Categorised data were then reviewed in relation to existing theory through a process of theoretical re-description (abduction). Data were also subjected to identify underlying contextual conditions in which specific generative mechanisms might be activated (retroduction). Adoption of DCA followed by CRQA increases the trustworthiness of the data-analysis by enhancing reproducibility, credibility, and potential transferability of the findings (Lincoln and Guba, 2000). Such criteria are commonly used to evaluate the quality of qualitative research (Cope, 2014), and are commensurate with post-positivist approaches to qualitative research (Morrow, 2005).

5.2.6 Sampling strategy and participant recruitment

CR informed interview studies aim to develop the researcher's theories in relation to participants' insights. Instead of being governed by the number of interviews likely to result in theoretical saturation, CR informed qualitative research requires a sufficient number of interviews to achieve relevance and rigor with regard to the explanatory power of the research (Manzano, 2016). A sample size of 20 to 30 interviews is usual in qualitative research at doctoral level (Mason, 2010). This affords an acceptable number or

participants to balance pragmatic considerations, likelihood of theoretical saturation and specific methodological requirements (Creswell, 1998). Therefore, in order to achieve a balance of relevance and rigor, interviews with 30 GPs working in NHS primary health care practices were sought through a purposive sampling approach.

5.2.6.1 Participant recruitment

The research student initially approached mental health leads within Nottingham city and Nottinghamshire county NHS CCGs. Additionally, the study was promoted through the National Institute of Health Research (NIHR) Collaboration for Leadership in Applied Health Research and Care (CLAHRC-EM) affiliated communities of interest, the Division of Primary Care Medicine at University of Nottingham, regional GP Vocational Training Schemes, the regional branch of the Royal College of General Practice and regional Local Medical Committees (LMCs) who are locally focused independent bodies representing the interests of GPs working in the NHS.

Summary information was disseminated amongst these GP communities informing of the intention to develop a tool to help GPs identity, assess and manage patient's suicide risk. GP's were invited to interview to help the research student understand when and how they might ask patients about suicidality risk, barriers to asking about suicidality and perspectives on how a CDSS could help

GPs expressing interest were requested to contact the research student directly. GPs were then provided with a participant information sheet (Appendix E) and a consent form (Appendix F) by the research student.

5.2.6.2 Consent process

GP's consent was obtained by their return of the consent form to the research student. Additional verbal consent was also obtained prior to interview by the research student.

5.2.6.3 Sample characteristics

A sample of 30 qualified GPs was recruited (years post-qualification $\bar{x}$ = 17, median = 16.5, mode = 10, range: 0-39). To balance relevance and rigor the sample included male and female, salaried and partner grade GPs working in the NHS, several of whom were also academic GPs maintaining NHS clinical practice as part of their role. Additionally, 2 GPs, holding GMC practice certificates, but whom were not currently providing direct patient care were recruited via academic or GP LMC networks. These participants were specifically recruited because of their positions of senior leadership within regional or national GP professional bodies. These participants were able to provide a distinctive perspective regarding the feasibility and acceptability of the CDSS from a systems of care and professional leadership perspective. The characteristics of the sample are provided in Table 5-1.

Table 5-1: GP interview participants (n=30)

GP characteristic	Male (n=13)	Female (n=17)	Total
Salaried	5	8	13
Partner	7	8	15
Non-practicing	1	1	2
Total	13	17	30

5.2.7 Ethical and research governance approval

The University of Nottingham undertook the role of the research sponsor (Protocol Reference 17053, Appendix A). Ethical and research governance approvals for the study were obtained prior to data collection from the Nottingham 1 NHS Research Ethics Committee, and the Health Research Authority, (REC reference: 17/EM/0317 Appendix B-C) as well as local CCGs or NHS Research and Development departments

5.3 Findings

5.3.1 Content Analysis - manifest analysis

Directed Content Analysis (DCA) was conducted to reflect GPs' manifest views on the process of identifying, assessing and managing patient suicidality, and the potential format, content and use of a suicidality CDSS. During the interviews, GPs described a wide range of factors relevant to the identification, assessment and clinical management of patient suicidality. Societal, institutional and organisational factors were frequently mentioned, alongside factors specific to patient presentation, risk assessment, and the primary-care context. 146 codes were assigned. The codes with the highest and lowest frequencies in the dataset are presented below.

5.3.1.1 Rank-order codes

Research question 1 (page 143) sought to identify GPs' perspectives on factors salient to the identification, assessment and management of suicidality. The most frequent codes can be seen in table 5-2, with time pressures in primary care the most frequently reported issue in relation to identifying, assessing and care-planning for patient suicidality.

Table 5-2: Most frequenct codes (RQ1)

Rank order, code and frequency		
1	Time pressures	55
2	Plans / preparations	49
3	Intuition / quick cognition	44
4	Arrange a follow appointment	41
5	Suicidal ideation / thoughts	40
6	CRHT referral	37
7	Holding risk in primary care	37
8	Pattern recognition	26

Assessing, and differentiating, patients presenting with suicidality plans or preparations, from those presenting with ideation or thoughts about potential suicidality, were GPs next most-frequently reported challenge.

The most frequently reported actions which GPs might take as a result of their assessment were arranging a follow up appointment or referral to CRHT services. However, difficulties in the referral process, such as the burden on GPs of convincing CRHTs that risk was real and imminent, led GPs to frequently expressing the view that they were left holding an uncertain amount of risk in primary-care.

GPs frequently reported use of intuition, or quick cognition, as pertinent to the identification, assessment and management of suicidality. A separate code was created for *Pattern Recognition* as this was specifically named as a method of how some GPs applied heuristic based cognition within their practice. Strikingly, if the codes for *Pattern Recognition* and *Intuition* or *Quick cognition* are combined, this becomes the most frequent code in the dataset (n=70). This suggests that use of clinical heuristics appears to be an important part of some GPs approach to identifying, assessing and managing suicidality.

36 codes had just one count in the data set in relation to RQ1, these were tied at rank 30 and are shown in Table 5-3 (below). These codes reflected divergence amongst GPs regarding their views of populations at risk, important risk factors, or different ways of assessing suicidality.

Table 5-3: Least frequent codes (RQ1)

Code	Count
Single mothers	1
Post-partum mothers	1
Vulnerable adults	1
Learning Disability	1
Alienation	1
Grief or loss	1
Stigma	1
Anger	1
Valentines' day	1
Christmas day	1
Personal warning signs	1
Acute triggers	1
Medication renewal	1
Patients' understanding of GP's language	1
Patient's affect	1
Patient's openness	1
Patient's ambivalence	1
Knowing the family circumstances	1
Gendered presentation norms	1
Risky behaviour	1
Suicidality schema	1
Suicidality as the patient's coping strategy	1
Under-resourced	1
GP's own support needs	1
Specific method	1
Mental State assessment	1
Build communication	1
Consideration of room layout	1
A face-to-face process	1
A patient led process	1
Signpost to Legal help	1
Signpost to Housing support	1
Suggest exercise	1
Suggest enjoyable activity	1
Teach relaxation exercises	1
CAMHS	1

Research Question 2 (page 123) sought to explore GPs' perspective on the format, content and use of a suicidality CDSS. 474 statements were coded amongst 33 codes. The most frequent codes are reported in Table 5-4 (below)

Table 5-4: Most frequent codes (RQ2)

Rank order, code and frequency (n=)		
1	Integration with consultation style	71
2	Integration with the IT system	36
3	Ability to be used flexibly	35
4	Perceived utility of the CDSS	34
5	Guides the assessment	29

Table 5-4 highlights that a major concern for GPs related to the integration of a suicidality CDSS with their current consultation style. The extent to which a suicidality CDSS could integrate with GPs existing medical records and IT systems also appears an important concern for GPs reflected in the relative frequency with which this code was recorded.

Linked to the first code (*Integration with consultation style*), GPs frequently expressed a desire that the tool could be used flexibly, rather than prescriptively, to fit with different ways of working and different consultation styles.

A further important characteristic of the CDSS is its perceived utility, referring to how useful GPs consider the CDSS could be in helping them to meaningfully identify, assess and care-plan for patients potentially at risk. The extent with which this code exists in the dataset suggests that GPs may have concerns about such a tool possessing practical utility.

Finally, GPs highlighted the need for the CDSS to support them in guiding the consultation, and providing a standardised way of recording and documenting clinical assessment.

The least frequent codes are reported in Table 5-5 (below)

Table 5-5: Least frequent codes (RQ2)

Rank order, code and frequency (n=)		
22(t)	Must use historical data in the EHR	1
	Patients' awareness of the CDSS will determine its use	1
21(t)	It must have a clear focus on suicidality	2
	Has a case-finding quality	2
	Prompts to ask about self-harm	2
20(t)	GPs' awareness of the CDSS will determine it use	3
	Must be available to the whole practice, not just GPs	3
19 (t)	Must help with risk prediction	4
	Has to rely on the accuracy of historical data in the EHR	4
	Must have good sensitivity and specificity	4
	Will have a helpful educational value	4
18	Helps produce a safety-plan	6

As can be seen from Table 5-5, a minority of statements suggested that the CDSS should only rely on historical data in the EHR, or have a case-finding or risk prediction ability. Interestingly few statements supported the notion that the CDSS should be clearly focused on suicidality, or help produce a safety-plan. This may reflect GPs different ways of working with suicidality.

This manifest analysis of the CA data reports the frequency of the most prevalent, and least frequent codes serving to highlight key information regarding GPs perspectives regarding the use, format and content of a suicidality CDSS. However, without examining the data in context the codes only infer limited information, and collation of similar codes into over-arching themes allows for greater consideration of GPs perspectives.

5.3.1.2 Category-based themes

During DCA, codes were collapsed into nine broad category-based themes, which highlighted GPs' primary concerns regarding the identification of patients at risk of suicidality, the process and content of suicidality risk assessment, risk management or care planning actions which GPs might take, and the characteristics or properties of the suicidality CDSS.

Table 5-6 shows that GPs more frequently talked about distal risk factors, risk assessment concepts (such as assessing suicidal ideation), risk management actions (such as booking in a follow up appointment) and characteristics of the CDSS (such as integrated into the consultation). Conversely, fewer code applications were categorised as pertaining to specific aspects of the patient's presentation, the risk assessment process, the impact of the primary-care context, or individual GP experiences and attitudes.

Table 5-6: Category based themes

Themes		Coded statements
1	Consideration of distal risk factors	195
2	Proximal warning signs	44
3	Patients' presentation	115
4	Primary care context	66
5	GP experiences and attitudes	143
6	Risk assessment concepts	295
7	Risk assessment process	65
8	Risk management actions	369
9	Tool characteristics and properties	474

The CA relating to these category-based themes are presented below. Within the over-arching categories some codes were grouped into sub-categories, reflecting semantic or conceptual areas of similarity; for example, historical depression and anxiety, were clustered together as *past mental health episodes*, within the over-arching category theme *consideration of distal risk factors*.

5.3.1.2.1 Theme 1: Consideration of distal risk

195 statements were coded as pertaining to GPs' consideration of distal risk factors (Table 5-7).

GPs identified that their perception of suicidality risk could be influenced by static risk factors, including history of suicidality, mental health episodes, historical alcohol or substance misuse problems, demographic factors, socio-economic factors, long term health problems and adverse life experiences. The most frequently coded statements pertained to demographic risk categories (30.26%), such as male gender (7.18%).

Consideration of previous mental health episodes were the second most frequent sub-category within this theme accounting for 37 coded statements (18.97%), with depression (9.74%) and self-harm (9.23%) singled out as important factors. Patient's past suicidality, or exposure to suicidality was the third most frequently coded sub-category accounting for 33 statements (16.92%)

Table 5-7: Consideration of distal risk factors

Consideration of distal risk factors (n=195)			
Sub-category	Codes	Number of coded statements (%)	Examples GP number, Sex (M/F), Salaried (S), Partner (P)
Past suicidality or exposure to suicidality n =33 (16.92%)	Self-harm	18 (9.23%)	*"People who repeatedly self-harm, each incident itself might be relatively low risk, but there's always the worry isn't there through repetition that they will eventually come to serious harm" (GP23,F,P)*
	Previous suicide attempts	13 (6.67%)	*"I'll also look back over their past history, to see if they've tried to kill themselves before, or if they've had any help for this before" (GP07,F,S)*
	Family history of suicidality	2 (1.03%)	*"If there is a family history of suicide" (GP21, M, P)*
Past mental health episodes N=37 (18.97%)	Depression	19 (9.74%)	*"Obviously it's the people who come who are depressed and I suppose they're the only times that we actively, or I actively ask" (GP13,F,S)*
	Personality Disorder	6 (3.08%)	*"I would just ask anybody who I think has got any sort of mental health or even personality problem about it. That would be my general rule" (GP14,M,P)*
	Psychotic features	5 (2.56%)	*"Psychotic thoughts are a red flag" (GP25,M,S)*
	Anxiety	5 (2.56%)	*"I get a lot of patients that come in with depression, anxiety, and they're looking for a diagnosis, and as part of my assessment it's always asking about any thoughts of deliberate self-harm, any suicidal ideation" (GP16,F,S)*
	Autistic spectrum disorder	2 (1.03%)	*"People on the autistic spectrum or in that dyspraxic, dyslexic end, sometimes get very weird reactions with SSRIs, so you have to watch them" (GP12,F,S)*

Past alcohol or substance misuse N=29 (14.87%)	History of alcohol use	16 (8.21%)	*"Alcohol is another factor, it's how they are drinking because you know it can disinhibit them" (GP03,M,P)*
	History of substance use	13 (6.67%)	*"One's sense of self care and awareness of risk is reduced when one is dependent on other substances" (GP25,M,S)*
Demographic factors n=57 (29.23%)	male	14 (7.18%)	*"Well if it's a man that comes in and tells me I'm more worried about a man coming in, because obviously you know, they tend to go ahead and do it rather than, you know, talk about it" (GP16,F,S)*
	Young people	14 (7.18%)	*"There's so much more mental health issues in young people" (GP28,F,P)*
	Older people	13 (6.67%)	*"In terms of risk groups, I guess, I think people who are older sometimes are more likely to successfully complete" (GP18,F.S)*
	Divorced / separated	5 (2.56%)	*"If they've divorced so they haven't got that support network there" (GP10, F,S)*
	Middle aged people	4 (2.05%)	*"We all know that there are certain groups which are more likely to complete suicide, so it wouldn't be wrong to be thinking in terms of ... Say for example a middle-aged unemployed male" (GP25,M,S)*
	Specific occupations	3 (1.54%)	*"Farmers I know are another high risk group because they've access to things like guns and stuff like that" (GP18,F,S)*
	Single mothers	1 (0.51%)	*"I tend to see a lot of single mums who probably are less of an actual suicide risk, that may have accidental suicide, they're more sort of parasuicidal and cries for help, but obviously accidental suicide are worth keeping in mind" (GP17,F,P)*

	Post-partum mothers	1 (0.51%)	*"Post-partum mothers can be at risk" (GP21, M, P)*
	Vulnerable adults	1 (0.51%)	*"I guess there could be risk, in particular around vulnerable adults" (GP20,M,S)*
	Learning Disability	1 (0.51%)	*"It could well be that they have low mental IQ" (GP29, F,S)*
	Ethnicity	2 (1.03%)	*"Some ethnic groups are more at risk. Afro-Caribbean in my opinion, male Afro Caribbean and female South Asians". (GP21, M, P)*
Socio-economic status N=12 (6.15%)	Socio economic background	10 (5.13%)	*"People living social in deprivation" (GP05, M, P)*
	Migrant populations	2 (1.03%)	*"Social and economic migrants can be at increased risk, people having moved sometimes great distances and without support networks" (GP05, M, P).*
Long term health problems N=15 (7.69%)	Long Term Health Conditions	11 (6.15%)	*"Those that have a chronic disease diagnosis" (GP18, F,S)*
	Chronic Pain	4 (1.54%)	*"People who have chronic painful conditions, like chronic back pain" (GP19, F,P)*
Adverse life experiences n=10 (5.13%)	Adverse Life Experiences	6 (3.08%)	*"There are some people who have had very, very difficult lives and are more likely to act, perhaps they've had very, very difficult disruptive childhoods and that's led to them being at higher risk". (GP18, F, S)*
	Domestic Violence	4 (2.05%)	*"People who have escaped from domestic violence or have been at risk of domestic violence" (GP20, M,S)*

5.3.1.2.2 Theme 2: Consideration of proximal risk

44 statements were coded as relating to GPs' consideration of proximal risk factors. Low levels of, or ruptures in, patient's social support systems or key relationships were the most mentioned code within this theme (40.91%), followed by features of patient attendance within the practice (25.00%). Other proximal risk factors suggested by GPs include hopelessness, acute stressors and patient-specific trigger factors, or days which stereotypically conjure images of interpersonal proximity and happiness (such as Christmas day).

Table 5-8: Consideration of proximal risk factors

Consideration of proximal risk factors (n=44)			
Sub-categories	Codes	Number of coded statements (%)	Examples GP number, Sex (M/F), Salaried (S), Partner (P)
Social isolation n=18 (40.91%)	Limited social support	15 (34.09%)	*"People who are isolated who don't have social support networks I always worry a bit about". (GP18, F, S)*
	Loneliness	3 (6.82%)	*"I think their experience is often that they have obviously been shunned by everybody" (GP19, F, P)*
Attendance pattern n=11 (25%)	Frequent attendance	5 (11.36%)	*"The frequent attenders are tricky as well, because there's a sort of cry wolf effect isn't there, where it's hard to spot those" (GP23, F, P)*
	Non attendance	3 (6.82%)	*"There are other patients, who kill themselves but they are non attenders, there is just nothing we can do about them, and if they are not coming in you just don't know…." (GP24, F, S)*
	Changes in attendance pattern	3 (6.82%)	*"Those who very rarely consult and then suddenly start consulting" (GP17, F, P)*
Malignant Hopelessness n=4 (9.09%)	Hopelessness	3 (6.82%)	*"Those who feel pretty hopeless and worthless " (GP19, F, P)*

	Alienation	1 (2.27%)	*"He was umm, he was really dealing with alienation, and that, the experiences he had of the world led him to an intense focus and awareness of his own ways of interacting"(GP24, F, S)*
Acute stressors and reactive suicidality n=7 (15.91%)	Criminal justice involvement	2 (4.55%)	*"Things that are common like, court issues" (GP24, F, S)*
	Shame or humiliation	2 (4.55%)	*"I'm looking out there for humiliation and shame" (GP24, F, S)*
	Grief or loss	1 (2.27%)	*"Grief or loss might be part of what they are dealing with" (GP05, M, P)*
	Stigma	1 (2.27%)	*"I think stigma is a massive thing with, for example depression, which may well give suicide risk anyway, for them to even talk about in the first place, so therefore trying to talk about suicidal ideation is even more stigmatising, because they feel very bad about that". (GP17, F, P)*
	Anger	1 (2.27%)	*"It might be that they are angry, or then those behaving in a way that is unusual for them, those that might be getting a bit aggressive". (GP 05, M, P)*
Personally specific triggers n=4 (9.09%)	Valentine's day	1 (2.27%)	*"Valentine's day can be a trigger" (GP24, F, S)*
	Christmas day	1 (2.27%)	*"Christmas can be a common trigger too" (GP24, F, S)*
	Personal warning signs	1 (2.27%)	*"It's specific to that patient and warning signs are quite important because they're the ones that really tell you that individual person might be at risk". (GP01, M, S)*
	Acute triggers	1 (2.27%)	*"Triggers are the things that particularly aggravate and frighten that person into a state of despair, and then possible suicidality". (GP25, M, S)*

5.3.1.2.3 Theme 3: Patient presentation

115 statements were coded in relation to aspects of the patient's presentation within the practice. The largest proportion of codes related to communication within the consultation (37.39%), and exploring the patient's reasons for the consultation (33.91%). GPs

also placed a high value on knowing the patient and their context (20.00%) and knowing their patients who most frequently demonstrate high-risk presentations (8.70%)

Table 5-9: Patient presentation

Patient Presentation (n=115)			
Sub-category	Codes	Number of coded statements (%)	Examples GP number, Sex (M/F), Salaried (S), Partner (P)
Reasons for the consultation =39 (33.91%)	Patient's stated reasons for the consultation	17 (14.78%)	*"Their presentation, why are they coming in the first place, if they are coming in for an explicitly to do with a mental health problem, but often you can't be 100% sure why they are in, or the main reason for their presentation" (GP03, M, P)*
	Passport symptoms	11 (9.57%)	*"Often in primary care, people don't just come with one thing, so they may present and frequently actually they do present with other things first, as a passport symptom". (GP22, F, P)*
	Getting to the patient's story	4 (3.48%)	*"It's very much getting their story and working with them." (GP08, M, P)*
	Medication renewal	1 (0.87%)	*"When somebody comes to me for some more antidepressants it is something I ask everybody, first time that I meet them certainly. I might be giving them a prescription for two months' worth of something and the last thing I want is for them to go away and take the lot or something". (GP14, M, P)*
	Brought to the consultation or accompanied	6 (5.22%)	*"You know you're really onto it when the relative brings them along" (GP12, F, P)*
Communication within the consultation = 42 (37.39%)	Non-verbal communication and facial expressions	24 (20.87%)	*"The non-verbal communication, their dress, their hair, whether or not they've applied makeup and sometimes they might have applied it, if they're female, they might have applied excessive makeup, almost to hide their mental unhappiness". (GP01, M, S)*

	Patient's use of language	3 (2.61%)	*"There are other issues which might lead you to suspect suicidality, it could be the way that they say things, the kind of words that they are using, for example how they might be talking about physical disorders, or if you get the sense that they are really just totally fed up". (GP05, M, P)*
	Patients' understanding of GP's language	1 (0.87%)	*"Basically the messages the GP are telling them are misconstrued" (GP25, M, S)*
	Communication Problems	2 (1.74%)	*"If the patient has communication difficulties, that could be another reason why this subject does not get talked about". (Gp29, F, S)*
	Patient's affect	1 (0.87%)	*"Those who are pretty flat and apathetic" (Gp19, F, P)*
	Patient's openness	1 (0.87%)	*"Openness, there was no concealment, he wasn't hiding anything from me…" (GP24, F, S)*
	Patient's ambivalence	1	*"Sometimes patients might give you a clue that is really ambivalent, the commonest might be, "Sometimes I wake up and wish I wasn't alive," you know something as vague as that". (GP25, M, S)*
	Concealing risk	4 (3.48%)	*"GPs are only human and actually you feel sometimes you made a mistake but some people when they're committed to doing it, they know exactly what to say" (GP27, M, S)*
	Readiness to disclose risk	6 (5.22%)	*"You know if someone isn't ready to tell you, you can sit there all day, and they'll really get pissed off, and they won't tell you until they are ready" (GP26, M, P)*
Knowing the patient and their context = 23 (20.00%)	Knowing the patient	18 (15.65%)	*"You might notice a change in their demeanour when they come or not presenting in the same way, or talking about the same things they would normally talk about, so in summary the advantage is, is knowing your patients well" (GP17, F, P)*

	Knowing the family circumstances	1 (0.87%)	*"You might be aware of some flags from relatives who have mentioned that person in passing" (GP17, F, P)*
	Awareness of cultural norms	3 (2.61%)	*"I think other thing to consider is cultural differences. I know in certain cultures suicide is not discussed, I mean suicide is bad, full stop, but I suppose there are certain cultural differences where the doctor might feel unable to ask the patient about their risk factors because of their cultural factors for example, a female doctor who is young qualified, asking this to a 60 year old Asian male …" (GP29, F, S)*
	Gendered presentation norms	1 (0.87%)	*"Males and females do present differently" (GP05, M, P)*
Knowing the patients who frequently present with risk =10 (8.70%)	Frequent risk presentation	2 (1.74%)	*"I had this one woman, … and she would be trying to kill herself every week, …, you know, cutting and overdosing and then ringing up and getting help" (GP12, F, P)*
	Impulsive patients	5	*"For some suicidal behaviour is something that's just a reaction to something and it's not been planned" (GP18, F, S)*
	Risk taking behaviour	1 (0.87%)	*"Sometimes you might see an increase in risk taking behaviour" (GP25, M, S)*
	Suicidality as a broad pattern in the person's life	1 (0.87%)	*"Maybe they have a suicide schema" (GP05, M, P)*
	Suicidality as the patient's coping strategy	1 (0.87%)	*"A reaction to being unable to cope. Not necessarily wanting, necessarily to be actively suicidal and die, but it maybe, just be their way of coping which may end up in their accidental death". (GP17, F, P)*

5.3.1.2.4 Theme 4: Impact of the primary care context

55 coded statements within this theme (88.33%) related to the time limitations which the primary care system is configured to allow per patient. GPs reported the challenges of working with complexity in such limited time, the knock-on effect of running beyond appointment

times, implications for patient care, and ways they attempted to manage this problem. 11 coded statements (16.67%) pertained to GPs sense of being responsible for managing patient needs and risk, whilst being exposed to potential notions of blame, needing to safeguard vulnerable people, and working in an under-resourced context.

Table 5-10: Impact of the primary care context

Primary Care context (n=66)			
Sub-category	Codes	Number of coded statements (%)	Examples GP number, Sex (M/F), Salaried (S), Partner (P)
Time per patient =55 (83.33%)	Time pressures and appointment duration	55 (83.33%)	*"I think the model of a 10 minute appointment for somebody who presents with mental health issues that might involve suicidal thoughts and self-harm is a problem, there's absolutely no way you're going to do it in 10 minutes and I think you just get to learn that actually, you have to invest the time at that initial appointment to make an appropriate assessment and then hope that at the next time it doesn't take quite so long. But there's no shortcuts, I think, you have to just accept that that's the way it is" (GP28, F,P)*
Responsibility and resources =11 (16.67%)	Blame and accountability	8 (12.12%)	*"One of the things about suicide and talking about blame, there is this general feeling if something bad has happened, and someone must be to blame.. .and honestly with suicide you get all these stories, well he saw his doctor this morning, you know and therefore the doctor must be to blame" (GP26, M,P)*
	Safeguarding processes	2 (3.03%)	*"I wouldn't immediately place safeguarding and suicide risk side by side, clearly it varies in every individual situation and there may be somewhere where it is clearly relevant". (GP24, F,S)*
	Under-resourced	1 (1.52%)	*"Primary care is very under-resourced and many practices don't have their full complement of doctors and often you're just about getting by really in terms of covering the workload and especially if people are away or something like that, so I think it's just getting harder and harder". (GP22, F,P)*

5.3.1.2.5 Theme 5: GPs prior experiences

143 statements were codes in relation to GPs prior experiences of working with patients presenting with suicidality. 86 statements (60.14%) related to GPs knowledge, skills and prior experiences of working with suicidality. 31 statements (21.68%) were in relation to GPs general and specific mental-health experience in primary care as mediators of their practice. 26 statements (18.18%) related to the emotional toll of working with suicidality, and the impact on GPs own sense of well-being.

Table 5-11: GPs prior experiences

GP prior experiences (n=143)			
Sub-category	Codes	Number of coded statements (%)	Examples GP number, Sex (M/F), Salaried (S), Partner (P)
GPs' general and mental health experience =31 (21.68%)	Prior general practice experience	18 (12.59%)	*"It does depend on you to a certain extent and the placements you have and the supervisors you have, and I think even though there is a massive curriculum and stuff, there is unspoken acknowledgement that not everybody is going to have done everything or know everything, can't possibly know everything by the end of your training so you need to be competent and that's what we look for now, competency, so you need to be good enough that most of the time you're going to pick things up and some of the time you aren't". (GP13, F,S)*
	Prior mental health experience	13 (9.09%)	*"It does depend on your experience, it does help if you've been offered some form of psychiatry training, either in undergraduate or as a part of our GP rotation. And I do feel that some of my colleagues that haven't done psychiatry will struggle when it comes to trying to deal with these patients". (GP29, F,S)*

Knowledge, Skills and Experience of working with suicidality =86 (60.14%)	Past suicidality exposure	12 (8.39%)	*"I think it depends on your experience and what's happened in the past and what patients you had that have or haven't committed suicide and the reflections that you might have had on those cases". (GP22, F,P)*
	Positive experience of working with suicidality	2 (1.40%)	*"Confidence in working with risk comes from past experiences of assessing risk, those cases where it has gone well, but we don't have too many cases in this area to draw upon". (GP24, F,S)*
	Negative experience of working with suicidality	11 (7.69%)	*"If things are going swimmingly well, you've been in practice for 20 years, and you've done all the things right and then suddenly someone kills themselves, your confidence is gone to pot, and so your response to the next person, in that sort of scenario, will be much more defensive" (GP26, M,P)*
	Reluctance to explore	13 (9.09%)	*"It can be difficult if they reply that they are potentially at risk or they are potentially thinking about it, because then that produces a clinical conundrum as to "What do I do about this?" (GP10, F,S)*
	Willingness to explore	3 (2.10%)	*"I mean you're not going to increase anybody's suicide risk by asking the questions and telling them that you're there for them, and I think that that has always been my feeling, my personal own feeling, is that the profession that people worry that if they open this Pandora's box, they're going to be culpable and liable for that person's actions". (GP17, F,P)*

	GP attunement to patient suicidality	10 (6.99%)	*"I guess in our practice, I'm the one that I guess, likes the mental health work the most, my colleagues will sometimes joke "this patient is one of yours" if they suspect it's a complex presentation with mental health…. but you know patients will tell different things to different GPs depending on the quality of the relationship or whether they think that GP is really working for them and listening to them. And not all GPs are very psychologically minded, for some of us it's easier to analyse and to listen extremely closely to what people are saying and then there are people at the other end, who need a memory jog" (GP24, F,S)*
	Practice Culture	8 (5.59%)	*"I think the ethos of the practice and how things are managed does highly influence individual GPs. Although you've always got outliers, I suppose GPs sort of conform to the mean of what the practice is doing". (GP23, F,P)*
	Training needs	16 (11.19%)	*"My training was a very long time ago and I did do a psychiatry attachment which was more out patient based. I don't remember ever having much training on suicide risk prevention (GP28, F,P)*
	Risk aversion	11 (7.69%)	*"I hate to think about practicing defensively because it's not something that I like to think I do, but it's a reality I suppose". (GP14, M,P)*
Emotional toll of working with suicidality =26 (18.18%)	Emotional labour	13 (9.09%)	*"To say I didn't worry about things, is not true, but it certainly wasn't the case that I would go home every night in tears, or wake up in the middle of the night, or go and visit people unexpectedly, I know some people do, and it destroys them…" (GP26, M, P)*
	Stress	5 (3.50%)	*"How stressed I'm feeling as a GP on a particular day as to my willingness to explore a mental health problem if it's there can influence" (GP03, M,P)*

	Frustration	4 (2.80%)	*"Dealing with suicidality it's a hot potato, that you are given that hot potato and you need to throw it to somebody else and you need to do that quickly and in a way that doesn't just wreck the rest of your day and all the other work that you have to do and all the other patients you have to see. It's very frustrating" (GP01,M,S)*
	Challenge of suicidality	3 (2.10%)	*"It is natural perhaps to think that you could have done something but the reality of the situation as far as the evidence is and I understand it, is that successful suicides are not always preventable and how does a doctor reconcile with that fact?" (GP08, M,P)*
	GPs' own support needs	1 (0.70%)	*"There can be doctors who may be suffering from mental health problems themselves, who have possibly not disclosed it and then they come in contact with a patient who's got similar or on the lines of mental health issues that they have, they might feel a bit awkward". (GP29, F,S)*

5.3.1.2.6 Theme 6: Risk assessment concepts

GPs described specific focal concepts that they considered as important to assessing suicidality risk. These included assessing suicidality ideation, plans, methods and access to methods, intent, and protective factors. Cumulatively, 165 statements were coded as pertaining to specific risk assessment concepts (55.93%); 9 (3.05%) statements were in relation to GPs working through a mental hierarchy of risk in relation to patient disclosures. The process of arriving at and making a clinical-decision was central to GPs concepts of suicidality risk assessment accounting for nearly half the coded statements in this theme (44.07%). In particular, intuition or quick cognition, a "*gut feeling*" as GPs in this study have described it; and, pattern recognition, which GPs described as "an in-built mechanism" resulting from years of experience, accounted for 70 coded statements (23.73%). Using their clinical judgment to reach a

decision about the severity of suicidality reported by an individual accounted for 26 coded statements. GPs also talked about the use of risk assessment scales as tools to aid their clinical decision making (32 coded statements) and their limitations in helping them reach decision as to who is suicidal and who is not.

Table 5-12: Risk assessment concepts

Risk Assessment concepts (n=295)			
Sub-category	Codes	Number of coded statements (%)	Examples GP number, Sex (M/F), Salaried (S), Partner (P)
Risk assessment focal concepts = 165 (55.93%)	Ideation	40 (13.56%)	*"If I perceive there might be any suicide risk I will definitely try and ask about whether they have had thoughts of ending their life" (GP01, M,S)*
	Plans	49 (16.61%)	*"Have they got plans about suicide, are those plans concrete, have they got equipment, the means to do it, and how specific are those plans, you know for example I'll overdose is different to ill overdose on something I know will kill me and I've been storing tablets" (GP07, F,S)*
	Specific method	1 (0.34%)	*"I actually ask if there's anything specific, if they thought of how they would kill themselves, which I think is a helpful question" (GP09, M,S)*
	Access to means	6 (2.03%)	*"I'd ask possibly about the modes and their access to those suicidal methods". (GP28, F,P)*
	Intent	21 (7.12%)	*"Is it just about them not wanting to be here or actually do they want to end their life? Because those are two different questions". (GP18, F,S)*
	Suicide notes	6 (2.03%)	*"If they tell me they've written a good-bye letter, that's it, I'm onto Crisis Team" (GP16, F,S)*
	Mental State assessment	1 (0.34%)	*"In terms of the assessment, I'll be just picking up the, essentially what we call the mental state examination in terms of how someone comes across" (GP06, M, P)*

	Protective factors	27 (9.15%)	*"Protective factors is another key thing that I would consider, so obviously if they have significant protective factors that, in my mind, would reduce the risk, but if there is an absence of any protective factors that can clearly put them at high risk" (GP20, M, S)*
	Urgency of support needs	5 (1.69%)	*"Often you'll pick up that people are actually frightened but in that way that, "I might do this, I'm worried that I might do this, I don't really want to do it but I'm worried that I might do this", the more people are at that end of the spectrum, the more likely it is that you're considering getting psychiatric help urgently". (GP06, M,P)*
	A hierarchy of risk	9 (3.05%)	*"I think there is a hierarchy or risk, moving from ideation, to plans, to intent. For me I always ask have you done an internet search? have you looked at blogs? Mechanisms? news articles? and so on. The answer to that gives me a sense of whether or not they are pre-contemplative, have they really considered the method and options for killing themselves. I guess the process is like a mental sieve". (GP02, M,P)*
The centrality of clinical decision making =130 (44.07%)	Intuition or quick cognition	44 (14.92%)	*"There's loads of risk factors, but I think sort of gut, really I would home in on. That's what general practice is about, it's the gut. And the longer you've been a GP the more gut feeling you get and you pick up tens of thousands of little things, how somebody walks in, how they talk, whether they make eye contact, whether there's lots of sighing going on, whether there's pauses at certain points when they actually think oh shall I say it or not". (GP19, F, P)*

	Pattern recognition	26 (8.81%)	*"You can never get away from pattern recognition because pattern recognition is inbuilt because it's experience. … it is, an inbuilt mechanism into yourself and that's just part of being human. That's why people who are very experienced do see things that you may not have done or have a lot more assurity or calmness about things because they've seen the pattern before, but I think it is dangerous and I do think when it comes to risk, not just documentation but when it comes to risk stratifying". (GP27, M, S)*
	Judgment	26 (8.81%)	*"You are making judgement about how suicidal they are…." (GP24, F,P)*
	GP uncertainty	2 (0.68%)	*"If they do say, 'well, yes I have thought about it and I can't be sure that I wouldn't do that', then you're in a difficult situation. You think, 'What do I do about this now?' and that can be difficult and uncertain" (GP10, F,S)*
	Limits of risk assessment	32 (10.85%)	*"Checklists have never worked terribly well in suicide awareness, there was one, I used to have it on my computer but it wasn't that useful, none of them have been. We've got to be able to differentiate between suicidalness and genuine suicidality. And that's not easy. And it's risky". (GP12, F,P)*

5.3.1.2.7 Theme 7: Risk assessment processes

In describing how they approach the process of identifying and assessing suicidality risk, GPs referred to the importance of contextualising and normalising patient's distress (47.69%), which was often seen as a pre-cursor to deepening patient's engagement in the consultation and gaining further risk information. 18 statements (27.69%) were in relation to ways of eliciting a deeper level of risk information including the importance of building communication and rapport; preferring face-to-face, as opposed to phone consultations; enquiring about suicidality openly and directly and, even considering

the layout of the consultation room to allow patients to time and space to talk freely. 16 statements (24.62%) related to GPs' aims of reconciling a patient-centred consultation with risk-assessment, which was both an analytical process and a patient-led endeavour, in which they would ideally be working collaboratively with patients to engage in shared decision-making.

Table 5-13: Risk assessment process

Risk assessment process (n=65)			
Sub-category	Codes	Number of coded statements (%)	Examples GP number, Sex (M/F), Salaried (S), Partner (P)
Contextualising and normalising =31 (47.69%)	Normalising	18 (27.69%)	*"You're actually almost saying really most people who feel like this, get some sort of thoughts going through your mind, so you are trying to normalise it for their mood states. That can be reassuring for them, therapeutic in a sense" (GP03, M, P)*
	Build trust	9 (13.85%)	*"I also think it is really important to be transparent about what I am asking and what I am writing in their notes, so to that end I have a second screen turned towards the patients, it's a mirror of my screen, so they can see exactly what I am writing". (GP02, M, P)*
	Build hope	4 (6.15%)	*"It's really important to try and give them a sense of realistic hope" (GP19, F, P)*
Gaining more information =18 (27.69%)	Build communication	1 (1.54%)	*"what is key, is the communication, and you know I've worked with a good number of people in acute distress over the years, and that really is the key". (GP05, M, P)*
	Consideration of room layout	1 (1.54%)	*"It's really important to think about the room layout to help with letting the patient feel they can talk" (GP02, M, P)*

	A face-to-face process	1 (1.54%)	*"It's particularly important I think, with patients with mental health problems, to see them face to face rather than talking over the phone, I don't think I'd feel confident assessing suicide risk over the phone, I think you need to have that patient in front of you" (GP10, F, S)*
	Ask direct questions	12 (18.46%)	*"I think the first thing to do, rightfully or wrongfully, as I guess we have been taught from medical school, is that you confront it and you put it on the table. We do that by asking directly" (GP15, F, S)*
	Ask open questions	3 (4.62%)	*"If I'm concerned about somebody's risk, or even if I've not, but I just want to clarify it, I will introduce it as a relatively straightforward question… I guess I might phrase it in terms of how low do you get at your very worst, and I would paraphrase by that to start with, and then ask them have they ever thought of doing any harm to themselves. Just as an open question and then exploring it more further" (GP17, F, P)*
A patient-centred risk assessment process =16 (24.62%)	Don't be led by psychiatric diagnoses	4 (6.15%)	*"It is separate to and in addition to any mental illness and then following the usual professional process of establishing a diagnosis and using NICE related guidance for example, you know the medication, the referral pathways, the psychological therapies. Separate to all of that and in addition to that is risk of suicide, so the two are not synonymous" (GP25, M, S).*
	Tailored to patient needs	2 (3.08%)	*"It's got to be sort of kept flexible and tailored to individual patient needs". (GP08, M, P)*
	A patient led process	1 (1.54%)	*"I will generally allow them to lead the conversation" (GP01, M, S)*

	Adopt a step-wise approach	4 (6.15%)	*"I would tend to start by saying, "You said you've felt very low, have you felt so low that you've had thoughts that life's not worth living?" and if they said yes, then I might go onto say, "Do you think that you would act on those thoughts?" and then ask them some more specifics around what sort of things they've been thinking, to try and find out how much they thought about it, whether they've got any specific plans or whether it's just perhaps a fleeting thought" (GP10, F, S)*
	An analytical process	3 (4.62%)	*"A lot of the questions around suicide, you're gathering information, but you're just asking specifically about suicide, so you might ask about alcohol, drugs, isolation, social situation trauma, family history and so on as part of your general assessment, it's an analytical process, but it's not about, you're not asking it just to know whether they're suicidal or not, you're asking to get a flavour of what their problem is". (GP30, F, P)*
	Shared decision making	2 (3.08%)	*"I'll always make sure I've got a plan with them on when they come back, what the potential is or what the aim is for any medication or treatment plan that we're putting in place, so give them a bit of self-empowerment," (GP11, F, P)*

5.3.1.2.8 Theme 8: Risk management

369 statements were thematically grouped in relation to risk management actions the GPs might take. Within this theme, the largest sub-category pertained to GPs needing to work with and reduce risk, with 221 statements (59.89%). The 3 most frequently reported codes were booking a follow-up appointment (n=41); holding and managing risk within primary care (n=37); and, the importance of listening and validating patients' concerns (n=28). 19 statements (5.15%) referred to the importance of applying generic 'safety-netting' in suicidality consultations, and 17 statements

(4.61%) specifically referred to creating a suicide safety-plan, a structured cognitive-behavioural intervention with promising evidence (Health Education England, 2018). If counted together, the codes for safety-netting and safety-plan become the third most frequent code within the sub-category (n=36), highlighting the importance to GPs of indicated ways of reducing risk.

The second sub-category was related to GPs' referral decisions, (40.11%) with the 3 most frequently reported codes: referral to CRHTs (9.76%); GPs dilemmas about deciding when the appropriate threshold to refer had been reached (7.32%); and, problems in the referral pathways (7.86%) to CRHTs, where GPs described the need to "*prove that they [patients] need to be seen today or tomorrow rather than in three days' time, it really is a game of hot potato as to who takes responsibility".*

Table 5-14: Risk management

Risk management actions (n=369)			
Sub-category	Codes	Number of coded statements (%)	Examples GP number, Sex (M/F), Salaried (S), Partner (P)
Working with and reducing risk =221 (59.89%)	Book a follow up appointment	41 (11.11%)	*"Follow up is really important, they have an appointment, I give them an appointment and it's in the diary it might be tomorrow or if not quite so seriousness it might be next week, but they definitely have a plan when they go out. Follow up is really important because I am expecting them to come back, and they know they can't go out and commit suicide they've got an appointment…. i know it sounds a bit silly, but there is something in that, it means that I believe they are going to stay ok and there something about that belief that is powerful" (GP03, M, P)*

	Hold the risk in primary-care	37 (10.03%)	*"For me the main thing, I guess is holding people, and by that I mean offering them space, and really trying hard to convey that we are not seeing them as a drain on our time, and giving them some space to talk through and look at ideas that might help their psychological stress". (GP24, F, S)*
	Offer continuity	5 (1.36%)	*"It is important to be trying to enable those patients to see the same GPs wherever possible, which is part of the reason most of us do General Practice, because of the holistic care, however on the other side of that, we're struggling with trying to do that with continuity now". (GP17, F, P)*
	Listen or validate	28 (7.59%)	*"The key thing we can do as GPs, is to listen, people want to be heard, that's why they are reaching out. Unless they are saying I'm going to kill myself now, and have access to the means to end their life, it's not a CRHT referral, instead what they need is to be heard and validated. (GP02, M, P)*
	Create a safety net	19 (5.15%)	*"A lot of it is about negotiation, What safety netting there is in their family or social network, where are they going to stay next, what are they going to do, and if they have actually told someone else in their family or someone in their family has brought them then that's much safer than nobody knowing and living on their own, so a lot of it is about negotiating safety structure with them" (GP03, M, P)*
	Create a suicide safety plan	17 (4.61%)	*"How useful are safety plans? … If it's the patient's that generally have co-produced that plan, and created that plan, they're probably useful, in the sense that they have validity. If they've been imposed on the patient, these are the sorts of plans where once the patient's outside of the door, they look at the piece of paper and think, "What a load of rubbish," and throw it in the shredder". (GP25, M, S)*

	Reduce access to means	8 (2.17%)	*"You've got to think about their access to the means of suicide and then to sort of address that there and then, because you don't really want to send them home to a home full of tablets because if some other trigger comes along that might just be enough for them to take them" . (GP19, F, P)*
	Involve social support	14 (3.79%)	*"I'll also ask about their family/ friends, who can help them?" (GP07, F, S)*
	Involve family members	5 (1.36%)	*"Sometimes I might ask 'would you mind if I speak to your wife about this?' or, 'would you mind if I speak to your mum about this?' because it can be helpful to elicit support from the family (GP06, M, P)*
	Prescribe self-help materials	4 (1.08%)	*"I have two self-help, well several self-help leaflets that I ask permission whether they would be interested, because again I think if somebody's very distressed and often they can't deal with all that information but if somebody's reasonably with it then I sometimes print off from a website" (GP19, F, P)*
	Signpost to financial help	2 (0.54%)	*"It may be that they need some active help sorting out their financial issues" (GP05, M, P)*
	Signpost to workplace help	3 (0.81%)	*"I'll encourage them to talk to their supervisor or line manager, if that's appropriate. If they're working, I might advise them to talk to their trade union" (GP01, M, S)*
	Signpost to Legal help	1 (0.27%)	*"Sometimes they might need some legal advice (GP01, M, S)*
	Signpost to Housing support	1 (0.27%)	*"Other times housing support can really help reduce risk" (GP01, M, S)*
	Work on problem solving skills	2 (0.54%)	*"We used some problem-solving strategies, some ideas of targets and management ideas and actually giving her agreed goals to work to" (GP11, F, P)*
	Suggest exercise	1 (0.27%)	*"I might suggest potentially little bits of exercise" (GP20, M, S)*
	Suggest enjoyable activity	1 (0.27%)	*"Or making sure that they're getting out of the house and doing some things that they enjoy" (GP20, M,S)*
	Teach relaxation exercises	1 (0.27%)	*"Sometimes just teaching them some relaxation techniques" (GP20, M, S)*

	Review medicine	10 (2.71%)	*"Looking at the medication and the sort of medication that they're on, whether that's for mental illness or whether it's something that's well-known to be dangerous and overdose, is another area which would immediately be in your mind" (GP25, M, S)*
	Prescribe anti-depressants	21 (5.69%)	*"You may start someone on antidepressants if they fit the criteria but again, you would be wanting to make sure they're aware that for some patients, could even increase suicidal tendencies in the early stages so trying to make sure that they've got someone watching over them and checking in on them" (GP06, M. P)*
Referral decisions = 148 (40.11%)	Referral to CRHT	36 (9.76%)	*"In my experience I would say that generally the crisis team have been very helpful to be fair. I think the referral process is somewhat lengthy, and the telephone conversation makes you feel at times like you're going through a test, and that if you don't pass the test and you don't use the right words then you're out". (GP15, F, S)*
	Deciding when to refer	27 (7.32%)	*"I'm not quite sure whether it is just a secondary care issue or a skill issue to do with doctors' thresholds and understanding of how they see risk, because risk is still rather vague, it's individually defined….I think there is a decision as to what you might see as serious risk versus risk that you feel you can work with, I think there's variation" (GP08, M, P)*
	Referral pathway problems	29 (7.86%)	*"I have had the experience of speaking to crisis mental health psychiatric nurses and the tone of voice and the pauses in conversations on the telephone, right from the outset, the implication is that they're very busy, they need to really, really get you to prove that your patient needs to be seen, even if they've agreed that the patient needs to be seen, you need to prove that they need to be seen today or tomorrow rather than in three days' time, it really is a game of hot potato as to who takes responsibility". (GP01, M, S)*

	Other mental health service	6 (1.63%)	*"People in that medium term risk I may be looking at, say, a secondary care CMHT referral but not the urgency of a Crisis Team referral" (GP20, M, S)*
	Psychiatry	4 (1.08%)	*"Do they need a psychiatric assessment? If I am really concerned, I can arrange a mental health act assessment" (GP05, M, P)*
	CAMHS	1 (0.27%)	*"If I'm worried about a young person children's services are pretty dire, I would say, not just locally, nationally, from what I hear. Having said that, I've generally been able to find somebody on call somewhere in CAMHS and they have been helpful when I've managed to track them down, but the issue is tracking them down" (GP18, F, S)*
	A&E	5 (1.36%)	*"The other option is presenting to A&E because there is the psychological liaison medicine, if needed" (GP18, F, S)*
	Out of hours care	5 (1.36%)	*"I make sure they know after hours you can call 111" (GP10, F, S)*
	Third sector agencies	16 (4.34%)	*"There are phone lines, Papyrus which is a phone line for young people who consider themselves at risk of self-harm or suicide, there's Samaritans, or Citizens Advice bureau if they have a financial, legal or housing issue" (GP01, M, S)*
	Talking therapy providers	14 (3.79%)	*"Talking therapies are very helpful. Definitely in the long-term I always say that that would be the mainstay treatment. However, as always resources are scarce within the NHS". (GP15, F, S)*
	Obligation to act on risk concerns	5 (1.36%)	*"The management option is first and foremost what do I need to do, to keep the patient safe and make sure I write that in the notes, that's important to keep the coroner off my back, and to satisfy the Bolam test…." (GP02, M, P)*

5.3.1.2.9 Theme 9: Characteristics of the CDSS

474 statements were grouped into the theme relating to the characteristics of the CDSS. 29.96% of statements were in relation to the way in which the CDSS might integrate with the existing IT systems and EHRs, as well as the way in which it could integrate with different GP consultation styles and be used flexibly. 28.48% of coded statements related to GPs views of the nature of the CDSS, with brevity of information entry (5.06%), ease of use (4.43%), and time taken to use (2.74%) amounting to significant concerns. A greater of number of coded statements related to the tool being integrated into the EHR than as a stand-alone internet tool. The additional utility this might provide included READ code activation (4.64%), use of READ codes in handling or recording data (2.74%), recording data directly into the patient's notes (2.95%) and taking the form of an embedded template within the EHR (3.38%).

Table 5-15: CDSS characteristics

CDSS characteristics (n=474)			
Sub-category	Codes	Number of coded statements (%)	Examples GP number, Sex (M/F), Salaried (S), Partner (P)
Integrates with different consultation styles and ways of working N=142 (29.96%)	Integrates into the consultation	71 (14.98%)	*"When you are working with people who are upset and distressed and you know if you are worried about them being at risk of suicide, it absolutely mustn't detract from communication with that patient. Particularly if it used with people with mental health problems, it is so important to maintain rapport and communication, and err if you lose that there will be a really negative impact on the consultation". (GP05, M, P)*

	Integrates with electronic health record systems	36 (7.59%)	*"The main advantage, is that if its on the computer, then you can link it up with their notes, and amend it easily if need be" (GP04, F, P)*
	Can be used flexibly	35 (7.38%)	*"Something you can use flexibily, you don't want to have to work your way through a long template for every patient". (GP07, F, S)*
Specific CDSS functions N= 80 (16.88%)	Guides an assessment	29 (6.12%)	*"It could be useful if it guides the GP through thinking about risk factors, and mental state exams, and then takes them through in to a risk classification, to guide the consultation, so that the GP knows where they are going" (GP04, F, P)*
	Produces a risk score	19 (4.01%)	*"I guess GPs would like a score or risk threshold, I can see that would seem attractive, it would be quick, and easy for the GP, but is that the consultation we want to offer....?". (GP02, M, P)*
	Helps produce a safety plan	6 (1.27%)	*"What also might be useful, from the tool, I've just thought, is whether there's any little links or things that you can have easily to print and give to patients in terms of where else they can get acute care when they're not able to speak to you or get through to GP services. If I can physically give them something to take away and put in their pocket, they've got something there as a sort of, you know, safety plan for an acute crisis moment, they've got something they can do". (GP17, F, P)*
	Helps with the referral process	10 (2.11%)	*"To have the communication and the sort of common language to use, that will be really useful". (GP19, F, P)*
	Contains helpful links	8 (1.69%)	*"if there's somewhere that people know that there is a link somewhere on the tool, to an internet website or whatever, a PDF or something, then I think that would be helpful" (GP09, M, S)*

	Prompts to ask about self-harm	2 (0.42%)	*"If they have self-harmed, 'how often', 'what type', so these are prompts to ask the questions, that would be useful" (GP01, M, S)*
	Has a case-finding quality	2 (0.42%)	*"You can have them installed on the computer somewhere so that when the doctor is not seeing patients on his study day or audit day or PLT session or whatever, they can run the search and get all the population of patients. Then you can then invite them, depending on how severe the risk is. Some of the risk algorithms can actually stratify patients in the various stages; very high risk, moderate risk or mild risk. Then you can then hone in on the very high risk patients and either invite them in to assess or, at a later date" (GP21, M, P)*
	Helps with risk prediction	4 (0.84%)	*"you know where this support toolkit is located on the system, you click it, it searches all the patients on your practice list who have the potential risk factor that you are looking for, it could help predict risk" (GP21, M, P)*
Perceived utility and awareness of the CDSS N= 68 (14.35%)	Has perceived utility	34 (7.17%)	*"I think you use CDSS tools to the extent that you find that they genuinely help or it's something that you are pretty much required to do, in terms of trying to make an assessment" (GP06, M, P)*
	GPs general attitudes towards CDSS	23 (4.85%)	*"CDSS tools doesn't necessarily translate into actually accurately meaningful information that the patient recognises, or that the next doctor in the series of consultations will find helpful. And in fact, it biases the next doctor who sees them, because they'll see those boxes and think, "Oh well, if someone's ticked a certain box three times in a row, chances are I can tick it again, whether or not I've really convinced myself of that." (GP25, M, S)*

	GPs awareness of the CDSS	3 (0.63%)	*"I think this is why the awareness bit is so important. So, there are some tools that all of us use all of the time and that's really helpful, but you've got to know they are available because actually if people don't know it exists it's of no use to anybody whatsoever," (GP18, F, S)*
	Patients awareness of the CDSS	1 (0.21%)	*"I suppose one thing that we do have in the waiting room is lots of posters and a TV screen which I've no idea what it says, but people sometimes say "I've just been reading your screen ..", so that kind of … I don't know, suicide awareness, they could come in and say can we go through that tool on the computer" (GP13, F, S)*
	Training for GPs	7 (1.48%)	*"I don't think you can just rely on the tool itself, I think you need to do some work around training how to use it or raising awareness, however that may be, whether that's through the college (GP18, F, S)*
Specific features of the CDSS N=135 (28.48%)	Embedded template in the EHR	16 (3.38%)	*"I'm thinking it would be along the lines of a template that, say, nurses use. I would counter that and say that probably doctors are nowhere near as good as nurses at filling in templates" (GP28, F, P)*
	Internet based	7 (1.48%)	*"If it's internet based, you choose to use it yourself; but if it's embedded, it will pop up and remind you to do something or to think about something. So, the main difference is your choice about whether you're using it or not. If it's something that's popping up that you're not necessarily seeking to use It feels like an annoyance" (GP22, F, P)*
	Brevity of information capture	24 (5.06%)	*"I think something like two or three check boxes with some type in would be good" (GP27, M, S)*

	Easy to use	21 (4.43%)	*"It would have to be easy to use, you want some things you have to fill out and some others you can skip, you don't want to have to check every box". (GP07, F, S)*
	Quick to use	13 (2.74%)	*"The barrier to using it, if it was going to include all of those things, just the time you take to input data, all those other things probably aren't coded, so actually that means I've got to put stuff into a tool. if I'm going to use that tool it needs to be really short and really quick and that's my concern, because actually the short, quick tools that we have on the system are because you're using coded data and I don't think most people will be coding any of this stuff". (GP18, F, S)*
	Available to the whole-practice	3 (0.63%)	*"Don't just think GPs would benefit from this either, think nurses, think receptionists, they're often forgotten but they know our patients sometimes better than we do" (GP12, F, P)*
	Records data in the EHR	14 (2.95%)	*"It must record information and save it in the patients notes" (GP24, F, S)*
	Uses historical data in the EHR	1 (0.21%)	*"It's interesting some people themselves aren't aware themselves, why they might be a bit miserable, that's one of the advantages we used to have of being in the practice a long time, you'll know his wife died 3 years ago, and he may not associate those two things, and he may not, but clearly you can't legislate for that because if you're the new guy there's no way you would know that, but it might be worth depending on your list of things, seeing if it's the possible type of thing to flag up" (GP26, M, P)*

	Uses READ codes	12 (2.53%)	*"It could use read codes or check boxes, but that approach is a bit crude, it can miss the nuances of what people are telling you" (GP24, F, S)*
	Has specific triggers for use	22 (4.64%)	*"If you enter read codes that imply there is depression on low mood or a risk of self-harm, then it triggers a few questions which pop up asking you to complete whether or not they have any suicidal thoughts and whether or not they had self-harmed" (GP01, M, S)*
	Is clearly focused on suicidality	2 (0.42%)	*"The thing about a decision-making tool, is that sometimes it tends to be all encompassing because they're trying to cover as wide and it loses that focus". (GP08, M, P)*
Added value of a CDSS N=41 (8.65%)	Defensive practice	23 (4.85%)	*"It would be useful to feel that you had some defensive cover, if it was validated then it could get more widely accepted as a sort of defence for doctors if you like, just to prove you'd asked the right things, it would feel quite nice to have a tool such as that to not miss anything" (GP30, F, P)*
	Educational value	4 (0.84%)	*"I suppose a decision-making tool would be great for people who are starting off their careers as GPs, so they're newly qualified, so the GPs in training, sort of giving them a cluster of relevant questioning to make sure that, they have tried to extract all the information from the patient" (GP29, F, S)*
	Standardises practice	7 (1.48%)	*"I think anything that standardises things to a certain extent and means that more people are working in an evidence-based way, I guess, can only be a good thing" (GP09, M, S)*

	Supports GP's wellbeing	7 (1.48%)	*"At the end it could say something like, if you are personally upset, make a point to talk to your colleagues in the practice, it could help to signpost towards the GP support helpline" (GP04, F, P)*
Problems with suicidality data N=8 (1.69%)	Extent of historical data in the EHR	4 (0.84%)	*"I would also say that I would have my doubts about how well a lot of those things are recorded in the notes in that if someone has done, as I say, a specific suicide risk assessment, they may well have been, but if that's never been done before a lot of those things are probably not going to be in the notes" (GP20, M,S)*
	Sensitivity or Specificity	4 (0.84%)	*"If you'd got a tool that would really identify those who are really suicidal and you want to just pull it on the system, it would be a bit awkward if you try to apply it, because all these tools will have sensitivities and specificities" (GP21, M, P)*

5.3.2 Latent analysis

The findings of the manifest analysis presented above offer an initial (and descriptive) view of (i) GPs' perspectives on factors salient to the identification, assessment and management of suicidality; and (ii) GPs' perspectives regarding the format, content and use of a suicidality CDSS. However, understanding the meaning of words or content in context may usefully deepen the analysis. Building upon the findings of the manifest analysis, the latent analysis carried out allows for more nuanced and in-depth exploration of the research questions.

5.3.2.1 GPs views of distal and proximal risk

GPs articulated a range of risk factors which reflected the scope of suicidality risk literature, ranging from demographics, and past attempts, or mental-health history, through to acute stressors and social isolation. It was striking how often GPs referred to suicidality within the context of mental health problems, and associated suicidality prevention as an extension of the mental health aspect of

their work. Yet, alongside the apparent medicalisation of suicidality, social models of suicidality were evoked through GPs reference to histories of abuse or domestic violence, socio-economic difficulties, social isolation, hopelessness and patient's experiences of acute stressors or personally specific triggers leading to reactive suicidality.

It appears that the GPs in this sample, may be prone to conceptualising suicidality risk as conferred by the presence of psychosocial risk factors and as a by-product of mental health difficulties.

5.3.2.2 Contextual factors and GP experiences

In keeping with prior literature in this area (Michail et al., 2016; Saini et al., 2015, Fox et al., 2015), GPs expressed difficulties managing complex patient consultations within the allotted 10-minute appointment time. Notions of blame and accountability were raised regarding the possibility of patient suicide, as well as statutory concerns such as safeguarding vulnerable adults. GPs described the importance of having prior exposure to working with suicidality as being an important mediator of their approach and willingness to open-up suicidality within the consultation. Similarly, however, having prior negative experience, or awareness of colleagues having negative experiences of working with suicidality, might mediate reluctance to explore suicidality in consultation. Practice culture, and the risk-averse nature of the healthcare system were further pertinent aspects of GPs contextual experiences. Prior exposure to psychiatric training, or close working relationships with psychiatric colleagues were seen as helpful by a number of GPs, instilling confidence in asking patients about suicidality. However, the historical variation in the mental health content of GPs training experiences and sporadic nature of specific suicidality training was highlighted as an ongoing issue. GPs also reported the specific stress, frustration and emotional impact that working with patient suicidality can generate. The emotional toll that working with suicidality might

produce in GPs, could then influence GPs ability to provide high quality care to subsequent patients. The possibility of increasing defensive practice was raised as a counter to the emotional toll of patient suicidality, particularly in the event of a patient death.

5.3.2.3 Suicidality risk assessment and barriers

The process of suicidality assessment and care planning was described as a complex balance between judging risk in relation to known population level, statistical risk factors, and patient-specific information. From the first moments that GPs recognised that a patient might be experiencing a degree of suicidality they reported trying to engage the patient in talking about the suicidality, in a process of attempting to reconcile patient-centred care and risk assessment. This reconciliation was seen as both potentially therapeutic for patients, but also allowing the GP to elicit more risk information, to inform their clinical decision-making process. A practical aspect of GPs approach to working with suicidality frequently involved offering follow up appointments and continuity of care, serving the dual purpose of offering a therapeutic space to patients, and another chance to assess risk, thus, highlight that risk assessment is an ongoing and dynamic process. Deciding when to refer on to another service or agency was an important aspect of GPs' role, and GPs articulated a spectrum of views in relation to the relative ease, or difficulty in having patients experiencing suicidality accepted into secondary specialist services. CRHTs were frequently mentioned as both really receptive of referrals, but also sometimes GPs felt they had to "*prove that the patient needs to be seen*" and this was akin to having to pass a quiz in order to get their patients accepted into the service; however, for busy GPs "*dealing with suicidality is a hot potato"* where "*you are given that hot potato and you need to throw it to somebody else*".

5.3.2.4 Characteristics and properties of the CDSS

GPs described a cautious enthusiasm for a suicidality CDSS. Such a tool was seen as broadly helpful if it could be used in a flexible way, including before, during or after a consultation. GPs also stressed the importance of the CDSS being able to integrate with GPs different ways of consulting. This might include administering the tool side by side with patients, or surreptitiously typing a few key words as they were listening to patients, or completing the CDSS from memory or hand written notes after the patient had left. A preference for a CDSS that was integrated into the EHR, rather than a stand-alone online system was expressed. The greater functionality afforded by a CDSS which was integrated or embedded into the EHR system was seen as potentially useful. However, GPs expressed the likelihood that they and their colleagues would only use such a tool to the extent that it seemed helpful and possessed functional utility in helping them provide patient care. The medico-legal nature of primary care practice was raised, with the potential of the CDSS to both standardise care, and providing a degree of defensive cover being discussed. However, GPs were also cautious that if an episode of patient suicidality ensued and they did not use the CDSS, they could be feel exposed and vulnerable. Finally, although a substantial number of GPs expressed a preference for the CDSS to produce some sort of risk score, the majority of GPs expressed a form of 'risk score fatigue', and frustration with numerous CDSS alerts 'popping up' on the system, which when coupled with the known problems in predicting suicidality risk, reduces the strength of such an approach. Nevertheless, a CDSS which guides GPs assessment and supports GPs in making a decision regarding the urgency with which they might need to get some additional help for their patient was seen as potentially useful. Importantly, rather than seeking to overly direct their assessment or replace GPs' clinical decision-making autonomy, the CDSS was seen as most likely to be of benefit if it supported GP's decision-making processes, and helped with associated tasks such as

collating information, recording data in the EHR and providing links or safety planning aids.

5.3.3 Structure and agency within suicidality consultations -a CR informed analysis

After the CA, an additional cycle of re-coding the data into CR informed categories of Structure and Agency was carried out to enable CRQA. Categorised data were then reviewed in relation to existing theory through a process of theoretical re-description (abduction). Data were also subjected to attempts to identify underlying contextual conditions in which specific generative mechanisms might be activated (retroduction).

5.3.3.1 Social Structures

Whilst there is no uniformly accepted definition of social-structures pertaining to healthcare practice or research (Nairn, 2009), key components of social structure include societal role, institutions, organisations, networks, or statuses (University of Minnesota, 2010). From this perspective, there are a number of social-structures apparent to the potential use of a suicidality CDSS.

5.3.3.1.1 Primary care commissioning

Primary care services in England are commissioned activity within the NHS, under a contract framework agreed between NHS England and the General Practitioners Committee of the BMA. The contract is renewed periodically and currently covers from 2019-2024 (NHS England, 2019a). Historically, the contract has highlighted focal areas for improvement, reflecting clinical or political prioritisation. Suicidality is not specifically mentioned in the contract. This may reflect the statistically low base rates of suicidality, but also belies the potential for suicidality to be considered as an after-thought within the mental health domain of the contract which is handled through a linked financial incentivisation scheme.

5.3.3.1.2 Financial incentivisation of primary care

Financial incentivisation of mental health delivery in primary care is enacted through the Quality and Outcomes Framework (QOF) for General Medical Services (Primary Care Strategy and NHS Contracts Group, 2019). Within the interviews, 3 GPs mentioned that if use of the suicidality CDSS was mandated in QoF, GPs would have to use it. However, suicidality is only mentioned within the current QoF in the context of depression. Previously, the QoF had specified that GPs were to use a depression assessment tool, such as the PHQ-9 (Kroenke and Spitzer, 2002) to identify and assess depression severity, over at least two appointments in keeping with NICE depression guidance (National Institute for Health and Social Care Excellence, 2009). This resulted in practices achieving a financial incentivisation payment, if GPs standard of care met the depression indicator. However, previous research has highlighted the intrusive and mechanistic way in which mandated depression assessment tools were experienced by GPs in consultations (Mitchell et al., 2011). As a result, some GPs felt that the QoF was unlikely to improve the standard of patient's depression care. Furthermore, research also suggests that the inclusion of depression targets within QoF has not led to reductions in suicide rates in locations where practices performed highly against the depression indicator (Grigoroglou et al., 2018). Historically, the QoF has also set the indicated appointment durations, such as the well-known 10 minutes, and the number of appointments a practice should offer in relation to the size of its patient list. In recent years guidance relating to appointment durations has begun to be revised. The current QoF specifies that GPs may offer extended duration appointments in relation to patients with complex needs, such as people presenting with dementia. Therefore, the QoF is a social structure which offers powerful potential to influence and shape GPs' practice, as well as normalising the way in which certain clinical presentations are treated. However, it also exerts the potential to be experienced by GPs, and possibly by

patients, as an unwelcome top-down interference in the inter-personal nature of the consultation.

5.3.3.1.3 GP annual appraisal and quality improvement

In addition to the QoF, another important social structure of consideration is GPs' annual appraisal. During the interviews, a GP mentioned a key aspect of promoting the CDSS could be to ensure the local GP appraisers network is aware of it, so that they might refer to it when discussing suicidality prevention with their appraisee. A GPs appraisal is a yearly meeting between the GP and a colleague who is appraising their practice (British Medical Association, 2020). The annual appraisal requires GPs to engage in a structured, reflective review of their professional performance, which must include discussion of their quality improvement activity (General Medical Council, 2020). GPs could satisfy the requirement for demonstrable quality improvement by using the CDSS to standardise and record their suicidality consultations. Therefore, whilst appraisals, reflect the Foucauldian concept of governmentality, defined as the ensemble of thoughts and techniques intended to devise and conduct, the conduct of the subject (Li, 2007), appraisals also offer potential to increase use of the CDSS with a view to improving clinical practice.

5.3.3.1.4 Medicolegal mediators of practice

The extent to which the CDSS was discussed by GPs in a context of defensive practice and medico-legal concern was not anticipated. GPs reported that the CDSS could be both useful if it provided a degree of defence against medico-legal claims or accusations of poor-practice. However, GPs also felt that should patient suicide occur after a consultation, and the GP had not used the CDSS, they would be subject to another form of blame and accusatory defamation. A scoping review conducted in 2018 suggests that the number of NHS

litigation claims, and associated costs to the NHS is temporally increasing (Birks et al., 2018). Furthermore, a recent review of findings from NHS suicide related claims found that records of patients' risk assessments in notes systems were often inaccurate, infrequently updated and poorly documented (Oates, 2018). Furthermore, the same review concluded that risk assessment could be improved if clinicians ceased to think about risk assessments as leading to stratified risk scores, and instead thought about richer formulations of risk, which could include input from the patient being assessed. Therefore, the increasing litigious culture of healthcare and primary care appears to be an important generative mechanism which could influence the format, content and use of the CDSS. There is clearly a potential case for use of a suicidality CDSS as a means to promote patient-centred clinical decision-making. However, GPs discussed needing an assessment that was thorough enough to stand up in court, yet brief enough, and quick enough to fit within the time-frames of typical complex consultations in primary care.

5.3.3.1.5 Lifeworld and systems world

The nature of primary care practice, as described by GPs, appeared as simultaneously an interpersonal meeting and the interface of the patient with the care system. In this way, primary care is entwined between the lived experience of the patient, and the needs of the wider population. This dualistic tension was something that could become more visible when GPs tried to refer their patients to mental health services and CRHTs in particular. At such times, the GPs could find themselves advocating why the patient needed to be seen by the mental health service, only to be subjected to a form of quiz or inquisition where they had to demonstrate the patient met a certain threshold of risk. GPs reported that knowing the right words, or phrases could help short-cut this process. The CDSS could potentially provide a common vocabulary and way of mediating suicidality

referrals. Significant challenges in this regard would include the tool being perceived as sufficiently rigorous by secondary care colleagues, yet adequately able to help GPs make clinical decisions about referrals in the time constraints they work within. Nevertheless, the CDSS may have a potential role in helping GPs mediate the interpersonal discussions of the patients' lifeworld, alongside the demands and requirements of the systems world and risk thresholds influencing referral processes.

5.3.3.2 Agency

Human agency provides the potential to reproduce, change or over-ride social structures and generative mechanisms (Archer, 1998b). Agential actions on the part of both GPs as healthcare providers, and patients as healthcare recipients, exerts influence to shape the use of, format and content of the CDSS.

5.3.3.2.1 GP's agency

GPs described that unless mandated to use a suicidality CDSS by QoF, they would exercise their own judgement as to the utility of the CDSS. GPs meet the definition of professional elite members of society, in that they are highly skilled, professionally competent and belong to higher socio-economic groups than many members of society (McDowell, 1998). As a feature of the independent GP model (Kennedy, 2014), and as a result of their professional elite status, GPs possess significant autonomy and ability to exercise personal and professional judgement. When describing their prospective use of the CDSS, GPs reported they would use the CDSS to the extent that they found it helpful to do their job. This invoked the possibility that even if their GP practice, their CCG, or primary care as a profession wanted them to use the CDSS, they might countermand such a motion. GPs also described how they might configure their use of the CDSS, perhaps only using part of it, or using it as an aide memoire to inform

their consultation, rather than complying with use of the CDSS completely or using it to inform their clinical decision-making process. GPs' agency is therefore a powerful generative mechanism exerting influence to shape the implementation, or rejection, of the CDSS in practice.

5.3.3.2.2 Patients' agency

GPs suggested that patients also possess agential capacity to influence format, content or use of the CDSS. The extent to which patients choose to respond to the specific language and phrasing of questions posed by GPs using the CDSS in consultations would shape GPs views of the CDSS. Furthermore, one GP described the potential that patients might find conversations structured around the content of the CDSS useful and may then wish to have subsequent conversations structured along the same lines. GPs also reported that patients exercise their agency in finding and seeking the GP in the practice that is most attuned to conversations about mental-health and suicidality. Additional ways in which patients might shape the use of CDSS systems is by providing feedback to GPs and practices through informal comments about its use, or in more formal contexts such as patient participation groups.

5.4 Discussion

This section presents a brief discussion and synthesis of the findings from this empirical study of GP interviews.

5.4.1 Summary of findings and answers to research questions

This study has highlighted GP perspectives in relation to the research questions; (i) how do GPs identify, assess and manage patient suicidality in primary care and (ii) How could a CDSS assist GPs to identify, assess, and manage suicidality in primary care.

GPs have reported a range of ways of attempting to work with suicidality, in the highly time-pressured context of primary care.

Often this appears to involve the use of heuristic based reasoning, or "gut hunches" interacting with analytical judgement of patient risk.

In a pragmatic attempt to manage risk, one of the main strategies GPs appear to use is to offer follow up appointments, affording patients more time to talk and potentially reducing risk, whilst allowing GPs more time to assess risk and determine if onward referral is necessary.

For some GPs, suicidality appears to be conceptualised as denoted by the presence of psycho-social risk markers or as a by-product of mental-health problems. For others, suicidality is considered as a mental health problem in its own right, potentially requiring referral to specialist mental-health services.

The process of referring to mental health services was often described as difficult, with GPs needing to prove to over-stretched service-providers that their patient needed to be seen, and feeling that they were left holding uncertain levels of risk whilst services deliberated over accepting referrals.

GPs expressed cautious enthusiasm regarding the potential of the CDSS to assist GPs with the challenges of working with patient suicidality. GPs suggested a suicidality CDSS must able to be used in a way that minimally intrudes in the consultation, and that it needs to be used in a flexible way to fit with wide variation in GPs consultancy style, it must also integrate with clinical IT systems such as the EHR. Should such a CDSS be created, it must easy, and quick to use, requiring minimal information entry at the point of clinical contact.

The ability of GPs and patients, to use their agential autonomy has been highlighted as factors potentially influencing the way in which GPs work with suicidality, and their prospective use of a CDSS. Patients may encourage or dissuade GPs from using health technologies in consultation by deliberate feedback or behavioural

responses. GPs may exert their agency by choosing whether or not to use CDSSs; and if they do potentially using CDSS in idiosyncratic ways, and not necessarily in the way which such tools are usually intended.

A range of structural entities have been identified impacting GPs way of working with suicidality, and potentially influencing their use of the CDSS. Such structural entities include the real and growing spectre of medicolegal fear and defensive practice amidst a culture of blame and accountability. Another key structural consideration appears to be the blurring of suicidality and mental health, perpetuated by GP commissioning and financial incentivisation models as well as the clinical referral pathway.

5.4.2 Implications for suicidality prevention in primary care

GPs highlighted the potential of the CDSS to help improve suicidality prevention in primary care, by helping them to work with the inherent complexity of patient suicidality presentations.

A major source of frustration and stress occurring in relation to suicidality consultations appears to be (i) difficulties determining when onward referral is necessary, and (ii) conveying the urgency with which patients need to be seen to busy CRHT services. The CDSS could potentially assist in this process, by guiding GPs assessment and helping them to undertake a functional assessment of risk, set in context of the patient's personal history and circumstances, to support a patient-centred clinical decision-making process. The CDSS could then provide a common framework for decision-making, and potentially facilitating GPs and mental health services to jointly review and discuss the outcome of a consultation in which the CDSS has been used.

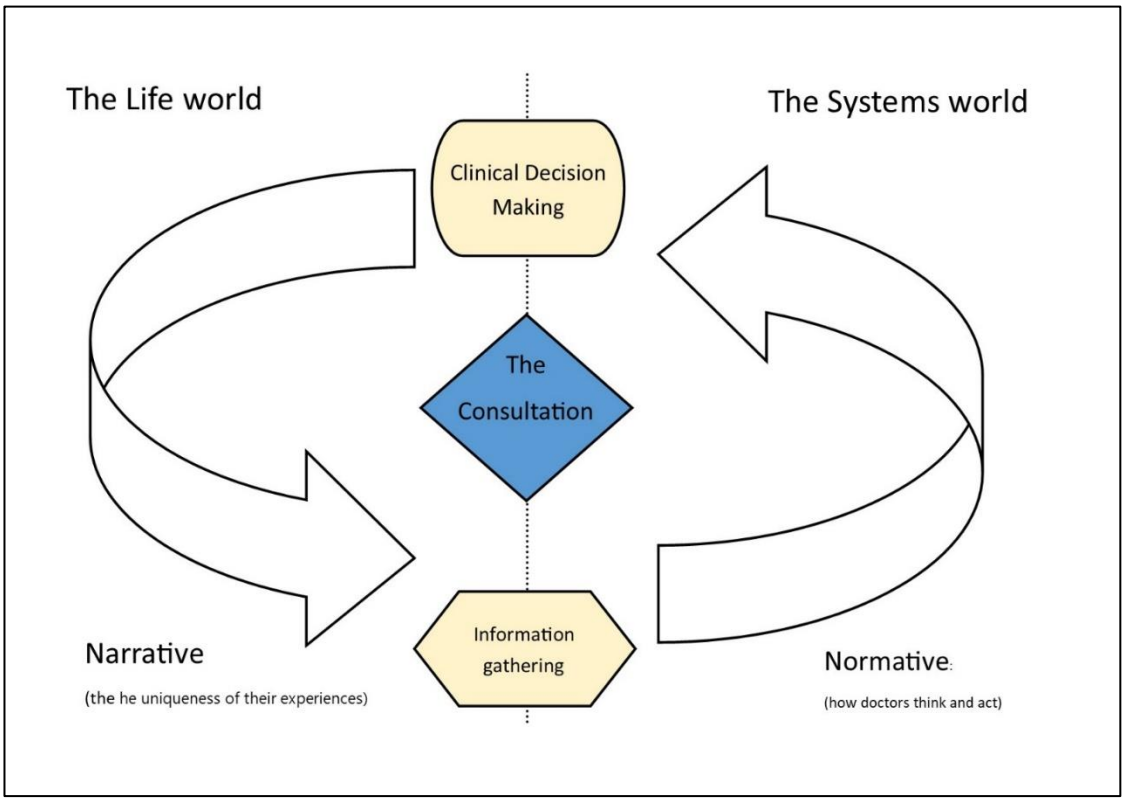
The CDSS could also improve recording of risk information in patients notes. Currently, records of suicidality risk assessments in patients notes are often inaccurate, infrequently updated and poorly documented (Oates, 2018). Improved documentation ensuing from a

suicidality consultation in which the CDSS has been used, could support clinical decision-making, including referral decisions. Improved documentation of episodic or transient experiences of suicidality could also potentially promote shared decision-making with patients, by helping to contextualise suicidality in response to psychosocial risk factors or disturbances in the patient's lifeworld.

Use of the CDSS intend to provide more standardised risk assessment, improved support for clinical decision-making and clearer documentation of suicidality consultations, could have important medicolegal considerations. Use of the CDSS could provide defence against medicolegal claims or accusations of poor practice, potentially indemnifying GPs decision-making. Conversely, GPs raised fear that non-use of the CDSS in a consultation preceding patient suicidality, would lead to heightened blame and assumption of poor-practice. GPs also cautioned that the CDSS could intrude on patient's consultations and their decision-making processes, potentially leading to poor outcomes for patients, which would be significant given the high stakes of suicidality consultation for GPs, patients and their carers.

Given the high stakes of suicidality consultation, the CDSS therefore may have some potential in helping GPs and patients work towards shared decision-making in a suicidality consultation. Such consultations occur at the interface of the patient's lifeworld and system world. The CDSS might help GPs to switch between medicalised and social perspectives in their decision-making process, and to navigate the competing interests of the lifeworld and systems world, as GPs navigate between normative and narrative modes of response to patient's presentation. The CDSS therefore offers potential to support information gathering and clinical decision-making as its key functions across the lifeworld-systems world distinction and the normative and narrative facets of the consultation.

Figure 5-1: Key functions of the CDSS within the consultation, (adapted from Dunkley et al., 2017 and Launer, 2018)



5.4.3 Implications for methodology

The study was grounded in the meta-theoretical perspective of CR and has highlighted generative mechanisms and the interaction between social structural entities and human agency, as influencing use of a suicidality CDSS.

The approach to interviewing built on previous qualitative studies, which sought to understand GPs experiences of working with suicidality (Michail and Tait, 2016; Saini et al., 2015). However, the approach taken in this study differs, through grounding interviews in CR, and informed by CRs' distinctive view of causality in which context interacts with individual agency. By doing so, a picture emerges of GPs feeling supported or empowered by using the CDSS, yet also the potential for GPs to feel obligated or compelled to use the CDSS due to non-clinical, organisational or medico-legal generative mechanisms. The dualistic potential of the CDSS to both empower and threaten doctors' autonomy seems apparent. The CDSS, therefore possess potential to further empower GPs in their role, as

independent, autonomous professionals (Kennedy, 2014), and manifest the culture of blame and accountability permeating primary-care in relation to potential patient suicidality (Kendall and Wiles, 2010). Systemically, this dualism may also reflect, the ongoing background schism between primary care being simultaneously empowered and yet overworked, and strained towards breaking point by a range of contextual factors. Writing in 2001, Smith observed primary care was receiving more resources than ever before, GPs had more time with patients than when the NHS was created and more of hands on role in running or commissioning primary care, yet simultaneously GPs were stressed by a large discrepancy between what they were trained to do, and what they were required to do (Smith, 2001). This contextual tension identified by Smith, has arguably only intensified in the years since, with proposed quality improvement initiatives such as the CDSS, inadvertently tapping into these latent contextual tensions.

This abductive, or theory led approach, to interpreting GP experiences, and consideration of a suicidality CDSS, has demonstrated the value of a CR informed approach in highlighting contextual conditions and structural entities, which might interact with GPs or patients' actions, to generate use of the CDSS.

CR informed approaches are well suited for intensive designs seeking to highlight factors influencing the adoption of information technologies, (Zachariadis et al., 2013), by identifying how structural entities and contextual conditions may interact to generate a use, or non-use of the technology (Wynn and Williams, 2012); thus, providing a better understanding of the meaning and significance of the technological advance in the real world, (Mingers et al., 2013). Mingers and colleagues, (2013) point out the distinctive quality of intensive CR informed research, in describing phenomena, constructing propositions, and identifying interactions between generative mechanisms. As such, CR affords great potential to

describe GPs experience of suicidality and CDSS use, to build theory as to when or why GPs might the CDSS, and identify possible generative mechanisms. However, no prior studies report development of CDSS explicitly informed by CR, yet contemporary approaches to CDSS development recognise the importance of contextual nuances, such as workflow integration, burden on end-users, and selecting the most meaningful way to evaluate changes in process or quality of care after CDSS introduction (Kawamoto and McDonald, 2020). The clarification of contextual conditions, structural entities, and agential inter-actions is therefore an important aspect of CDSS development. Adoption of a CR informed method therefore allowed a theoretically grounded approach whilst enabling epistemological relativism and judgemental rationality to inform the CDSS development.

5.4.4 Strengths and limitations

Stemming from the meta-theoretical underpinning of CR, this study employed both CA and CRQA, to provide layered qualitative insights, to elaborate and triangulate how GPs identify, assess and care-plan for suicidality and how a CDSS might assist GPs with this task.

Utilisation of a layered analytic strategy highlighted the interaction of structure, agency, CDSS content, and GPs conceptualisation of suicidality. Working with suicidality, and use of a CDSS is therefore strongly influenced by a complex array of interacting generative mechanisms. This complexity may account for both the way in which working with suicidality and prospective use of a CDSS, may simultaneously possess an emancipatory and threatening or repressive characteristic for GPs, whilst they try to support patients at risk.

However, there are limitations to the study. The sample of GPs was limited by both size and geographic region. As the study was advertised widely among clinical commissioning groups, GP academic networks, CLAHRC-EM communities of interest, and GP professional

organisations, the number of GPs opting to take part is a small purposive sample, reflecting a minor proportion of the GP workforce. It is not possible to determine the number of GPs who were aware of the study but who opted not to take part. There is also, the possibility that the sample reflects a self-selection bias of GPs particularly interested in suicidality. Furthermore, there is the possibility that regional variation in ways of working with suicidality, quality and ease of referral pathway and availability of suicidality specific training may exist. Nevertheless, the participating GPs are important stakeholders possessing relevant situated knowledge and expertise.

A reflexive consideration is warranted. As a clinician with many years' experience of working in primary care and crisis mental health services, the author's perspective may have biased coding and interpretation of data. The potential for this bias was recognised, therefore reflexive strategies included use of a reflective diary, and second coders, alongside frequent discussion with supervisors and colleagues. These reflexive strategies were used in attempt to question and examine the author's assumptions and perspectives since reflexivity is an ongoing process of reflection and recursivity (Barrett et al., 2020)

5.5 Conclusion

This study offers unique insights into the complexity for GPs in working with suicidality, and potential use of a suicidality CDSS. A layered analytical strategy was used to advance understandings of the interaction between structure, agency, and context regarding suicidality prevention in primary care, and potential use of the CDSS. However, GPs are only one part of primary care consultations. How patients might view GPs' use of a CDSS in relation to their experiences of suicidality is open to question. The following chapter will report a qualitative study undertaken with primary care patients.

Chapter 6: Patients' perspectives

6.1 Introduction

This study reports the service-user consultation process within the context of developing a CDSS for the assessment and management of suicidality in primary care. Two research questions guided this study:

iii) How do primary care patients with lived experience of suicidality understand and experience GP consultations in relation to suicidality including how GPs identify, assess and manage suicide risk in primary care?

iv) What are the views of primary care patients with lived experience of suicidality on the content, format and use of a CDSS for suicidality?

As such, this chapter follows on from Chapter 5 which explored GP perspectives of the way in which suicidality might be identified, assessed and care planned for in primary care via a CDSS. It is important to gain the perspective of primary care patients regarding the format, wording, content and use of a suicidality CDSS, as potential recipients of a consultation in which the CDSS could be used. Furthermore, within this thesis, patients with lived experience are considered relevant experts by experience who might be able to identify additional generative mechanisms potentially influencing GPs practice in this regard.

6.2 Method

6.2.1 Setting

2 Advisory groups of patients with lived experience of consulting a GP in relation to suicidality were recruited and convened. Advisory group meetings were held in selected meeting rooms on the University of Nottingham campus. Meeting rooms provided a safe space to talk about suicidality in primary care, free from interruption and where participants' confidentiality could be protected. The meeting rooms

were situated in the middle of the university campus, surrounded by green spaces in the event any participant needed a break from the meeting, and where participants could enter or leave the room without restriction.

6.2.2 Study Design

A qualitative design was adopted to explore patient's perspectives.

6.2.3 The purpose of the method

Advisory groups were recruited and convened to provide patient's perspectives in relation to the research questions (page 189) and to inform the shortlist of items of prompts within the CDSS.

Involving public and patients in research is increasingly seen as imperative to maximise the impact of research, since the insights and experiences of people with lived experience can improve research, often leading to changes and improvements in the quality or relevance of research (NIHR Involve, 2020). Health service users can be seen as having important knowledge to impart regarding their experience of the care delivery, context and potential quality improvement (Batalden and Davidoff, 2007). It has been shown that actively co-producing research with primary care patients, can add a real-world, lived-experience perspective enhancing quality improvement projects (Hertel et al., 2019). Furthermore, primary-care patients, may have some power to recursively influence GPs' perspectives of quality improvement initiatives, or interventions, based on GPs' perceived outcome of consultations (Lau et al., 2016).

The perspectives of primary-care patients who have consulted a GP in relation to suicidality are therefore directly relevant to this thesis, with situated knowledge regarding GP suicidality consultations and a suicidality CDSS.

Previous research has highlighted that involving people with lived experience of suicidality provides rich and valuable data (Lees D et al., 2016), which can highlight patients' lived experience of suicidality

and perceptions of care, enabling richer understandings of suicidality prevention (White, 2016). However, there is a dearth of studies which have involved patients as co-producers of suicidality related research (Littlewood et al., 2019).

There is also a dearth of studies involving patients in coproducing CDSSs, despite co-produced health technology based outputs, such as lists of question and prompts for use in consultations, typically having moderate to high acceptability and usability (Lim et al., 2020).

Where patients have been involved in previous CDSS co-production, this was shown to increase patients' understanding of their conditions and engagement in interventions (Rawson et al., 2018). However, there are no prior studies which have included patients in developing and co-producing a suicidality CDSS.

A participatory co-production approach was adopted. Such an approach included elements of co-design, but also seeks to empower people with lived experience as partners in designing and delivering the research (Roper et al., 2018). This specific model of co-production adopted has been termed embedded consultation (Hughes and Duffy, 2018). Embedded consultation enables regular discussion and iterative development through meeting with patient advisory groups at regular intervals over the different stages of the research project following governance approvals, including data collection, data analysis and dissemination.

6.2.4 Methods of data collection

A participatory co-production process was utilised involving six consultations with two advisory groups (aged less than 25, and older than 25 years of age) of primary care patients who have had experience of visiting or discussing with their GP experiences of suicidality.

Advisory group meetings took the format of small group discussions, of 90 minutes duration, with a loose agenda submitted to the group

members in advance of the meeting, so that participants knew what the focus of meetings would be.

Group meetings commenced with 10 minutes of unstructured "check in" time and concluded with 10 minutes of "checking out time" allowing participants to raise any comments or questions and to emotionally and cognitively process the content of the meeting. In addition, 15 minutes of unstructured time was included in the middle of each meeting, allowing for general topic related conversation and new information to emerge. Refreshment breaks were also scheduled, allowing time for informal interaction, and to reduce the emotional intensity of discussing suicidality.

Six advisory group meetings in total were conducted between 2017 and 2019.

6.2.4.1 Advisory group agenda content

The loose agenda for the meetings aimed to move sequentially through a range of material. This included asking patients

i) What helped or hindered disclosure of suicidality during a GP consultation.

ii) What were patient's experience of GP suicidality consultations and any treatment or referrals

iii) The potential impact of a suicidality CDSS on their experience of accessing and receiving care.

iv) What questions or prompts should be within the CDSS.

The research student kept detailed field notes and facilitated the group meetings. The meetings were not audio-recorded, as the research student considered this could shift the power dynamic towards more traditional researcher led involvement and away from a participatory co-production ethos.

6.2.5 Methods of data analysis

A decision was made pre-ethics application to neither audio record, nor fully transcribe and analyse transcripts of the advisory groups. This was because the research student felt that doing so would move the groups conceptually more towards traditional researcher led involvement than co-production, since participatory co-production seeks to engage members as partners and not research subjects (Roper et al., 2018). Roper and colleagues summarised this shift in the conceptualisation of co-production as a theory encompassing the values of "doing with, more than doing to"(Roper et al., 2018). Therefore, an alternative data recording and analytic strategy was chosen, comprising qualitative analysis of brief written field notes and of aspects of participants' narratives.

After introducing the loose agenda for each meeting, the research student kept field notes, as the discussion groups began. Whilst writing field notes the research student was striving to maintain eye-contact with participants and encouraging continued exploration of participants' perspectives, without losing the flow of the discussion. This a familiar challenge encountered in the use of field notes (Phillippi and Lauderdale, 2018).

Field notes were handwritten jotted notes, comprised of small sentences or keyword-based notes taken by the research student during the meeting. These field notes sought to record brief information relating to participants' accounts of their experiences of accessing and receiving care in the primary care context, the content and process of GP suicidality consultations, outcomes and actions, perspectives on the CDSS and the research student's own reflections and experiences to help formulate ideas and theory. Field notes therefore provided a combination of thick description of participants' experience and the research student's own reflexive process.

The way in which field notes can contribute towards building theory has been more succinctly described as capturing information relating

to the context, content and concepts pertinent to the research questions (Fetters and Rubinstein, 2019). In this case, the context referred to the advisory groups as a method of data collection, and the primary care context surrounding GP consultations. The content referred to thoughts about what should be in the CDSS, as well as the content of GP suicidality consultations. Concepts referred to larger theoretical insights linking to participants' accounts of their care, and the sequences, events and timing of GP suicidality consultations. In keeping with a CR informed perspective, it has been suggested that most sequences which can be observed or experienced are underpinned by deeper generative structures or processes that are likely not observed, and the challenge for researchers is to ask what the constructs underlying obtained data might be (Pentland, 1999). Therefore, information about critical events leading up to or during participants' consultations with GPs and any ensuing actions, characteristics of the actors and experiences of the processes of care, could serve to highlight important generative mechanisms.

After the advisory group meetings, field notes were typed up into more comprehensive field notes by the research student, who then coded data into potential content of the CDSS and CR based categories of structure and agency, informed by CRQA (Fletcher, 2016), to identify possible generative mechanisms.

6.2.5.1 Reflexivity

The practice of critical reflection and self-awareness, based on field note content is vital when undertaking qualitative research (Maharaj, 2016). Considerations include the research student's role, professional background, positionality, thoughts, feelings, assumptions and hunches during the advisory groups. Since reflexivity is an ongoing process of reflection and recursivity (Barrett et al., 2020), strategies were used to manage reflexivity before, during and after advisory group meetings, including use of a reflective diary, reflective content within the field notes, and de-brief with a service-user representative employed by CLAHRC-EM.

6.2.6 Sampling Strategy and participant recruitment

Participants aged over 18, with experience of suicidality (past and/or present), who had consulted their GP for suicide-related concerns, and were proficient in English, were eligible to participate in the advisory group meetings.

6.2.6.1 Participant recruitment

A multi-method approach to recruitment was adopted to ensure a wide and diverse selection of participants. This included using professional and research networks, such as the research student advertising in the PPI bulletin of the East Midlands Academic Health Sciences Network, contacting local voluntary sector organisations (such as Self-help Nottingham, CALM, Harmless and Student Minds) and CCGs in Nottinghamshire. In addition, the research student places advertisements on social media, and flyers (appendix G) around the university on designated notice boards.

In response, numerous individuals contacted the research student, but declined to participate once informed there was no financial recompense attached to their involvement. One male patient expressed interest but declined to participate in advisory group meetings. A recently suicide bereaved parent also expressed interest but had not consulted their GP in response to personal experiences of suicidality, nor been asked about suicidality by their GP.

2 participants were recruited via Twitter, 1 by professional and clinical networks, and 1 participant approached the research student directly at an academic conference.

6.2.6.2 Consent process

Eligible patients contacting the research student, were provided with a participant information sheet (appendix H) and consent form (appendix I). The research student then met with each patient in person to go through the consent form and formally consent the patients to the study. Patients were provided with the required

cooling off period prior to returning their consent forms. Patients were also required as a condition of the ethical approval, to provide consent for the research student to notify patient's GPs of patient's participation in this study.

All participants were formally recruited, providing informed valid consent prior to participation. All participants were asked to provide additional verbal consent at the commencement of each meeting with their right to withdraw reiterated.

6.2.6.3 Sample Characteristics

In total 6 participants provided valid informed consent (age range:21-56, $\bar{x}$ 33.83 years old). All participants identified as women. 2 of the 6 participants formally recruited, never attended an advisory group meeting. Of the remaining 4 participants who did attend group meetings, 2 were aged less than 25 years old at the time of recruitment.

6.2.7 Ethical and Research governance approvals

Formal research governance approvals were obtained from the University of Nottingham undertaking the role of the research sponsor (protocol reference 17053). Ethical and research governance approvals were obtained prior to recruiting participants, from the Nottingham 1NHS Research Ethics Committee (REC), the Health Research Authority (HRA), and local CCG or NHS Research and Development departments (REC reference: 17/EM/0317).

Whilst asking people with lived experience of suicidality to draw on their personal experience might be an emotive experience, there is no evidence that participating in research is associated with increased distress or suicidality (Blades et al., 2018) or that asking people about suicidality increases suicidality risk (Dazzi et al., 2014). Nonetheless, it is important to ensure that patient involvement in suicidality research can be conducted in way which protects patients safety (Littlewood et al., 2019).

Patients' psychological and emotional safety was maintained throughout group meetings, by interspersing topic focused activity with unstructured time, informal peer interactions and opportunities to move around. Participants were free to enter or leave the room at any time.

6.3 Findings

All of the participants had experience of more than one GP consultation in which they had either been asked about suicidality, or had volunteered information about suicidality. The context and precursors to participants discussing suicidality with their GP centred around a wide range of personal experiences including sustained low mood, traumatic stressors, historical abuse, suicide bereavement, self-harm and difficulties associated with neuro developmental conditions. Shaped by the analysis of field notes codes to structure or agency, two major themes were identified:

- Experiences of suicidality care in primary-care
- The potential added value of the CDSS

Each theme was comprised of sub-themes, and these are presented below.

6.3.1 Experiences of suicidality care in primary care

This theme reflected participants' experience of accessing primary care, GP consultations and outcomes.

6.3.1.1 Experiences of accessing primary care.

All participants reported frustration at the current way in which appointments were arranged at their respective GP practices. Patients had to phone through to the practice and speak to the person booking the appointments. Raising suicidality at such times felt impossible for many group members.

> "*Contacting the surgery can be a nightmare, all I wanted is to make an appointment for me to go and see them, it was the thing I wanted and needed".* (paraphrased field note)

To get through this barrier some would try to say they were feeling unwell, or named other conditions as the passport symptom to get the appointment. Others had appointments that could be booked by email but again were asked to specify something about the nature of the appointment on the practice system. These difficulties at the front-end of primary care served as barriers, which at times had been experienced as insurmountable by participants experiencing significant psychological distress and led to people failing to get an appointment. When people did manage to marshal their resources sufficiently to persevere with the booking process, having to articulate a reason for seeking an extended appointment instead of the routine ten minutes was a significant further barrier. Participants suggested that it would help enormously if it was possible to book appointments, ideally longer than ten minutes, without having to specify a reason at the point of booking.

When participants did get to speak to a GP, some were met with a more human corrective to the sense of interacting with an impersonal system of care. This was enhanced if it was a GP with whom the patient had a good prior experience. Frequently however, particularly in large multi GP practices, the experience was more usually in-continuity of care, where participants would have to begin afresh with a new GP at each consultation. Sometimes patients had the sense that GPs had read their notes, others seemed to not have done so. Sometimes this experience of being met by a stranger GP was helpful, yet at other times could increase distress.

6.3.1.2 Experiences of GP consultations

All participants had positive and negative experiences of discussing suicidality during consultations with a range of professionals including GPs. For all, conversations about suicidality with their GP were memorable as being either helpful or unhelpful.

Helpful factors included perceptions of GPs' genuine care, and a collaborative, interpersonal interaction. Less helpful factors included

the experience of being dismissed and simply referred to secondary care services.

6.3.1.2.1 Experiences of a collaborative interpersonal interaction

Participants suggested GPs vary significantly in their interpersonal style, and their assumed receptivity to talking about suicidality. GPs' attitudes towards suicidality were seen as key to a helpful consultation, particularly when GPs seemed to demonstrate genuine care. How GPs asked about suicidality was often less important than the specific words that they used. The way in which the GP asked, was taken to convey something of the GPs attitude. GPs who seemed to demonstrate a caring or concerned attitude could encourage people to open up further information about their experience of suicidality. Conversely, GPs who tried to rush into 'fixing things' could lead to people closing down the topic or not talking about their suicidality experience. Meeting a concerned and caring human being was a powerful aspect of the consultation. This human element was key, but sadly reported as often missing from conversations with GPs and mental health professionals. Some participants described their GPs as trying to be 'aloof care co-ordinators', whereas others were active in trying to understand the level of risk and working with the participant to contain or reduce risk. GPs who appeared responsive to disclosures of suicidality, actively engaging patients in thinking about how to lower risk, were perceived as more helpful than GPs who dismissed risk.

6.3.1.2.2 Experiences of talking about suicidality with GPs

Talking about suicidality was reported as difficult, for both participants and GPs, within the recursive patterns of conversation occurring in a consultation.

How participants perceived GPs' attitude, and assumption of whether they actually cared, could shape participants' decision as to whether or not to disclose suicidality; and mediated the extent of information they might disclose. Rather than naming suicidality outright,

sometimes participants would give some clues about suicidality, such as saying they felt extremely lonely, unhappy or unwell.

At other times, some participants found themselves not being able to articulate their distress or express that they were experiencing suicidality.

> "*Sometimes when I am feeling like that it is not a rational process, I maybe can't explain it… I might not be thinking right*". (paraphrased field note)

At such times being able to communicate suicidality to GPs was experienced as incredibly difficult and draining.

Once the subject of suicidality had been broached, participants felt it was very important that GPs used concrete language. For example, instead of asking 'have you thought about hurting yourself' they could find ways of asking in more specific and concrete language (see section 6.3.2.4 for specific suggestions for wording within the CDSS). Participants felt that many of the GPs they had spoken to had used phrases that were either a little bit vague, or open to misinterpretation. Instead, participants thought GPs should explicitly name suicide as the subject of their questioning, and such direct questions were felt as helpful in opening up the topic, especially when approached with care and compassion. Participants reported that if they disclosed suicidality, GPs could helpfully normalise experiences of suicidality to put experiences in context, and to help inform their judgement of personal risk.

6.3.1.2.3 Experiences of being judged to be at risk

GPs process for determination of risk appeared to be variable, with some GPs apparently placing a lot of emphasis on how participants 'looked' or articulated themselves during a consultation.

Sometimes participants felt that if GPs appraised them as looking insufficiently suicidal, or insufficiently at risk they might not be taken seriously.

"*I'm quite good at masking, and not always when I want to, they would see me as looking calm, they wouldn't see me as a risk, even when inside I feel like I can't go on"* (paraphrased field note)

Participants felt that they almost needed to spoon feed some GPs information about their experience of suicidality, to reduce or interrupt the chance that GPs would effectively retreat from the inter-personal conversation, back into a more detached analytical head-space

"*It's the human contact that matters… but the human element is so often missing*".(paraphrased filed note)

Some GPs appeared able to convey their acceptance of uncertainty of risk, others were perceived as 'blagging it' and instilling false hope by perpetuating narratives that 'this can all be easily sorted'. Participants' experience of suicidality was often complex, and multi-faceted, underpinned by myriad contributing factors which coalesced. Unpicking such an array of overlapping factors was not considered simple or easy by most participants. Participants felt strongly that if GPs did not have a clear view of risk, or up to date knowledge of possible interventions, they should not try to portray themselves as experts, and instead meet the person in a more interpersonal conversation. At such times participants felt it would be acceptable for GPs to say something like

'I don't have all the answers but there is hope. Neither you or I might know exactly what you need right now but let's meet again in a day or two'.
(paraphrased field note)

Therefore, it appears a more active, and interpersonally invested GP was considered more helpful than an aloof 'care coordinating' GP, particularly since GPs knowledge of suicidality care pathways and interventions seemed to vary.

6.3.1.2.4 Being referred and receiving interventions

GPs appeared to have varying knowledge and awareness of suicidality interventions and care pathways. Some GPs appeared very familiar with what patients could expect when referred to a crisis team or psychiatric liaison services; others seemed to instil false hope by suggesting secondary care providers would be able to provide interventions, such as long-term counselling, which was not available.

Difficulties were reported between GPs and mental health services communicating with regard to possible interventions, and medication prescribed or adjusted. Coupled with the apparent gaps in GPs' knowledge of what interventions would be offered in secondary care, participants sometimes perceived there was no formal suicidality care pathway.

> "*It's like they don't really talk to each other. Sometimes you get discharged without medication, or they haven't told the GP what medication you are on now*" (paraphrased field note)

When interventions, such as medication, were initiated, GPs and mental health workers seemed oblivious to the ease with which participants could obtain a range of pharmaceutical products and appeared to think participants only had access to compounds they had been prescribed. Participants suggested GPs need to have more open conversations about prescribed medication and people's access to medication elsewhere, including from fellow patients, or online retailers. In reality, several participants had taken medications that they were not personally prescribed whilst trying to manage experiences of suicidality. Participants thought therefore it was important that GPs asked:

> "*Have you started, finished or changed medication recently, or changed how you are taking medication.*" (paraphrased field note).

Suicidality consultations frequently led to referral related contact from other professionals, such as crisis team staff. Contact from other professionals was often experienced as rather more cursory and less personal than the conversations with GPs. Frequently, such contacts were from a previously unknown professional and made by telephone. One surmises these calls were in effect a form of triage assessment, intended to determine the level of risk to self. Such impersonal contact was experienced as relatively intrusive and unpleasant but accepted by participants as a necessary part of the referral pathway. Unfortunately, sometimes such contacts precluded further specialist support, and ended with people with lived experience being told to '*go and have a nice bath*' or otherwise feeling summarily dismissed. In such circumstances, people would try to cope in whatever way they knew including going back to their GP.

6.3.1.2.5 Time pressures

Participants were very aware of the time pressures that GPs operate within. However, having time was important because sometimes people might need precious minutes to process their thoughts and feelings before they could even begin to articulate them. Participants also reported requiring time to process their own thoughts and feelings, and to get a sense of how the GP might respond to disclosures of suicidality, as they were effectively working out whether or not they thought the GP actually cared.

An over-reliance on verbal reporting of suicidality compounded this problem. Participants suggested that having communication aids such as access to pens and paper, or other methods of communication, such as tablet computers, might help people to disclose suicidality more completely, during time-pressured appointments.

6.3.2 The potential added value of the CDSS

This theme related to the potential of the CDSS, to help GPs and participants discuss suicidality in consultation, thus enabling GPs to identify, assess and care-plan with patients, regarding their

experiences of suicidality. Participants suggested the CDSS could help improve access to care and the experience of care.

6.3.2.1 Improving access to care

Participants expressed their views about the impact of the CDSS in accessing care. Participants suggested, that if the CDSS was implemented, it could powerfully short-cut the problems accessing care. For example, a participant said;

> "*It would really help if I could ring up the surgery and say I need a GPS[3] [the name of the CDSS] consultation*" (paraphrased field note)

Being able to easily articulate a purpose for the consultation, without naming suicidality in the impersonal contact with a booking system or clerk, could help participants feel more empowered and less like they were interfacing with a large impersonal system of care. Furthermore, participants thought the CDDS could help with referral processes:

> "*If my GPs filled it out, and it's on the computer, can they send that to crisis? I'm sure they'd ask me all the same questions, but it might speed it up?"* (paraphrased field note)

The CDSS therefore could have potential to improve both access to care, and patients' experience of accessing care.

6.3.2.2 Improving personalised continuity of care

Participants suggested the CDSS could go some-way towards reducing the in-continuity of care sometimes experienced when seeing different GPs. The CDSS could be of potential benefit if it recorded information in participants' EHR, about what they found personally helpful in their experiences of suicidality.

> *"If it recorded what I actually find helpful, that might be really good to remind me, I am so fed up with them kind of going through their list, telling me to have a bath, or listen to some music, or do something nice … "* (paraphrased field note)

The CDSS therefore could have potential to embellish and improve the quality of data-recording in primary care, potentially enhancing

and improving GPs ability to offer personalised care. Such an improvement could also enable shared decision-making to a greater extent with regard to care-planning.

6.3.2.3 Improving care planning

Linked to improved personalised continuity of care, a more individually nuanced care-plan was suggested as being what participants could find helpful. Participants reported that sometimes they had perceived GPs as assessing them as either being at risk, or not being at risk of suicidality. In contrast, for some participants, suicidality was experienced as a complex phenomenon, consisting of multiple shifting elements including their sense of personal resilience and agency; and their psychological and emotional state fluctuating in response to life events, and social and interpersonal factors. Some participants considered it was crude and woefully inaccurate to attempt to reduce the complexity of suicidality in this way:

> "*It is not a binary distinction between risk and no risk. It can be fluid and multiple"* (paraphrased field note)

Risk was experienced as occurring in both internal and external domains of experience; and comprised of multiple overlapping, or intersecting strands of risk. Suicidality was experienced in different ways at different times. Sometimes it was frightening and accompanied by feelings of helplessness or inevitability. At other times, it was strangely familiar and reassuring because participants had felt this before and come through it. Yet for another participant, suicidality was a space for escapism in both a fantasy sense, as well as providing a sense of actual final escape if the person's experience became finally unbearable:

> "*I don't want the GPs to take away my last sense of escape. I just want them to remind me I have ways of coping, and I have some choice of what to do next".* (paraphrased field note)

Such comments serve as a reminder of the complex and multi-faceted experience of suicidality, and the likelihood that suicidality

can be experienced in very different ways between people, and sometimes in variable ways within the domain of an individual's personal experience.

As a result, participants suggested GPs conceptualisation of risk could be more sophisticated than a binary distinction. Similarly, attempts at risk stratification could be misguided. Instead, participants suggested working with patients to agree how urgently someone might need additional support. Such a decision would need to be made on a case-by-case basis, however the CDSS could potentially support this process by presenting general recommendations and patient specific risk and coping related information.

> "*If it reminded me of how I've coped before that could be useful. Also if it suggests actually you might need to be referred to crisis team because you're in a bad place right now…that might be helpful too"*
> (paraphrased field note)

The CDSS therefore could have potential to support GPs with making patient specific clinical-decisions, informed by a collaborative consultation combining assessment of risk and tailored care-planning.

6.3.2.4 Prompts and items within the CDSS

The way in which suicidality is referred to within professional and academic literature was examined in advisory group meetings. Terminology, phrases and ways of talking about suicidality within existing assessment tools and instruments were compared and contrasted.

Some specific prompts, phrases or questions were endorsed by participants and others were rejected. Wording or phrases that were endorsed by participants tended to mirror previous comments about how GPs' could approach identifying, assessing and care planning using concrete language. Phrases or questions which participants endorsed were noted down.

Instead of vague or potentially misinterpreted questions such as 'have you thought about hurting yourself' direct questions about

suicide were preferred, such as '*are you thinking about suicide'*, '*is life worth living*' and '*are you finding it really hard to carry on living right now'*.

If suicidality was disclosed, participants suggested GPs could helpfully normalise their experience. This could be as simple as GPs reflecting '*this is an understandable reaction to the situation you are dealing with*', or '*this is a symptom of your condition*' if appropriate. Further questions that might help people to elaborate details of their suicidality included asking '*how long have you been feeling like this'*, '*are you aware of anything that might have contributed to how you are feeling'* and '*what makes these feelings better or worse?*'.

Other important questions related to a safety plan, including '*has this happened before?'* and if so '*what helped?*' as well as '*what stopped you acting on these thoughts or feelings last time?'*. Participants also thought it was insufficient to check if patients had anyone at home, since aspects of relationships could be either helpful or a contributing factor to suicidality, or sometimes both. Instead, it was thought better to ask 'w*hat is your situation at home?*', '*are there people who are able to help you?*' '*if so are they being supported by anyone else'*. These concerns were because often, in the face of rejection from mental health services, or whilst waiting for assessment, patients turned to friends or family for support, some of whom had their own experiences of suicidality or psychological distress.

In summary, participants reported on their perceptions of how GPs identify, assess and manage suicidality in primary care. Differences in GPs' ways of responding to suicidality disclosure were reported, potentially impacted by variation in GP knowledge, skills or attitudes, the availability and quality of suicidality care pathways, and contextual time pressures. Participants suggested consultations where the GP was experienced as caring, interested and inter-personally involved were more helpful than consultations where the GP was more aloof, or more concerned with risk management. The

human contact was considered most helpful, but participants were also acceptant of GPs roles as gatekeepers needing to determine when onward referral might be needed.

Participants suggested a CDSS could helpfully contribute to their experience of consultations by usefully improving access to care, promoting personalised continuity of care and individually tailored care-planning. A range of potential prompts or items for inclusion in the CDSS were suggested by participants. The CDSS was considered as potentially helping GPs and patients to move away from binary distinctions of risk or no-risk, and risk stratification, towards a more person-centred and personally nuanced conceptualisation of suicidality.

6.4 Discussion and implications

This chapter reported the findings of 6 consultations with 2 advisory groups of primary care service users for the purposes of exploring patients' understanding and experiences of GP consultations in relation to suicidality, their perceptions of how GPs identify, assess and care plan for suicide risk; and their views on the content, format and use of a suicidality CDSS. The findings of the advisory group meetings indicated that participants are aware of potential generative mechanisms which could influence GPs and GP's experience of consultation. Prospective generative mechanisms include time pressures in primary care resultant from service-pressures, demands and resource constraints, the existence and quality of suicidality care pathways, and variations in GP knowledge, skills and attitudes.

The CDSS was suggested as potentially possessing qualities and capabilities to help GPs work in more person-centred ways with people in distress and to enhance personalised-care and care-planning.

6.4.1 Implications for CDSS development

There is currently no suicidality CDSS that has been produced with explicit co-production or robust PPI processes underpinning their development. The current study therefore represents an important first step in presenting a co-production approach to developing a suicidality CDSS.

Since the CDSS is likely to be used during in-vivo appointments, patients as integral agents within a consultation, have a valid contribution to make regarding the format, content and use of a CDSS. Patient perspectives appear to be rarely and infrequently incorporated into CDSS development, with just one co-produced CDSS identified in a recent scoping review (Lim et al., 2020). This study has brought into focus the benefits of incorporating patients as participants in co-producing a CDSS.

Participants in the advisory groups, suggested specific prompts, phrases or questions for inclusion in the CDSS. Including participants suggestions in the CDSS could be appropriate since studies show that where patient's design questions or prompt lists they have moderate to high acceptability and usability (Lim et al., 2020). The phrases and words suggested by participants for inclusion within the CDSS present clear, unambiguous and specific items, which could help GPs work more effectively with patients experiencing suicidality.

Involving patients as co-production participants has also highlighted the relative importance of wider contextual factors and quality improvement systems and processes relevant to CDSS development and possible implementation. For example, participants highlighted difficulties accessing primary care in relation to suicidality, and identified that the ability to ask for a consultation featuring use of the CDSS could short-cut the difficulties interacting with the front-end of primary care services.

Participants also highlighted potential generative mechanisms, which could influence GPs' ways of working and their experience of

suicidality consultations. Prospective generative mechanisms include time pressure in primary care resultant from service pressures, demands and resource constraints, the existence and quality of suicidality care pathways, and variations in GP knowledge, skills and attitudes. This is line with previous research reporting on organisational and contextual factors complicating suicidality prevention in primary care (Leavey et al., 2017, Michail et al., 2016, Saini et al., 2015).

The use of embedded consultation, to enable co-production of CDSS development, has therefore helped to identify potential generative mechanisms, which could influence use of the CDSS; and helped to shape its content, format and prospective application. Such considerations are important to help GPs as the intended end-users to meaningfully incorporate use of the CDSS into their workflow when consulting patients experiencing suicidality. The ease of use of CDSS, and extent of integration with end-user workflow are two of the key recommendations for CDSS research (Kawamoto and McDonald, 2020). Ease of use is an established concept describing the experience of interacting with CDSS systems. However, perceived ease of use could also reflect perceptions of the clinical utility of CDSS use (Sutton et al., 2020). Incorporating perspectives of advisory group participants in co-production, has shaped the prospective content of the CDSS, to maximise its ecological validity from patients' perspectives, within the context of suicidality consultations. This has led to specific ideas for improving the ease of use of the CDSS and its clinical utility. Patients have suggested items and phrasing within the CDSS and suggested functions and abilities, which could help GPs identify, assess and care plan with patients in response to suicidality.

In summary, the embedded consultation approach has provided real-world value in the process of developing a CDSS which is grounded in

lived experience and patients' perspectives on its content, format and use.

6.4.2 Implications for suicidality prevention in primary care

Participants articulated how a CDSS could contribute to improving access of care, experiences of personalised care and tailored care-planning. Such concepts are inherently complex, since GP consultations in relation to suicidality are simultaneously an inter-personal interaction focused on the wellbeing of the patient, and a meeting with a health professional working for the state, who is determining levels of risk to patients, the health-care system and wider society. This dualism within the consultation could lead to a sense of being negatively judged or evaluated in relation to system requirements, such as risk thresholds and perceived level of risk. Such decisions felt anathema to some participants' experiences of the interpersonal nature of some GP consultations. The GP consultation remained a place where personal experience could be discussed, if the conditions were judged and experienced as favourable. GPs could respond in warm interpersonal caring ways. Yet, on another level GPs were operating as agents of the state, assessing risk and deciding whether or not to refer to specialist services and carrying out a gatekeeping role.

The CDSS is therefore also potentially subject to these same dialectical considerations. The CDSS could potentially facilitate more personalised care, such as highlighting prior coping-strategies experienced as helpful, or presenting prompts and items in clear, unambiguous and recommend language. The CDSS could also compile risk information, and healthcare system requirements, potentially detracting from patient-centred care.

People with lived experience articulated a preference for GP consultations which were more obviously centred on their needs, and less on the system's norms and processes. At a fundamental level, such a consultation may require an epistemological shift from

consultations focused on risk-assessment towards patient-centred care. Actively engaging patients in patient-centred care, focused on their assessed clinical needs and experiences, can lead to reduced suicidal ideation, greater engagement with treatment interventions and less psychiatric symptoms (McDowell et al., 2011).

Historically however, the NHS has been an institution run according to the beliefs, values, and agendas of commissioners, managers and medics, and not led by the beliefs, values and agendas of patients (Owens, 2012). A switch in the nature of primary care consultations, towards more patient-centred care, and less system oriented care could be at odds with these historical norms, and the long-held doctrine of GP as gatekeeper to specialist referral (Loudon, 2008), which requires GPs to control access to expensive specialist services, particularly in times of austerity (Majeed, 2013). Gatekeeping requires a more objective and less personally invested judgement of patient needs, and some consider gatekeeping GPs' key goal in primary care suicidality consultations (Sequeira et al., 2019).

In contrast to primary-care consultations being focused on gate-keeping decisions, it has been suggested that consultations can be a much richer interaction; balancing professional's theories and beliefs about patient's presentation and clinical needs, alongside allowing patients space to articulate their story, enabling the consultation to become an opportunity for dialogue between the GPs professional story and the patient's personal one (Launer, 1999). Such an approach has been referred to as lifeworld led healthcare (Dahlberg et al., 2009), where doctors and patients meet as partners engaged in an existential practice, acceptant of different levels of expertise, to consider potential avenues for the patient to explore.

In the context of suicidality consultations, concepts such as lifeworld led care may be considered by some as ideological and unrealistic. After all, when lives may be at risk, society will want patients to access competent care, led by doctor's medical and professional

knowledge, delivered within a policy and funding framework, shaped by the decisions of democratically elected officials (Fitzpatrick, 2005). Therefore, lifeworld led healthcare appears at odds with clinical reality, that sometimes vulnerable patients need to rely on doctor's professional and practice knowledge. Instead, suicidality consultations may require a space in the middle between the extremes of lifeworld led and systemworld led care. Consultations could thus seek to balance the narrative and normative aspects of medical encounters (Launer, 2019). Doing so could allow primary care suicidality consultations to retain their place as a profound meeting point between the lifeworld and systems-world. Within this context the scope for shared decision-making (SDM) is clear.

SDM requires doctors to collaboratively discuss care-planning or treatment recommendations with patients, and confirming patient's treatment preference (Elwyn et al., 1999). Such an approach seeks to achieve an active partnership between patients and doctors, and has been described as the pinnacle of patient-centred care (Barry and Edgman-Levitan 2012). Adoption of SDM is recommended as a helpful approach in suicidality consultations (Bellairs-Walsh et al., 2020). However, challenges to SDM in suicidality consultations include the potential for some patients to withhold risk information (Schulberg et al., 2004), and patient's cognitive functioning, and decision-making ability, which can be severely impacted by stress or mental-health problems (Shanker and Bakhle, 2018). The CDSS may afford some scope to support SDM in primary care suicidality consultations, by enhancing personalised continuity of care and care-planning.

6.4.3 Strengths and limitations

Embedded consultation has provided real-world perspectives of patients on the process of accessing GPs and receiving GP care for suicidality. This study has shown that embedded consultation, using

advisory groups, is a valuable way of engaging patients in CDSS development.

Participants have shaped the prospective content of the CDSS and highlighted potential generative mechanisms influencing its use. As contributors to primary care consultations, patients have valid knowledge to share, from perspectives of quality improvement (Bataladen, and Davidoff, 2007), and theoretical development (Pawson, 1996).

The embedded consultation approach enabled frequent discussion and iterative contributions, whilst allowing the perspective of a range of patients to be incorporated, rather than restricting involvement to one or two individuals. These are some of the major strengths of embedded consultation (Hughes and Duffy, 2018). The flexibility of the approach is also particularly relevant when working with patients who may experience fluctuation in their wellbeing, such as people with experiences of suicidality, allowing people to contribute in different ways, to different extents at different time-points during the project life-cycle (Hughes and Duffy, 2018).

Embedded consultation appears therefore to be an effective, and acceptable way of facilitating PPI in suicidality related research, potentially affording a way to address the dearth of published studies incorporating involvement (Littlewood et al., 2019). The approach has also enabled co-production of a CDSS, in a way which has not been reported elsewhere.

However, there are limitations to this study, which need to be taken into account. Firstly, co-production is conceptually problematic on the basis that patients and healthcare providers frequently have different views on experiences of care and rationales for treatment. Co-production has been critiqued as providing patients with an illusion of having influence, whilst power over the process resides with the professional (Owens and Cribb, 2012). Moreover, the evidence base and academic literature is not always clear as to what co-production

actually is, nor what is produced, or the circumstances under which co-production takes place, and the implications for participants are rarely acknowledged (Filipe et al., 2017). In response, Filipe et al., (2017) suggest co-production should be understood as an exploratory space, and generative process, leading to knowledge, values and social relations that cannot always be specified in advance. This study has sought to enable the qualities described by Filipe et al. (2017), within the parameters conferred by research governance approvals. Consequently, co-production commenced after initial research questions had been formed and a scope of research decided, arguably meaning true open-ended co-production was impossible.

Furthermore, there are recognised costs to co-production, affecting both co-production members and researchers (Oliver et al., 2019). Potential costs to participants included financial expense, time, and risk of potential distress. Practical costs to the researcher included additional administrative burden, associated with meeting room bookings, catering requirements, maintaining regular communication with participants, and managing financial expenses.

Despite attempts to recruit a wide cross-section of participants, the purposive sampling approach used resulted in the recruitment of a very specific sample, of highly educated, confident and articulate people identifying as women. Such a sample is neither representative nor generalisable of all who experience suicidality. Males expressing an interest in participating either did not want to be part of a discussion group or expected payment for their involvement. As such, there appeared to be a gendered aspect of participation that was not anticipated. This may reflect wider social gender roles, norms and values, where males are less likely to use health services (Brown et al., 2019); and may still be more likely to be primary earners in their relationships. In addition, there are many known difficulties with engaging males in talking about suicidality specifically, owing to social stigma and the way in which suicidality is framed (Robinson et al.,

2013). Because of these complex problems surrounding male suicidality, it has been argued that suicidality should be considered as both a health and gender inequality, requiring a focus beyond individual mental health to encompass social and cultural contexts (Wyllie et al., 2012). Attempting to navigate such complex terrain is an important consideration but is a broader concern than the scope in which it was encountered in this study. Consequently, the sample of participants in this study is a limiting factor, potentially reflecting gender norms, structural aspects of society and socialised behaviour in relation to healthcare utilisation and GP consultation.

6.4.4 Implications for further research

Future research could seek to increase the scope and democratic nature of co-production by allowing people to contribute more flexibility in less defined ways, such as allowing people to participate individually outside discussion groups. Moreover, larger sample size, multiple groups of participants, and targeted recruitment of males, and under-represented populations known to be at risk of suicidality could have added increased value to this study. Further research could be undertaken to maximise co-production with a wider range of participants and replicate advisory groups with greater attention to gender inclusivity, seeking to enable males to participate. This may necessitate methodological and procedural flexibility, for example allowing males the option to attend remotely via platforms such as video conferencing, or telephone, in attempt to remove barriers to participation.

Conceptually, undertaking co-production within the parameters of quality improvement (QI), rather than the tightly regulated framework of health-research, may enable greater scope for true open-ended co-production. Due to the impact of research governance frameworks, the research student suggests fidelity to the spirt of co-production is limited by the regulatory process. Therefore, further co-

production work could be undertaken, as a QI project, to continue iterative development of the CDSS post implementation. Such work could explore participants' experiences of care after being in a consultation where GPs use the CDSS, and exploring its contribution to suicidality prevention.

6.5 Conclusion

This chapter has highlighted patients' perspectives, obtained through convening regular co-production advisory groups of patients. This embedded consultation approach enabled patients to shape the format, content and prospective use of the CDSS whilst also identifying potential generative mechanisms pertinent to its use. Patients have identified ways in which the CDSS could help improve experiences of suicidality consultations with GPs. The perspective of patients, as experts with lived experience, and agential actors within suicidality consultations has added depth to the thesis and serves as an important part of methodological triangulation. However, patients do not always experience consultations in the same way GPs do. Within the interpersonal meeting of a consultation, GPs are still working within the healthcare system, requiring them to switch between life-world concerns, and concerns of the profession of medicine, belonging to the normative culture of the systems-world. The ease or competence with which GPs can manage such switching may be an important part of GPs consultation skills, potentially impacting patient disclosure of suicidality. Questions or phrases considered relevant or helpful by patients, in this way, may be received differently by medical professionals. The logical next step is therefore involving both GPs and patients in reviewing potential content and creating a short-list of items before continuing to prototype build. The next chapter reports the use of co-production workshops involving multiple stakeholders, to refine the potential content of the CDSS.

Chapter 7: Stakeholder input to the development of a suicidality CDSS

7.1 Introduction

Building on the GP interviews (chapter 5) and patient advisory group consultations (chapter 6), this chapter reports an empirical study, which aimed to bring together multiple stakeholders (GPs, patients, topic specific experts, and commissioners), to agree and refine the content in the CDSS achieving consensus agreement on a short-list of items or prompts within the tool and identifying potential generative mechanisms relevant to the CDSS.

7.2 Method

7.2.1 Setting

Stakeholder consensus workshops and a CDSS content refining and implementation-oriented workshop, took place over three half-days in June 2018. The workshops took place in meeting rooms within the Institute of Mental Health, University of Nottingham where the research student was based.

7.2.2 Study Design

This study utilised a mixed-methods design, featuring two phases; a modified Delphi expert consensus study, and a CDSS content refining and implementation-oriented workshop. This design avails the CDSS of stakeholder input to achieve a synthesis of co-design and coproduction.

7.2.3 The purpose of the method

These methods were chosen by the research student in relation to the intended outcomes:

i) Achieving stakeholder consensus agreement on a short list of items or prompts for inclusion with the CDSS.

i) Eliciting stakeholder views to agree and refine the content of the CDSS, explore barriers and facilitators towards implementation and elucidate potentially relevant generative

mechanisms influencing the use and implementation of the CDSS.

7.2.4 Methods of data collection

7.2.4.1 Phase 1: Modified Delphi expert consensus study

The Delphi-process is one of several methods used to explore the collective opinion of experts with the intention of arriving at consensus in a systematic manner (Fink et al., 1984). The Delphi-process replaces direct debate with a systematic programme of enquiry, where respondents provide individual answers to set questions, interspersed with information and feedback regarding other participant's responses and aggregated consensus scores (Brown, 1968). Despite its original focus on scoping expert opinions in the field of defence and military planning, the Delphi process has since been applied to a variety of healthcare related situations (Fitch et al., 2001). Healthcare specific applications of the Delphi process have included developing clinical guidelines (Murphy et al., 1998) and arriving at consensus for treatment approaches or ideal response for a wide variety of specific clinical problems (Boulkedid et al., 2011; Eubank et al., 2016; Meshkat et al., 2014; Miller et al., 2020; Wood et al., 2013).

Delphi processes have also been applied to agree consensus in mental health treatment and research (Bijl, 1992; Dewa et al., 2018; Jorm, 2015) as well as gaining consensus regarding suicidality prevention guidelines and interventions (De Silva et al., 2016; Hill et al., 2019; Kelly et al., 2008; Manning et al., 2018; Robinson et al., 2018; Sellin et al., 2018; Setkowski et al., 2020). In its original form, the Delphi technique involves expert participants, who take part anonymously, and sequential iteration with feedback, which features statistical aggregation of group data (Trevelyan and Robinson, 2015). Over the years, a range of modifications to the Delphi process have been made, including interspersing rounds of questionnaire responses with individual or group discussion; comparing the Delphi group with

a secondary control group who receive no feedback on group scores; adjusting the number of rounds; completing a literature review, or gaining expert opinion through interview, prior to the Delphi commencing (Brown, 1968; Monguet et al., 2017).

This study utilised a modified Delphi process, featuring rounds of questionnaire responses interspersed with group discussion conducted during workshops. A face-to-face process, as opposed to anonymised Delphi, was preferred. Whilst anonymity can allow respondents the opportunity to review and re-evaluate their own responses, it has been argued additional gains may be obtained by allowing face-to-face interaction. Such gains can include enhanced information exchange, and development of a common terminology with respect to the Delphi content (Dick, 2000). The latter point was considered particularly important by the research student given the proliferation of terms in relation to suicidality, suicide and self-harm in clinical practice and research. Furthermore, it has been suggested that maximising interaction between experts involved in Delphi panels may allow experts to access their own intuitive knowledge (Helmer, 1967). Therefore, the modified Delphi process used encouraged participants to take part in small group discussions before and after each round.

7.2.4.1.1 Development of the master list of items or prompts

A master list of one 152 items, phrases or prompts for inclusion in the CDDS were compiled, from the extensive literature review (chapters 2 and 3), qualitative interviews with GPs (chapter 5) and embedded consultation with patients (chapter 6). Prospective items were drawn from a range of clinical and academic sources, including risk assessment tools, such as the Columbia Suicide Severity Rating Scale (Posner et al., 2011), and Suicide Status Form (Jobes, 2006),theoretically based constructs such as the eight volitional factors from the IVM (O'Connor, 2018), clinical practice guides such as the decision tree interview (Van Orden, 2013), and GP facing

literature suggesting ways of asking about suicidality (Morriss et al., 2013; Sinclair and Leach, 2017).

As a clinician contributing to regional suicide prevention strategy steering groups the research student was also able to engage colleagues possessing topic expertise in a limited number of 'sense checking' conversations. This enabled reviewing the master list of items against latest clinical guidance and indicated best practice across different health sectors and settings. Prior to the Delphi process commencing, duplicates or very close iterations of the same item were removed, resulting in a revised list of 93 items.

7.2.4.2 Phase 2: CDSS content refining and Implementation-oriented workshop

The third stakeholder workshop aimed to refine the content of the CDSS and explore expert panel members' views on the pathway towards implementation of the CDSS, anticipated barriers and facilitators, and potentially relevant generative mechanisms.

A theory-based qualitative workshop format was adopted, since qualitative approaches are well suited to developing new healthcare technologies or interventions (Yardley, 2018) and workshop based group discussion can enable exploration of relevant domain specific work and knowledge processes elaborating human interactions with information technology systems (Ørngreen and Levinsen, 2017). Furthermore, theory-based qualitative work can be used to inform the development and implementation of changes in routine-healthcare practice (Atkins et al., 2017). In this workshop, a theory-led approach informed by CRQA (Fletcher, 2016) was adopted, seeking to gain participants' views of structure, agency, context and specific content of the CDSS. The specific benefit of theory-led qualitative workshops is to identify, articulate, and explore ill-defined or fuzzy aspects of research involving technology (Ørngreen and Levinsen 2017). The procedure for this workshop mirrored the process for earlier Delphi rounds. This included establishing group agreement, followed by a short presentation providing feedback on the previous

Delphi rounds; and contextualising the background and context to prospective use of the CDSS situated against current treatment as usual. After the short presentation, panel members were afforded time to discuss in small groups, prior to large group discussion, facilitated by the research student with support from the academic supervisory team. In addition, the lead clinical advisor from PRIMIS, (Primary Care Medical Information Systems; a business unit of the University of Nottingham which provides a range of primary care health informatics services to health and research organisations) was party to the discussion to reconcile expert suggestions with technically feasible solutions. Prior to the workshops, PRIMIS were contracted to build the prototype CDSS following the supervisory team obtaining grant funding from the East-Midlands Patient Safety Collaborative.

A brief topic guide was created before the workshop, informed by the thesis methodology and underpinning theories; as well as iterative comments recorded during group discussion in the Delphi-rounds.

Questions within the topic guide focused on activation or triggering of the CDSS, how the CDSS might contribute to referral decisions, impact on referral pathways; and facilitators or barriers to GPs' use of the CDSS in practice. Brief written field notes comprising keywords or short sentences were recorded, reflecting expert's stated opinions.

7.2.5 Methods of data analysis

7.2.5.1 Delphi consensus ratings

This section describes the method for obtaining consensus ratings.

7.2.5.1.1 Pre-round activity

Workshops commenced with participants engaging in informal networking and information sharing. Each workshop commenced with briefly establishing a group agreement, or guideline for the session, including clarifying confidentiality boundaries pertaining to discussions within the group, and expectations pertaining to listening,

sharing and respecting differences of opinion. Baseline expectations for group conduct were important to establish, given panel membership included senior healthcare and research professionals, healthcare managers and commissioners and people with lived experience of consulting GPs about suicidality.

A short presentation was then delivered to the participating stakeholders by the research student. This was to communicate the research student's formulation of the background and context pertinent to prospective use of the CDSS, situating the concept of the CDSS against current treatment as usual. Such an approach is advocated to ensure that the expert stakeholders understand the researcher's conceptual model of the project, and to reduce the risk of misinterpretation (Helmer, 1967).

7.2.5.1.2 In-round activity

In-round activity proceeded after the presentation and commenced with panel members invited to engage in small group discussion to exchange information and knowledge. Helmer (1967) suggested such discussion amongst participants is helpful to allow them to centre their thoughts and connect with their own intuitive knowledge. Such a process could also be considered as interactions encouraging panel-members to access their system one and system two cognitive processes (Croskerry, 2009).

Participants were then presented with a set of questions to which they were required to assign a relative rating (on a 4-point ordinal scale) for each question. The scale used was based on the Content Validity Index (CVI) (Polit et al., 2007). The CVI is a widely used method of collating expert ratings of relevance, where each item is assigned a score on an ordinal scale for perceived relevance ranging from 1 (not relevant) to 4 (highly relevant). Total ratings and proportions were calculated. Scores in relation to each proposed item

in the CDSS could be collated and average scores for each proposed item calculated. Incorporating the CVI into a modified Delphi enables collation of expert judgement in order to agree both face validity and content validity of proposed items. A global content validity score was obtained for each item by totalling responses. The content validity of individual items were calculated, referred to as the content validity index score (I-CVI). The I-CVI calculates agreed relevance of each item, by totalling each rating scoring 3 (somewhat relevant) or 4 (highly relevant), divided by the number of respondents to provide the proportion agreeing with the relevance of the item. Scores of 0.80 are usually considered the lower acceptable limits regarding relevance determined by the CVI (Polit et al., 2007). In contrast across one hundred Delphi studies, a score of 0.75 was the median threshold specified for determination of consensus (Diamond et al., 2014). Therefore, an agreed relevance of 0.75 was considered the minimum criterion for consensus in this thesis, but scores of 0.80 or greater were desired. The content validity index for the whole range of items included in the final model, referred to as the scale content validity index (S-CVI/Ave) was calculated by summing the average of the I-CVIs and dividing by the number of items retained.

Two rounds of successively reviewing CDSS content with key stakeholders and topic experts was conducted, in order to develop consensus regarding the content and phrasing within the CDSS.

7.2.5.1.3 Post-round activity

Each round finished with brief small group discussion, followed by a structured large group review of panel members' opinions of factors which might help or prevent GPs from using the CDSS. A prepared topic guide was created by the research student prior to the large group review, based on the Consolidated Framework for Implementation Research (CFIR) (Damschroder et al., 2009), the Achieving Change in Primary Care model (Lau et al., 2016) and the Quality Improvement Change model (QIC) (Batalden and Davidoff,

2007). This was in keeping with the philosophical and methodological positions underpinning the thesis, such as the guiding perspective of methodological triangulation, as well as allowing participants to describe in their own words' prospective generative mechanisms relevant to the use of the CDSS. Brief hand-written written field notes were recorded to capture key aspects of participants stated opinions.

7.2.5.2 CDSS content refining and implementation workshop Data Analysis

The research student recorded handwritten field notes. Essentialist coding in a thematic analysis approach (Braun and Clarke, 2006) was applied by the research student to participants' statements recorded in the field notes. Essentialist coding seeks to capture participants' experiences, meanings, and perceptions of reality (Braun and Clarke, 2006).

The primary academic supervisor attended this workshop and recorded independent field notes, to supplement the research student's field notes and ensure key material was not missed.

All Field notes were coded by the research student in relation to context, agency, social structures, or specific content of the CDSS. Data were then analysed in accordance with the process for contextualist thematic analysis (Braun and Clarke, 2006) which sits between essentialist and constructionist approaches to thematic analysis. The steps of thematic analysis followed Braun and Clarke's (2006) methodology, consisting of generating initial codes, then searching for, reviewing, and defining themes, based on the coded data.

7.2.6 Sampling Strategy and participant recruitment

Delphi processes rely on careful identification of experts to ensure panel members possess disciplinary, professional, or personal expertise and experience in the topic area, are capable of contributing helpful insights, yet willing and able to revise their initial opinion to enable a group consensus (Hsu and Sandford, 2007).

Therefore, experts were invited by the research student to attend, based on their prior contributions to the thesis, or because they possessed expertise in discussing suicidality in primary care consultations. This included GPs drawn from the qualitative interview study (chapter 5) and patients who were part of the embedded consultation and lived experience advisory groups (Chapter 6). In addition, clinical and academic subject experts in suicidality and representatives of key primary care, healthcare leadership, commissioning and suicide prevention stakeholder organisations were also purposively invited to participate. A purposive convenience sampling approach was used.

7.2.6.1 Consent Process

Participants included GPs or patients who had previously provided formal consent to the research student to take part in the study. Additional clinical or academic subject experts choosing to attend the workshops provided implied consent through their participation in the workshops. Participants present also provided their verbal consent to participate prior to each workshops commencing.

7.2.6.2 Sample Characteristics (expert panel formation)

35 experts in suicidality prevention, primary care delivery, lived experience of service-use, leadership, or commissioning were invited to participate. The sampling approach yielded 16 participants, an acceptance rate of 45.71%. Participant characteristics across the co-production study are described in Table 7.1 (below)

Table 7-1: Co-production - participant characteristics

Characteristic	*Round 1 n=8*	*Round 2 n= 6*	*Implementation Workshop n= 11*
Gender			
Female	4 (50.00%)	5 (83.33%)	4 (36.36%)
Male	4 (50.00%)	1 (16.7%)	7 (63.64%)
Role / expertise			
Nurse Consultant	1 (12.50%)	0 (0%)	0 (0%)
Consultant Psychiatrist	1 (12.50%)	1 (16.7%)	1 (9.09%)
Suicidologist	1 (12.50%)	0 (0%)	1 (9.09%)
Lived Experience advisor	3 (37.50%)	2 (33.3%)	3 (27.27%)
GP / GP trainer / RCGP representatives	0 (0%)	3 (50.0%)	4 (36.36%)
Suicide Prevention worker	1 (12.50%)	0 (0%)	1 (9.09%)
CRHT Commissioner	1 (12.50%)	0 (0%)	1 (9.09%)

7.2.7 Ethical and Research governance approvals

As per the previous empirical studies within the thesis, the University of Nottingham undertook the role of the research sponsor (Protocol Reference 17053, Appendix A). Ethical and research governance approvals for the study were obtained prior to data collection from the Nottingham 1 NHS Research Ethics Committee, and the Health Research Authority, (REC reference: 17/EM/0317 Appendix B-C).

7.3 Findings

This section reports the findings from the modified Delphi consensus study and the implementation focused workshop.

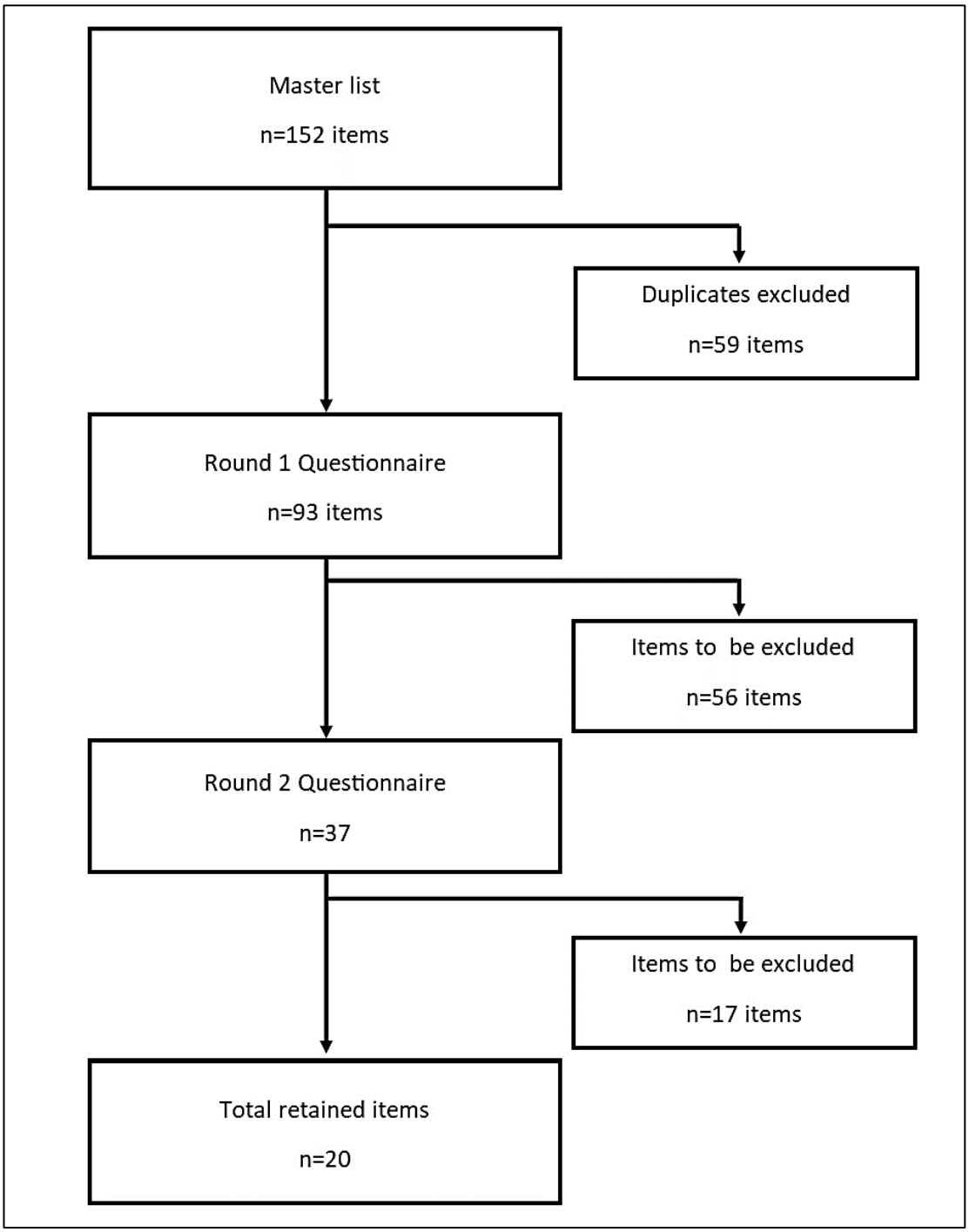
7.3.1 Phase 1: Modified Delphi findings

Eight experts took part in round one, 6 in round two, and 11 in the workshop. Only 2 attendees from the first Delphi round were able to participate in the second round. This could potentially pose problems for a traditional Delphi process, where the expectation is that all participants take part in each round. However, the use of the CVI method means that consensus scores could be obtained from all participating experts (n=14). Scores were then calculated across both rounds of the modified Delphi.

7.3.1.1 Consensus scores

Prior to the first Delphi round, the master list of 152 items was reduced (Appendix J) to 93 items by removing duplicated items, or items with very close iterations. The ensuing Delphi rounds then removed items scoring a I-CVI less than 0.7. The first round removed 56 items, the second round a further 17, as per Figure 7-1.

Figure 7-1: Flow chart of included items



After two Delphi rounds, a shortlist of 20 items was retained. These included items yielded I-CVI values ranging from 0.71 to 0.93, and median scores ranged from 3 to 4. (Table 7-2)

Table 7-2: Shortlist of reatained items (n=20)

Item	Wording	Count rating 3	Count rating 4	Median rating	I-CVI
2	Has anything especially stressful happened to you recently?	3	8	4	0.79
4	Are you aware of anything that might be contributing to how you are feeling?	3	8	4	0.79
5	Have you started finished or changed medication recently?	2	8	4	0.71
7	Have you suffered a significant loss?	4	7	3.5	0.79
11	Have you thought about ending your life? If so, please tell me about what you have been thinking	2	9	4	0.79
22	Are you finding it hard to carry on living?	2	9	4	0.79
26	Have you made any plans to end your life? Please tell me more about your plans	0	13	4	0.93
30	Would you carry out these plans?	4	6	3	0.71
33	Are you worried that you might do this in the next few hours / days / weeks?	2	9	4	0.79
39	Have you done anything to prepare for ending your life? E.g. writing a will, or suicide note	3	9	4	0.86
45	Do you want to die, or are you finding it really difficult to go on living at the moment?	3	10	4	0.93
46	Have you thought you would be better off dead or wished you were dead?	3	7	3.5	0.71
59	In the past when you've had these thoughts, or felt like this, what happened?	6	5	3	0.79
64	How do you see the future?	4	6	3	0.71
79	What prevents you from killing yourself?	5	7	3.5	0.86
80	What matters most to you in life?	3	7	3.5	0.71
87	How safe do you feel? Can you keep yourself safe when you leave here?	2	9	4	0.79
88	When you are feeling low how do you cope?	4	7	3.5	0.79
91	What are you going to do when you leave this room?", "Can I see you again tomorrow/three days' time/a week"	3	9	4	0.86

This shortlist of 20 items was discussed at the end of the second round. After application of the pre-determined threshold for consensus of an I-CVI rating of 0.75, 14 items remained, covering a range of suicidality constructs (Table 7-3).

Table 7-3: Revised shortlist of retained items (n=14)

Item	Wording	I-CVI	Suicidality Construct
2	Has anything especially stressful happened to you recently?	0.79	Precipitating factors
4	Are you aware of anything that might be contributing to how you are feeling?	0.79	Precipitating factors
7	Have you suffered a significant loss?	0.79	Precipitating factors
11	Have you thought about ending your life? If so, please tell me about what you have been thinking	0.79	Ideation
22	Are you finding it hard to carry on living?	0.79	Intent
26	Have you made any plans to end your life? Please tell me more about your plans	0.93	Plans
33	Are you worried that you might do this in the next few hours / days / weeks?	0.79	Urgency of risk
39	Have you done anything to prepare for ending your life? E.g. writing a will, or suicide note	0.86	Preparations
45	Do you want to die, or are you finding it really difficult to go on living at the moment?	0.93	Intent
59	In the past when you've had these thoughts, or felt like this, what happened?	0.79	Coping strategies
79	What prevents you from killing yourself?	0.86	Reasons for living
87	How safe do you feel? Can you keep yourself safe when you leave here?	0.79	Urgency of risk
88	When you are feeling low how do you cope?	0.79	Coping strategies
91	What are you going to do when you leave this room?", "Can I see you again tomorrow/three days' time/a week"	0.86	Urgency of risk

In summary, the modified Delphi process and use of the CVI scale, enabled group consensus to emerge, in relation to preferred items or prompts for inclusion in the CDSS. The items retained are questions, or prompts which GPs could ask of patients during a consultation or when using the CDSS. The retained items achieved acceptable

consensus across an expert panel comprised of academics, clinicians, GPs, topic specific experts, people in healthcare leadership and people with lived experience of consulting GPs in relation to suicidality.

7.3.2 Phase 2: CDSS content refining and implementation workshop findings

This section presents findings from the implementation-oriented workshop, with the research student's narrative of the content supported by field notes recorded during the workshop.

Eleven participants were present and provided perspectives on refining the CDSS content prior to prototype development; and the pathway towards implementation of the CDSS, anticipated barriers or facilitators, and potentially relevant generative mechanisms. Essentialist coding was applied to participants' statements.

Theory led coding and data analysis in accordance with contextualist thematic analysis (Braun and Clarke, 2006) enabled the identification of 3 overarching themes: i) Shaping CDSS content for primary care; ii) barriers and facilitators to using the CDSS; and iii) contextual generative mechanisms. The thematic framework is presented below (Table 7-4)

Table 7-4: Thematic framework

Overarching Theme	**Shaping CDSS content for primary care**	**Barriers and facilitators to using the CDSS**	**Contextual generative mechanisms**
Sub-themes	Alerts and trigger-codes for launching the CDSS	Recognising patient's clues	Discontinuity of care and time-pressures
	The gateway prompt question for GPs	GPs' skills in working with suicidality	The impact of health-care rationing
	Finalising prompts and items	Ease of use of CDSS within consultation	De-stigmatising suicidality

	Referral decisions, clinical management and defining urgency of support needs	Integration within clinical IT systems	Medicolegal considerations
	Using the CDSS to create a safety plan	GPs' awareness of the CDSS	

7.3.2.1 Theme 1: Shaping CDSS content for primary care.

This theme captured concrete suggestions and iterative recommendations relating to the content, format and use of the CDSS, and included how and when to trigger the CDSS, specific suggestions for items and prompts, defining clinical care-planning recommendations, and creating a safety plan using the CDSS.

7.3.2.1.1 Alerts and Trigger-codes for launching the CDSS

Expert panel members discussed the crucial issue of how and when the CDSS might be activated; and suggested both manual activation, and keyword or Read-code activation was useful. However, experts also reiterated caution about CDSS systems causing alert-fatigue, and stated that for the CDSS to retain validity with GPs, the issue of when the tool is triggered, and for which individual patients or patient groups, is a key factor likely to influence its use.

GPs taking part commented on their experience of CDSS 'alert fatigue':

> *"We get so many of them popping up, this needs to flag for who it really needs to, but not for others, or it will stop being used, and that is really a challenge…"* (Paraphrased field note - GP)

Another GP embellished that a CDSS triggering too often, or for too wide a range of patients, could negatively influence their use of the CDSS:

> "*The sepsis one,… it triggers all the time at the start of a consultation, and that's probably important, but half the time*

we just close it down, if there is no sign or symptom relevant" (Paraphrased field note - GP)

Therefore, the issue of how and when an alert to consider using the CDSS might be triggered is important. When asked for which clinical presentations, or for which patients the system should prompt GPs to use the CDSS, a range of clinical characteristics (Table 7.5) were suggested, in keeping with recent evidence (The National Confidential Inquiry into Suicide and Homicide by People with Mental Illness, 2016; The National Confidential Inquiry into Suicide and Homicide by People with Mental Illness, 2017; The National Confidential Inquiry into Suicide and Safety in Mental Health, 2019).

Patients presenting with identified clinical problems, could trigger a prompt for the GP to run the CDSS when specific keywords are entered into a current consultation, or by Read coded data in patients' records.

Whilst panel-members were in broad agreement regarding suggested presentations which could trigger use of the CDSS, it was noted significant challenges remain between discriminating what might be clinically coded in patients EHRs, versus what might only be entered in free-text narrative.

"*The trouble is, a lot of that information, a lot of key things, are not coded"* (Paraphrased field note - GP)

This discrepancy could confound targeted triggering, yet how and when the CDSS prompt triggered appears to be a key factor in reducing GP alert-fatigue.

In response to these problems, panel-members suggested presentations, which they considered necessary to trigger the prompt to run the CDSS (table 7-5, below).

Table 7-5: Suggested presentations triggering the CDSS

Frequent attenders
Any lifetime mental health diagnosis
Recent psychiatric discharge
Current CRHT contact
Long term health conditions
Current or recent ideation, plans, or intent.
Past suicide attempts.
Autistic spectrum disorders, or ADHD diagnosis.
Current or historical alcohol or substance use problems

Whilst the suggested triggering presentations are likely to encompass many people who are not experiencing suicidality, panel members agreed on their clinical relevance, and the potential benefit of alerting GPs to consider using the CDSS when working with such patients.

7.3.2.1.2 The gateway prompt question for GPs

During a patient consultation, where a patient presented with coded data in their record relating to the suggested trigger presentations, the CDSS could automatically prompt GPs to use it, via a pop-up alert. Panel members felt that the most effective form of alert is one which encouraged them to think about the clinical presentation and background of the specific patient. This could be via a 'gateway prompt question', asking GPs to consider assessing patient's possible suicidality using the CDSS.

Panel-members suggested the benefit of the gate-way prompt, was to help highlight that there could be an aspect of suicidality as part of patients' presentation and to help GPs calibrate their clinical-reasoning within the consultation accordingly.

> "*Any use of the tool, is part of a GP consultation, where there will be more information in the situation, so this doesn't want to put GPs off investigating more, but it needs to make them think about suicide*" (Paraphrased field note - GP)

The function of the gate-way question, and its specific wording were important. Some GPs felt a specific benefit of a gateway prompt could be in terms of helping them think carefully about the specific patient in question:

> *"I like the wording, in that Dementia thing we got, it said would you be surprised if this patient develops dementia in the next few years, or we've got another one, where it's getting near end-of-life care and it says, would you be surprised if this patient died within the next year, they can really make you think more"* (Paraphrased field note - GP)

Panel members discussed how such questions may help GPs to think analytically about risk in the context of individual patients, whilst filtering out patients that they thought would be extremely unlikely to be at risk. For GPs, this might be about elaborating intuition or gut-hunches and switching from quick cognition to more analytical modes of patient consultation.

> "*Sometimes you have a gut-hunch, but it might not be well defined in your mind, you might need a minute to think, hang-on is this patient at risk?"* (Paraphrased field note – GP)

In essence, a gateway question might allow GPs to engage reconciliation of their analytical thinking, and implicit knowledge, as a form of cognitive balancing. No panel members refuted this suggestion, and so the gateway prompt was endorsed by those present as:

> *"Would you be surprised if this person attempted suicide in the near future?"*

A response of 'Yes' would lead to no further action, whereas 'No' would lead to a second prompt asking.

> "*Do you want to run the GPS3 protocol?*"

The PRIMIS expert advised wording could be relatively easily changed in the future, if required; and the experts present concurred that the prompt seemed appropriately worded to help GPs begin to calibrate their thinking about patient risk.

7.3.2.1.3 Finalising prompts and items

A key aim of the workshop was to refine the content, format, and wording of items within the CDSS. Panel members were presented with the list of 14 items produced by the modified Delphi process (Table 7-3), and items' I-CVI scores for review. It was noted that all 14 items appeared to cluster around a small number of suicidality constructs, namely ideation plans, intent, preparations, access to means and urgency of risk. Where items appeared to duplicate suicidality constructs, panel members were asked to specify their preferred item, resulting in the following final list of 8 retained items, (Table 7-6, below)

Table 7-6: Final shortlist of retained items (n=8)

Item	Wording	Source	I-CVI	Suicidality construct
2	Has anything especially stressful happened to you recently?	Patient advisory group	0.79	Precipitant factors
11	Have you thought about ending your life? Please tell me about what you have been thinking.	Morriss et al	0.79	ideation
22	Are you finding it hard to carry on living?	Patient advisory group	0.79	intent
26	Have you made any plans to end your life? Please tell me more about your plans.	Morriss et al	0.93	plans
33	Are you worried that you might do this in the next few hours / days / weeks?	GP interview	0.79	Urgency of risk
39	Have you done anything to prepare for ending your life?	GP interview	0.86	preparations

45	Do you want to die, or are you finding it really hard to go on living at the moment?	GP interview	0.93	intent
87	How safe do you feel? Can you keep yourself safe when you leave here?	Patient advisory group	0.79	Urgency of risk

The content validity index for the whole range of items included in the final model (S-CVI/Ave) was 0.83, (6.67÷ 8) indicating acceptable consensus of the overall content of retained items. Together with the I-CVI ratings for each individual item, consensus was therefore reached for both individual items and overall content, conferring face and content validity.

The 8 items, covering constructs related to ideation, plans, intent, access to means, and safety planning were thus endorsed for use in the CDSS. However, panel members suggested 8 items in the CDSS was too many to be used during suicidality consultations, and the list was refined further.

Item 2 was discarded (*Has anything especially stressful happened to you recently*?), as between contextual information in the EHR, and emergent information in the consultation, GPs present felt they would be able to encourage patients to disclose this information.

Item 22 (*Are you finding it hard to carry on living?*) was also discarded, as experts noted the similarity in wording and underlying construct behind that item and item 45.

Similarly, item 39 was removed (*Have you done anything to prepare for ending your life?*) as panel members suggested in their opinion, similar information might be elicited in item 26. Moreover, experts suggested that preparations are not always relevant to impulsive suicidality, but attempting to gauge patient's perspective on their sense of risk immediacy might be useful.

Items 87 and 33 prompted discussion amongst panel members. Whilst both questions addressed urgency of risk, these items were considered important, as potentially helping patients to articulate

their view of the urgency of risk to self, enabling GPs to safety plan with their patients in attempt to reduce the urgency of risk.

Therefore, the final 5 items suggested for retention were as Table 7-7.

Table 7-7: Final retained items (n=5)

Item	Wording	I-CVI	Suicidality construct
11	Have you thought about ending your life? Please tell me about what you have been thinking	0.79	Ideation
26	Have you made any plans to end your life? Please tell me more about your plans	0.93	Plans
45	Do you want to die, or are you finding it really hard to go on living at the moment?	0.93	Intent
87	How safe do you feel? Can you keep yourself safe when you leave here?	0.79	Urgency of risk
33	Are you worried that you might do this in the next few hours / days / weeks?	0.79	Urgency of risk

This final proposed model therefore contained discrete items in relation to suicidality ideation, plans, intent, and items regarding patient safety in terms of proximal risk and perceived urgency of risk. The content validity of the final 5 items (S-CVI/Ave; 4.23÷5) was 0.85 conferring face and content validity.

7.3.2.1.4 Referral decisions, clinical management and defining urgency of support needs.

Panel members felt that optimising content of the CDSS to help GPs consider when onward referral might be indicated was a key consideration. The issue of whether specific questions were needed to assist referral to secondary care was discussed. GPs felt that the CDSS needed to prompt certain specific questions to be able to have information required for secondary-care referral, including information about patient's suicidality ideation, plans and

preparations. However, in contrast, a panel-member working in secondary-care suggested:

> "*There aren't a few key questions that we need, because we will need lots more information in any case, for example we would need to find out from the patient why maybe their protective factors were failing them now*" (Paraphrased field note - Psychiatrist)

When considering accepting a referral, secondary services might therefore require additional information, beyond patients responses to items in the CDSS. However, it was commented that there are certain specific information CRHT's are likely to need:

> "*The CRHT does need specific contextual information, so the CDSS does need to have information in it that they might want to know*" (Paraphrased field note - Suicidologist)

The specific information required for referral to CRHTs included information in relation to ideation, plans, intent, access to means, and mitigating factors; thus the items retained for use in the CDSS were endorsed as helping to inform referral decisions. Whilst there was not a magic formula of specific questions that would unlock access to secondary services, panel members suggested the CDSS could provide helpful parameters to guide GPs' referral conversations with secondary care colleagues:

> "*This will help to frame a referral discussion, about what they [the CRHT] need to know and what we've been able to get within the consultation*" (Paraphrased field note -GP)

The refined content of the CDSS was thus considered helpful to GPs to work out with their patients, a level risk which could be managed in primary care; and when necessary, to inform and guide referral decisions to secondary services such as CRHTs.

Whilst the refined CDSS content could help GPs decide when onward referral was necessary, panel members felt that it was important that

the CDSS provide some assistance with defining the urgency with which referral might be indicated and suggesting other clinical management actions which GPs could take.

However, panel-members cautioned against replicating the fallacy of stratifying risk assessment into high or low risk:

> "*I can see GP colleagues would like a risk score and risk threshold, but that's a red herring, what's more useful is trying to get a sense of what needs to be done, now and how soon, alongside trying to instil a degree of hope"* (Paraphrased field note - GP)

Instead of attempting to stratify risk into no risk, low risk or high risk, panel members suggested that the CDSS encouraged GPs to consider the urgency of risk, with suggested actions:

> *"I don't think stratifying into high or low risk is necessarily useful, but thinking about how urgently this person might need some support might be, but then you also need to think about what action matches the perceived urgency*" (Paraphrased field note - Suicidologist)

A spectrum of urgency of need was suggested from low to high, with attendant actions proposed (Table 7-8).

Table 7-8: Urgency of support needs and suggested clinical management

Perceived urgency of support needs	Suggested clinical management actions
Low urgency	• Complete a safety plan • GP follow up in the week or two • Consider referral to psychological therapy • Review medication • Signpost or refer to self-help organisations

Medium urgency	• Complete a safety plan • GP follow up in next few days • Consider secondary care mental health referral • Signpost to suicide prevention resources • Consider referral to third sector suicide prevention organisations
High urgency	• Complete a safety plan • Ensure patient's immediate safety. • Consider an emergency mental health act assessment • Consider urgent referral to A&E or recognised other place of safety • Ask patients permission to urgently involve a safety companion to come and be with them (e.g. to meet the patient at the GP practice or accompany the patient if going to A&E)

The CDSS could therefore help patients and GPs to discuss relative urgency of support needs, and present specific clinical management options tailored to the perceived urgency of need. Such an approach was considered clinically helpful and appropriate to facilitate person-centred care and enhancing patient safety.

7.3.2.1.5 Using the CDSS to create a safety-plan

The use of the CDSS to assess risk and identify positive coping strategies or ways of reducing risk had been recurring concepts across GP interviews (chapter 5) and patient advisory groups (chapter 6). Specifically, it was suggested a function of the CDSS could be to help patients think about existing coping skills, and to help GPs think about safety-netting and collaboratively working with patients to create a suicidality safety-plan.

When discussing the wording of items in the safety plan, a panel member drawn from the patient advisory groups commented:

> "*Too often safety-plans are impersonal, its like, no offence, it has been written by a GP or a mental health worker without*

actually thinking about the person in question" (Paraphrased field note – patient advisor)

To improve the personalised nature of the safety plan, panel members reiterated that items in the safety plan needed to be worded in a clear and unambiguous way, phrased in the first person, and intended to help people remember they have some choice over their immediate action, bolstering their sense of agency:

"*The key thing is, that it would be giving me a sense that something is being done to help me, whether that's getting help from a service, or reminding me of ways that I might be able to help myself*" (Paraphrased field note – patient advisor)

A range of suggestions had been provided by the patient advisory group prior to the workshop as to questions or items which might be most helpful to include in a safety plan. Suggested items included "what stopped me acting on these thoughts or feelings before", "How can I keep myself self-safe", "who can help me to feel safer", "what do I need to change to feel safer", "what helps me when I feel like this" and "how can I stay safe for the next few days".

These suggested items were discussed amongst the expert panel and refined, with minor adjustments made to phrasing and to more closely align items in the safety-plan with corresponding items in the CDSS. This resulted in 6 safety plan items being retained (table 7-9)

Table 7-9: Safety plan items (n=6)

Safety plan item	Corresponding CDSS item
What helps me when I have thoughts about suicidality?	11
What might help me not to act on these thoughts?	26
What really matters to me and what might help me to go on living at the moment	45
What or who might help me to feel safer in the short-term?	87
What do I need to change to feel safer?	

What might help me to look after myself for the next few days?	33

The potential utility of the safety plan was discussed, and felt to be a valuable additional feature of the CDSS, particularly if the safety-plan could be printed off or sent electronically to the patient and any services that had been referred to:

> "*If we can fill that out, print it off, and give it to people to take away with them that would be helpful*" (Paraphrased field note - GP).

Further additional value of the safety-plan component of the CDSS could be adding more personalised information to the care-record:

> "*If it can record that person's previous answers, in a way that can be easily retrieved outside of clinical coding searches, that could be useful*" (Paraphrased field note - psychiatrist).

Therefore, the safety plan function of the CDSS could assist with both current and future care-planning, by recording patient's personalised coping-strategy information in the EHR, which could be easily retrieved when needed, or reviewed, amended and updated.

From a patient's perspective, the retention of personally specific coping information in the safety-plan could be experienced as big step towards improving personalised care:

> "*If it retained that sort of information, that would be huge. As it is my GP doesn't know me, and doesn't know what helps me when I'm distressed*" (Paraphrased field note – patient advisor)

In summary, the CDSS could possess value in assessing risk and helping to identify, define and record personalised coping strategies, within a suicidality specific safety plan. Such data could be useful for patients and GPs with regard to current, or possible future episodes of suicidality, whilst amounting to improved personalisation of care

7.3.2.2 Theme 2: Barriers and facilitators to using the CDSS

This theme captured additional information in relation to barriers and facilitators influencing GPs' potential use and adoption of the CDSS in practice. Categories within this theme included the necessity of GPs recognising patients' clues about suicidality, GP skills in working with suicidality, the ease of use of the CDSS within consultation, its integration with existing EHR systems, and GP awareness of the CDSS' existence.

7.3.2.2.1 Recognising patients' clues

The complexity of a primary care suicidality consultation was discussed by panel members. One GP raised the challenge of trying to discern who might experience suicidality, and who might be at risk of more serious suicidality:

> "*The trouble we have is separating those who are truly suicidal and those are who fed, up or struggling and just need to off-load a bit … sometimes we need patients to give us a bit of a clue*" (Paraphrased field note - GP)

Participants from the patient advisory group reiterated that sometimes they could not easily express suicidality, and so conveying information relating to severity of suicidality thoughts or behaviour was difficult. However, the CDSS was considered to have value in the sense of potentially helping to orient GPs towards prospective suicidality, particularly if alerting them to clinical presentations they might not have previously associated with suicidality:

> "*Long term conditions for example, we're miles from that, we are thinking about how to cure, or how to reduce symptoms of the illness, were not usually thinking about suicide with those patients*" (Paraphrased field note - GP)

GPs' own mental-models, or heuristics, about which patients might experience suicidality could therefore exert influence over their clinical reasoning, potentially influencing GPs' ability to pick up on

information patients could share, or clues, about experiences of suicidality.

The combination of purposive manual activation of the tool, and the use of the alerts triggered by keyword entry, or Read codes in the EHR, was considered the most helpful solution to help GPs recognise patient's clues about suicidality and to calibrate their clinical reasoning towards possible suicidality.

7.3.2.2.2 GPs skills in working with suicidality.

Panel members accepted that among the GP workforce, there was likely variation in GPs' skills and comfort in working with suicidality. Despite the attention paid to the wording of prompts and items within the CDSS (section 7.3.2.1.3), panel members felt strongly that whilst precise wording, was important, the specifics of which words were used was secondary to how questions about suicidality were asked

> "*All the attention to wording doesn't really matter, if the GP isn't asking this from a place of genuine care and concern and taking note of nonverbal messages*" (Paraphrased field note - Psychiatrist)

Therefore, the way in which the CDSS could be used by GPs, could reflect GP's attitudes towards working with patient suicidality, as well as their clinical and inter-personal clinical skills. To help GPs with the task of working with suicidality and use of the CDSS panel-members suggested training GPs might be useful:

> "*I think this will need some sort of training, you could use the tool anyway, but to best use it, some training on how to incorporate it into a consultation might be needed*" (Paraphrased field note - Suicidologist)

GPs felt that the training package could include GPs and patients experiences of using the CDSS.

"*If you had training which highlighted GPs who have had positive experiences of using the CDSS could help. And if that had patient testimony too*" (paraphrased field note – GP)

However, there are known problems with engaging GPs in suicidality training, and potentially limited benefits in terms of reducing patient suicidality. Therefore, whilst suicidality training might be beneficial, it was arguably more important to focus on the ease of use of the CDSS.

7.3.2.2.3 Ease of use within consultation

Panel members re-iterated themes noted within the GP interviews (chapter 5), regarding the need for minimal data entry, and a CDSS which was quick and easy to use:

"*What you don't want is the GP with their head in the computer the whole time*" (Paraphrased field note – GP)

A GP present elaborated further:

"*In a consultation like this, you have to be there with the patient, emotionally and physically, you can't be on the computer for long, in fact might be better if not at all until the patient has left*" (Paraphrased field note –GP)

This comment reflected the need for the CDSS to be able to be used quickly and easily within the consultation, or to be retroactively completed after the consultation was concluded. The CDSS therefore needed to be a flexible tool that was easy to use, in order to maximise its uptake and adoption in practice.

7.3.2.2.4 Integration within clinical IT systems

Related to ease of use, panel-members commented on the necessity of the CDSS being integrated with clinical IT systems:

"*It's got to be in the EHR. We haven't time to log into an external website, and wait for it to load up etc. It's got to be*

there on the system when we need it" (Paraphrased field note – GP).

Furthermore, the potential of the CDSS to help navigate the information technology infrastructure of primary care and secondary care was discussed:

"*It needs to be in, TTP SystmOne so that content can be easily shared across and between services*" (Paraphrased field note - commissioner)

The ability to share content across primary and secondary care could be an important facilitator to using the CDSS. From an IT infrastructure perspective, sharing content maybe challenging, but is possible:

"*F12 in SystmOne lets us do that*" (Paraphrased field note – GP)

The F12 pathfinder facility, is a local pilot within Nottinghamshire to streamline referrals and information sharing between primary and secondary services with regard to specific clinical presentations (eGPlearning, 2018). The F12 pilot may increase in scope over-time, therefore, it is important to design the CDSS to fit with the requirements of primary-care EHRs and anticipated future elaboration of the F12 or similar information pathfinder schemes.

Some panel-members did not know about the F12 pilot development, highlighting that people working in primary care may have variable knowledge and awareness of developments in health information technologies.

7.3.2.2.5 GP awareness of the CDSS

Whilst training GPs on how to use the CDSS in consultations might be helpful, panel-members suggested a larger issue was making GPs aware that the CDSS exists:

"*We've got lots of templates, such as those in F12, but lots of GPs don't even know what's in there, they tend to use a few*

templates and stick to the ones they know" (Paraphrased field note – GP)

To ensure that GPs are aware of the CDSS, particularly with regard to post-prototype implementation, ways to promote awareness of the CDSS amongst the GP workforce were discussed:

"*I think you would need to target educational events such as the PLTs*" (Paraphrased field note -GP)

Protected Learning Time (PLT) events are peer led sessions for continuous professional development and learning, in which GPs working in CCGs can benefit from dedicated learning time away from their routine clinical work.

Panel-members returned to the concept of producing training on using the CDSS within consultation:

"*It would be good to have training at the PLTs, showing how to use the template*" (Paraphrased field note -GP)

To maximise awareness of the CDSS in primary care, it was also suggested that it would be important to incorporate into GPs professional training:

"*An important place to have that training would be part of the speciality training programme*" (Paraphrased field note - GP)

Ensuring future generations of GPs were aware of the CDSS, and how to use it in consultation could lead to the eventual production version of the CDSS being used and implemented.

In summary, this theme reported categories relating to barriers and facilitators of use, and implementation, of the CDSS in routine clinical practice. Training and awareness raising were highlighted, along with properties or characteristics of the CDSS; and how it could support GPs when working with suicidality. However, in addition to these specific barriers and facilitators, additional contextual generative mechanisms were also highlighted and are reported in theme 3.

7.3.2.3 Theme 3: Contextual generative mechanisms

In addition to previously identified barriers and facilitators, panel members were also asked for views regarding potential generative mechanisms relevant to use and implementation of the CDSS. This theory led discussion contextualised and elaborated the prospective mechanisms identified in previous chapters (Chapter 3 literature review and chapter 5 GP interviews). The panel-members contextualised and elaborated the way the mechanisms and the CDSS might interact, and thus the mechanisms are reported here in a process of triangulation to re-emphasise their relevance. Suggested mechanisms possessing potential to influence use and adoption of the CDSS included; problems with continuity of care and time-pressures, difficulties for GPs and patients of talking about suicidality born of healthcare rationing, medicolegal implications of suicidality consultations, and the enduring stigma surrounding suicidality.

7.3.2.3.1 Discontinuity of care and time pressures

Patients and clinician panel-members described the contextual challenges of suicidality prevention in primary-care, with one patient remarking

> "*You never get to see the same GP*" (paraphrased field note – patient advisor)

GPs echoed these problems, stating they would much prefer to offer continuity of care, but this was extremely difficult to within the resource demands in primary-care

> *"We would all love to be able to see our named patients. We used to be able to, and you would really get to know someone and what might be their risk factors, but these days it's so much harder [to do so]*" (paraphrased field note –GP)

Another GP commented, on the challenges of assessing risk within the time-parameters of primary-care.

"*and so you might have someone coming in, who is high risk, and this is the first time you've ever seen them. And you've got 10-minutes*" (paraphrased field note –GP)

The challenge for GPs is clear, particularly if they do not know the patient, and have to rely on quickly reading through the EHR and previous consultation history

"*… you'd want to have read all the notes, and you probably should, but in reality, you sometimes don't have time*" (paraphrased field note –GP)

The experiences of GPs not knowing patients' histories, or circumstances influencing risk tallied with patients on the panel

"*When I go to the GPs, there's an absence of knowing me as the patient, the GP doesn't know what will make me feel more, or less, at risk*" (Paraphrased field note – Patient advisor).

This apparent disconnect between GPs' and patients' desire for continuity of care, and the frequent operational realties, may present challenges for quality of care, and GPs ability to safely manage risk in primary-care. The CDSS was recognised as perhaps being useful in response

"*if it can highlight some of that person's past then it might be useful for the GP, and help the GP know more about that person as an individual*" (Paraphrased field note – Patient advisor)

The CDSS therefore may have helpful features which could mitigate some of the contextual pressures in primary-care, however there appear to be inter-related generative mechanisms, including difficulties for patients, and sometimes GPs, of talking about suicidality

7.3.2.3.2 The impact of healthcare rationing in primary-care

A theme apparent in the data, related to the challenges of patients disclosing suicidality, or GPs keying-in on clues that patients might be able to give them in the time and space available in primary-care. Patient panel-members reiterated comments made in the advisory groups, that sometimes disclosing suicidality is incredibly difficult.

GPs implied their own difficulties with this, as they were trying to help patients to the best of their ability in the time available

> "we have 10 minutes per patient, and of course the reality is many consultations, particularly these type will need longer, but we've got 10 minutes, and when I started we had 5 minutes. 5 minutes per patient, can you imagine…." (Paraphrased field note – GP).

The time-constraints the GP was referring to are set-by the GP contract and QoF, which impose time-pressures, as a direct result of healthcare rationing. The impact of rationing as a contextual generative mechanism is that GPs may be trying to make educated guesses about patient's level of suicidality in response to information disclosed and their own intuitive interpretation of patient's presentation. In order to help short-cut this analytic process of trying to identify potential clues to suicidality, a GP present suggested

> "why don't we have a way that people can let us know more easily about suicide" (Paraphrased field note -GP)

When asked to elaborate, the GP continued

> "Years ago in the practice they used to have all these paper questionnaires behind reception, patients could come in and say I have come in for my appointment, and the receptionist knew what it was about and could give them the right questionnaire before they came in [to the consultation]. I'm not saying we should do that, but we could learn from that.." (Paraphrased field note -GP)

Patient advisors were cautious in this regard, reiterating previously expressed experiences of having to give a reason for the consultation at the time of booking

> "sometimes having to say on the phone, to the receptionist, why you need an appointment is just too hard to say that to a receptionist (Paraphrased field note – Patient advisor)

The panel discussed further and the same GP opined

> "Why can't you have either a paper version of the CDSS questions, or maybe a couple of questions, that patients could come in and ask the receptionist for, so as to shortcut a lot of the difficulty raising suicidality" (Paraphrased field note - GP)

Picking up on the GPs theme of easing the process of letting the practice know the reason for the consultation, and disclosing suicidality in primary care, a patient advisor commented

> " if you could just ask for a GPS3 [name of the CDSS] consultation, you'd be letting the practice know what you needed, but it might be easier than saying the 'suicide' word" (Paraphrased field note – patient advisor)

The CDSS could therefore have important potential to help navigate some of the practical challenges of patients disclosing and GPs asking about suicidality, within the time constraints. The time constraints in primary care are consequent of healthcare rationing, which appears an important generative mechanism influencing talking about suicidality in consultation. However other inter-dependent generative mechanisms likely interact, including stigma of suicidality.

7.3.2.3.3 De-stigmatising suicidality

Panel-members referred to the special stigma attached to suicidality, with some patients not even able to share experiences of suicidality with their significant others.

"*Its just such a stigmatised experience*" (Paraphrased field note – GP)

Another GP picked up this theme,

"*We have public health campaigns for all sort of things, you know get a vaccination, or if you have blood in your stool… go and see your GP. Why isn't there anything like that for suicide?"* (Paraphrased field note - GP)

A public health campaign might serve to destigmatise and normalise suicidality, potentially making it easier for people to disclose suicidality to GPs. Panel members therefore implied that awareness of GPs abilities to work with, and willingness to support patients experiencing suicidality could be improved. The contribution of the CDSS in this regard was not explicitly named, but it could have important indirect contributions to destigmatising suicidality by easing the process of booking-appointments and letting GPs know the purpose for the consultation, and supporting GPs to more routinely assess, and record information about suicidality in patient's notes.

However, whilst de-stigmatising suicidality could help patients present for appointments, medico-legal considerations appear an alternative generative mechanism which could encourage, or dissuade GPs use of the CDSS.

7.3.2.3.4 Medicolegal considerations

The relationship between the CDSS and litigious culture was touched upon by panel-members when discussing medicolegal considerations potentially influencing GPs use of the CDSS:

"*if you can show GPs that the CDSS helps indemnify GPs, that would be important and if it recorded something about the content and outcome in the notes showing what you've done*" (Paraphrased field note - GP)

The CDSS therefore could have important role in promoting accountability and quality of care, whilst documenting content and

outcomes of consultations. Other GPs were much more cautious about the medico-legal implications of the CDSS

> "*What if it says refer do xyz and you don't, because you know this patient doesn't need that, but something else happens, and they attempt suicide, you will be in serious trouble. But you know sometimes we have to over-ride these tools, like the sepsis one, that's always flagging patients and sometimes you ignore it because you know for that patient it is wrong*"
> (Paraphrased field note - GP)

The GP was referring to manually over-riding care-planning recommendations suggested by the CDSS, and implying that divergence from suggested clinical management actions could expose GPs to medico-legal risk.

The implicit relationship between the CDSS, the increasingly litigious nature of society, and the culture of blame and accountability seems apparent in this exchange. The use of the CDSS therefore could be influenced by medicolegal considerations as underlying generative mechanisms influencing GPs practice.

In summation, this theme has reported contextual generative mechanisms identifiable in the primary-care context. These generative mechanisms could encourage or dissuade GPs from using the CDSS and influence its adoption, or rejection within primary care. The next section discusses these findings and implications.

7.4 Discussion and implications

This chapter reported findings of 3 stakeholder consensus workshops featuring an expert panel comprised of patients, GPs, topic-specific experts, GP leaders and healthcare commissioners. The workshops utilised a modified Delphi process to achieve consensus on CDSS content; and a theory led qualitative approach to then refine CDSS content and explore generative mechanisms relevant to its use and implementation.

7.4.1 Implications for CDSS development

The stakeholder consensus process in this study highlighted that triangulation of expertise from patients, GPs, and other relevant stakeholders including GP leaders and commissioners, is possible. The study shows use of the CVI can be incorporated into a modified Delphi expert consensus approach to agree CDSS content. The use of a theory-led qualitative approach was advantageous to refine CDSS content, and highlight generative mechanisms potentially influencing its use and implementation. The study highlighted generative mechanisms which can possess a dynamic characteristic impacting across multiple domains of established implementation taxonomies, such as the CFIR (Damschroder et al., 2009). For example, healthcare rationing, can be seen as a generative mechanism in the outer-setting (the economic, social and political contexts), yet simultaneously may exert influence over the inner-setting (internal structural contexts in primary-care), shaping the characteristics of the intervention (brevity of data capture to fit with limited duration of GP consultations) and influencing GPs agency to determine whether or not to use the CDSS. The theory-led, CR informed approach in this study has therefore complemented the explanatory models underpinning this thesis (CFIR, Damschroder et al., 2009, ACiPC, Lau et al., 2016, and QIC, Batalden & Davidoff, 2007) to add theoretical depth to the study.

Healthcare rationing, is a social structure, arguably reflecting the marketised and capitalist nature of society which underpins public healthcare provision. In capitalist societies, public health services provide interventions aimed at restoring normative patterns of neoliberal functioning, to enable patients to resume their place as productive contributors to the economy (Esposito and Perez, 2014). Therefore, rationing is related to neoliberal marketisation of health, whilst suicidality may reflect demands placed on the individual by the marketised society, to be productive and high achieving individuals (Kokaliari and Berzoff, 2008). This complexity, of rationing and

societal expectation, is part of the system-world concerns, whereas the private experiences of suicidality, may reflect the impact of the systemsworld on the lifeworld of patients. The primary care consultation can be the meeting points of these concepts (Greenhalgh, 2014), and suicidality consultations may be imbued with a resonance of this complexity. Therefore, understanding the dynamism of contextual generative mechanisms is important, and a CR informed perspective highlights the limitations of attempting to confine mechanisms to constructed theoretical boundaries (such as the outer setting in the CFIR). To do so runs the risk of epistemic-fallacy, or confusing transitive knowledge with intransitive reality.

The implication of this, is that CR appears to be an appropriate meta-theoretical perspective to inform CDSS development and which can enhance theoretical depth of implementation research, by uncovering and highlighting complex generative mechanisms, which may be activated across multiple domains of existing implementation theory. A more detailed understanding of generative mechanisms occurring in context, and across the structure-agency divide may have important benefits in tailoring CDSS development to the demands of the intended end-users in primary care.

7.4.2 Implications for suicidality prevention in primary care

The study has highlighted implications for suicidality prevention in primary care. The challenge of identifying, assessing and providing care for people at risk of suicidality in primary care was clearly articulated in the co-production study. The need to balance clinical risk assessment with attending to patient experience was apparent. GPs described that when working with suicidality they are faced with the unenviable task of therapeutically engaging people in distress, trying to contain and reduce risk, whilst at the same time making decisions about risk thresholds and referral to other services, or starting or reviewing clinical interventions such as medication. This tension between being engaged with the lived experience of patients,

and yet trying to evaluate risk in a detached professional manner was once again present. GPs and people with lived experience also described the complexities accessing primary care in response to suicidality, and voicing suicidality in consultations. The ability to request a consultation featuring the CDSS, could usefully short cut this process for both patients, and GPs. However, the way in which suicidality is still comparatively stigmatised, and rarely discussed amongst the populace at large may not help. Such stigmatisation maybe recreated in primary care, where despite initiatives such as zero suicide, there have been no large-scale public health promotions to normalise accessing primary-care for suicidality related concerns. Such a programme could make it easier for people to come into primary care in relation to suicidality, and once they were in the consultation, the CDSS could afford an important and meaningful step towards personalised care and shared decision-making.

7.4.3 Strengths and limitations

7.4.3.1 Strengths

This is the first study to bring together representatives of key-stakeholder groups to triangulate the expertise of panel members and co-produce the CDSS. The combination of a modified Delphi to achieve group-consensus and the CR informed, theory led qualitative workshop approach, amounted to a theoretically grounded intensive mixed-methods study to agree and refine CDSS content.

However, experiences of how equal the power-sharing relationships in the co-production workshops was varied, with one patient advisor commenting afterwards:

> *"You had to express yourself in a way they would listen… you had to use a clinical voice to be taken seriously "* (paraphrased field note – Patient advisor)

In contrast, another member of the patient advisory group commented:

> "*Everyone listened to each other. It felt properly collaborative and the only workshop I've been to where people actually collaborated… but it was good there was space for disagreement, it was ok to disagree. It was good that the finer points were discussed*" (paraphrased field note – Patient advisor)

Indeed, the experience of taking part had been too much for one patient advisor who left one of the Delphi sessions mid-way. Afterwards, the research student contacted her to check if she was ok or needed any support within the remit of the thesis. She commented:

> "*I'm ok, I was furious with the GP who said, 'women just say they are suicidal, but don't actually follow through with it, whereas men just do it'. I was furious because we had people in the room who had been bereaved by a female relative".*
> (paraphrased field note – Patient advisor)

The GP's statement about gendered aspects of suicidality may reflect the extent to which some GPs might rely on heuristics and cognitive shortcuts (system one thinking; Crosskerry, 2003) in their approach to working with suicidality. Whilst there is insufficient data to make confident assertions, it is theoretically possible that the CDSS could potentially help GPs develop more accurate heuristics, or help shift their clinical reasoning approach from quick cognition to analytical thinking.

Despite the variation in how equal the stakeholder consensus process might have been experienced, this study is an important attempt to meaningfully co-produce a suicidality CDSS. There is a dearth of research which reports co-production of CDSS. The current study is novel in this regard and addresses this gap in the literature on CDSS development.

The coproduced suicidality CDSS may afford important benefits to GPs and patients including improving the ease of disclosing or asking about suicidality in time-limited consultations, more consistently recording the content and outcomes of suicidality consultations and supporting personalised care-planning and safety-plan creation. The CDSS therefore could have benefit in improving GPs ability to work with patients experiencing suicidality.

7.4.3.2 Limitations

Limitations of the study concerned the small sample-size of the expert panel. This group of experts, may not represent all views of how a CDSS could best support GPs to work with suicidality. Furthermore, only 2 panel-members were able to take part in both Delphi rounds. Whilst these limitations may raise questions regarding the reliability and validity of the study's findings, the opinions of experts can nevertheless provide important considerations regarding the format, content and use of the CDSS, and prospective generative mechanisms regarding its use. Findings from expert consensus studies are widely used in healthcare, when expert judgement is required where limited prior theory exists to guide clinical practice situations (Fitch et al., 2001). As such, the Delphi method is appropriate to this study. Expert stakeholders provided opinions to agree and refine content, of a theoretically based and co-produced CDSS, to improve suicidality prevention in primary care.

Recruiting and bringing together an expert panel of stakeholders to participate in the co-production study was challenging. The time commitments, clinical and professional obligations may have served as barriers to participation. Furthermore, the prospective challenge of taking part in co-production bringing together clinicians, people with lived experience and commissioners may have served as disincentive to some people who were invited to participate. Nevertheless, a small but highly knowledgeable expert group were recruited to take part, who were able to share their knowledge and nuanced expertise of

primary care commissioning and delivery, suicidality consultations, and CDSS development and use.

The reliability of the Delphi process was arguably compromised by the face-to-face nature of the modified Delphi, and the failure to return any participants from the first to second rounds. Workshops took place within a two-week period, which meant it was difficult for panel members to participate in consecutive workshops. Difficulties attending could have been mitigated by using an on-line format or postal questionnaire. However, the face-to-face and more discursive approach was arguably more useful in allowing participants to provide their intuitive opinion on CDSS content.

Although GP participation in the co-production study was limited, GPs did participate (n=7) and committed a large amount of time to the process. Despite financial back-fill being available to support GP participation in the study, no GPs taking part availed themselves of this resource. This contrasts with previous research (Salmon et al., 2007) which reported difficulties engaging GPs in research without financial incentivisation. The co-production workshops were promoted by the regional branch of the RCGP, and local LMCs, with GPs taking part able to record participation as part of their annual research activity or CPD. This may have been an important incentive aiding participation. Additionally, the workshop format provided ability to network with professional leads, commissioners, and topic experts, and this may have been an important attraction for some participants. Furthermore, being able to contribute to the co-production study and having the chance to shape a prospective CDSS intended to help GPs with a challenging area of clinical practice may have assisted GPs engagement in the study.

7.4.3.3 Implications for further research

There are several important implications for further research.

Firstly, to overcome the limitations of the sample size and composition of the panel, future research could build on this study by recruiting multiple stakeholder panels across geographic locations, comprised of a wider array of stakeholders. Due to advances in video-conferencing software, this could be in an on-line format, as opposed to face to face, potentially reducing barriers to recruitment and participation.

Secondly, it is possible that optimal use of the CDSS may depend on well-developed consultation skills on the part of GPs and familiarity integrating CDSSs into their consultation. Training may beneficially increase GPs' awareness of the CDSS and their confidence in its prospective use. Such training could be co-produced, but this would likely require extensive time commitment from health professionals and people with lived experience.

Thirdly, CDSS systems may possess educational potential in helping GPs develop more precise clinical heuristics, or helping GPs shift their clinical reasoning approach from quick cognition to analytical thinking. The educational benefits, or cognitive forcing functions of CDSS systems is implied in the literature (Greenes et al., 2018; Robson, 2014), but there is a dearth of studies investigating these aspects of CDSS. Future research could usefully explore the contribution of the CDSS in this regard.

Whilst the study highlighted implications for future research, more immediately, the study has led to expert-panel members agreeing on and refining the content of the CDSS, which could be subject to further evaluation.

7.5 Conclusion

This chapter has reported on a stakeholder consensus study of 3 half-day workshops which brough expert panel-members together in a group consensus and CDSS content refining exercise. The modified Delphi process, and theory-led qualitative workshop approach led to experts agreeing upon, elaborating and refining the format, content

and potential use of the CDSS. Use of the CVI and modified Delphi process generated face and content validity. In addition, important generative mechanisms potentially impacting the use and implementation of the CDSS were highlighted. The process of co-production was complex and challenging, but has added significant depth to this thesis, and resulted in a co-produced CDSS. Gaining feedback from GPs on the use of the tool in a real-world context would be important to guide further iterative development of the tool. The following chapter reports the fourth empirical study in this thesis, which sought to develop and evaluate the prototype CDSS within a usability study involving one GP practice in the East Midlands.

Chapter 8: Prototype Build and Usability Testing

8.1 Introduction

This chapter reports an empirical study related to the prototype build and initial usability testing of the suicidality CDSS to support GP clinical decision-making. The prototype was developed through methodological triangulation of findings from previous chapters alongside literature pertaining to CDSS development and usability testing.

Usability testing sought feedback from GPs on the ease of use of the tool, its integration with existing IT systems and practices (workflow) and its overall relevance to suicidality consultations. Overall, this pragmatic application of a mixed-method, intensive design, allowed methodological triangulation and adds to the development of domain-specific theory regarding the use of a suicidality CDSS.

8.2 Method

8.2.1 Setting (identification of a test site)

4 GP practices across the Nottingham city and Nottinghamshire county CCG areas were approached by the research student and invited to participate; 2 declined citing workload concerns, and the remaining 2 expressed interest. However, only 1 practice agreed to host the study and provided formal consent to host usability testing.

This practice was the University of Nottingham health service, within the city CCG. The practice has the largest registered population of any practice in this study's geographic area and higher than average rates of suicidality related risk behaviour, such as self-harm, reported by the practice population. Pragmatic advantages for hosting usability testing in the University health service included a higher likelihood that consultations might involve some aspect of suicidality; and GPs' familiarity and expertise in working with suicidality during patient consultations. At the time of the study, the practice was using the

Egton Medical Information Systems (EMIS web) Electronic Health Record (EHR). Prior to the CDSS being available within the practice, a contractual agreement was signed (Appendix K) by representatives of the university, as study sponsor, and the practice. Thereafter, a short demonstration of the CDSS in use was provided to the practice medical team during a staff meeting, by the research student and a health informatics expert from PRIMIS.

8.2.2 Study design

A mixed methods intensive design (Danermark et al., 2002) was adopted to explore and explain the use of the prototype CDSS with a small number of cases in a specific context (one GP practice).

Usability testing of the prototype took place with reference to an established framework for CDSS development (Kannry et al., 2015), combining actionable decision-support, and usability development and testing consisting of both non live and live usability testing.

Insights from the previous chapters of the thesis were brought together, with the CFIR, ACiPC, and QI as guiding theoretical frameworks (Damschroeder et al., 2009, Lau et al., 2016, Batalden & Davidoff, 2007) in relation to identified generative mechanisms. Together, these theories and mechanisms suggest characteristics of the CDSS which may be key to determining its use including: how the CDSS interacts with GP's autonomy, and whether or not the CDSS can be used within, prior to, or after patient consultation. Additionally, the degree to which the CDSS seems to fit with the primary care context, organisational culture and extant information systems are also highlighted by these underpinning theories as key determinants shaping its use. Furthermore, to possess perceived legitimacy, these underpinning theories highlight that the CDSS should be seen to be in-line with broader suicidality prevention policy and practice frameworks.

In attempt to account for the apparent multi-layered complexity, influencing its prospective use and implementation, the CDSS was conceptualised as a 'knowledge based CDSS' (Berner, 2009).

Knowledge based CDSS are intended to offer expert consultation to clinician's decision-making at the point of use, along with general references to support subject knowledge acquisition, links to key policy papers, and specific clinical management guidance taking account of patient's clinical presentation.

A knowledge based CDSS was thus created and refined through the stakeholder consensus process. A published framework for the development of CDSS (Kannry et al., 2015), was adopted to guide iterative prototype development and usability testing. The framework (Kannry et al., 2015), incorporates sequential rounds of non-live and live usability testing to evaluate the CDSS' ability to provide actionable decision-support. This framework guided iterative development of the CDSS, refined the content of the final prototype CDSS, and enabled assessment of usability and initial evaluation of the CDSS in practice.

8.2.3 The purpose of the method

The methods adopted were designed to explore and explain the use of the prototype CDSS with a small number of cases in a specific context and to provide a framework for an initial evaluation of the CDSS in relation to an established framework for CDSS development. The evaluation of the CDSS included non live and live usability testing.

8.2.4 Methods of data collection

In this mixed methods intensive design, a range of methods of data collection were used in non-live and live usability testing.

8.2.4.1 Non live usability testing data collection

Non-live usability testing examined ease of use of the CDSS (usability and user-interface), integration of the CDSS with existing systems and practices (workflow) and its over-all applicability to suicide consultations (relevance).

Non-Live testing entailed members of the practice medical team completing data entry into a dummy patient record, within the

prototype CDSS, based on 2 clinical vignettes (round 1), and a thinking aloud exercise (round 2) and completing brief evaluative questionnaires. Non-live testing was conducted in the GP's normal consulting room during lunch break between surgeries, or during allotted administration or research time.

In round 2 (think aloud exercise) GPs were asked to think-aloud their response to a third clinical-vignette, regarding their perception of ease of use, and navigability within the CDSS, impact on their thinking style, and their overall satisfaction with CDSS content and interface. Refinements were then built into subsequent usability testing prior to use with patients.

Data was collected by the research student, recording GP's comments and administering specific questionnaires during the non-live usability testing.

8.2.4.1.1 Round 1: Data entry into the dummy CDSS

GPs taking part were asked by the research student to enter data into the CDSS in relation to simulated suicide consultations based on 2 clinical vignettes. The clinical vignettes (appendix L) were previously published as clinician training aids for assessing suicidality risk (Chehil and Kutcher, 2012). Permission was gained from the publisher to use the 8 vignettes, which were adapted to reflect primary care presentations and contexts, rather than psychiatric services. Each GP participating in round 1 completed data-entry in response to 2 vignettes. The specific vignettes were assigned at random using the online random number generator (www.random.org).

The time taken to work through the vignette and the CDSS was recorded by the research student, along with GP's comments and responses on specific questionnaires.

8.2.4.1.2 Round 2: Thinking aloud exercise

Participating GPs were asked to complete a "thinking aloud exercise". The think aloud exercise is a structured process, which can be time consuming since it requires users to explicate the typical tasks they would undertake in response to their interaction with the simulated patient, and the CDSS interface. The principle advantage conferred by the think aloud method is that it can provide detailed data regarding usability problems (Akhloufi et al., 2019). To fit the pragmatic resource requirements of the PhD thesis, and the research student as the single investigator, a simplified thinking aloud procedure (Nielsen, 1994) was adopted. Simplified think aloud involves exposing real end-users of a system to typical tasks they might encounter in naturalistic use of the system. Such techniques are now commonplace in CDSS development and are sometimes referred to as 'cognitive walkthrough' of the system (Fossum et al., 2012; Horsky et al., 2011). GPs were asked to work through the CDSS, with reference to a third vignette, previously unused with that GP. The exercise asked the GP to describe any possible next questions they might ask, or lines of enquiry following on from prompts or items within the CDSS. The research student was present and observing GPs' use of the CDDS, observing usability and recording field notes of GPs verbal comments.

8.2.4.1.3 Questionnaires

A brief, validated questionnaire, the System Usability Scale (Bangor et al., 2008) was used to measure the usability of the prototype tool (Appendix M). Additionally, a non-validated questionnaire adapted from previous work (Gray., 2014) conducted in NIHR CLAHRC North West, provided supplementary information on GPs views of the CDSS' impact on workflow, relevance to consultations where suicidality is discussed; and an indication of how well the CDSS supported GP's clinical decision-making during 'cognitive walkthrough' (Appendix N).

8.2.4.1.4 System Usability Scale (SUS)

The SUS has been extensively used to assess the usability of a wide range of products and services including computer hardware and software applications, mobile devices, and websites (Bangor et al., 2008). The SUS is a validated instrument, which comprises 10 statements rated on a 5-point Likert scale (strongly agree to strongly disagree), used to record respondents' views of the usability of the CDSS. The wording of the original SUS statements were modified by Bangor et al (2008) to increase ease of participant understanding and the modified SUS was used in this thesis.

8.2.4.1.5 Evaluation questionnaire

To supplement the SUS generic focus on usability, and to provide greater insight into details or causes of identified usability problems a short survey questionnaire was also used to assess GPs' views of the overall relevance of the CDSS to consultations in relation to suicidality presentations. The survey questionnaire used a combination of Likert scales and free-text responses. The content of the questionnaire was based on a questionnaire used in the evaluation of a CDSS previously completed by CLAHRC north West (Gray, 2014), and adapted to provide an indication of acceptability of the CDSS to GPs, in relation to clinical appropriateness, contextual appropriateness and quality of actionable decision support. Additionally, clinical outcomes of consultations featuring the CDSS were recorded. These clinical outcomes of interest were identified in the literature review, GP interviews and patient advisory groups, and included clinical referrals and interventions commenced or prescribed.

8.2.4.1.6 Thinking aloud questionnaire

Cognitive walkthrough (Horsky et al., 2011) is commonly used to determine the ease with which the end-user can interact with a CDSS interface. In order to determine how well the CDSS interface

supported GPs decision making with regard to identification, assessment and management of suicidality, GPs completing data entry were asked to 'walk through' predetermined clinical scenarios with regard to a third vignette. A thinking aloud questionnaire was developed (appendix N), adapted from previous work conducted in NIHR CLAHRC North West (Gray., 2014).

8.2.4.1.7 Severity and classification of usability problems

Whilst GPs were completing the thinking aloud questionnaire, a well-known validated severity rating for categorising the severity of usability problems was used to distinguish between cosmetic problems, minor problems, major usability problems and usability catastrophe (Nielsen, 1993). Nielsen's taxonomy (1993), allows identification of the proportion of users experiencing the problem, the severity of the problem and the impact of the problem on the end-user.

In addition, an established classification system for categorising CDSS usability problems was adopted (Richardson et al., 2017). The classification has been previously used to categorise usability problems in CDSS development studies.

GPs' qualitative comments in relation to their experience of interacting with the CDSS were recorded by the research student in brief field notes and analysed in accordance with the classification system.

8.2.4.2 Live usability testing data collection

Live usability testing examined use of the CDSS in live patient consultations. Given the potential for these GP consultations to be intense and cognitively or emotionally demanding for GPs, the research student decided that data collection from the GP needed to be brief and easy to complete.

8.2.4.2.1 Live usability outcomes

GPs were asked to record relevant outcomes on a tally chart (appendix Q) after use of the CDSS and completion of their clinic session in which usability testing was taking place.

Outcomes were adapted from the published framework for developing effective clinical decision support (Kannry et al., 2015) and included: adoption (the extent to which the CDSS is used), acceptance (the extent to which GPs followed recommendations within the CDSS), changes in behaviour (the CDSS impact on the content of the consultation and clinical outcomes (referral and prescription rates).

8.2.5 Methods of data analysis

8.2.5.1 Non live usability testing data analysis

Analysis of Non live usability testing involved the research student calculating GP's responses on the SUS and brief evaluation questionnaire, and recording GP's ratings of the CDSS with regard to clinical and contextual appropriateness, and its ability to provide actionable decision support.

In addition, GPs' qualitative comments were analysed from field notes recorded by the research student during the non-live usability test and free text responses on the cognitive walkthrough and brief evaluation questionnaires.

Measures

8.2.5.1.1 Analysis of the System Usability Scale (SUS)

The SUS comprises 10 statements rated on a 5-point Likert scale (strongly agree to strongly disagree), used to record respondents' views of the usability of the CDSS. Total scores for each GP, and mean average scores across the sample were calculated by the research student. The SUS yields a composite score for overall usability. The formula for calculating individual's SUS scores involves transforming raw scores into scaled scores, then multiplying totals by 2.5 in order to arrive at a total SUS score ranging from 0 to 100

(Brooke, 1996). Published guidance (Bangor et al., 2008) suggests that products with average usability will score 68 and adequate usability is indicated by total SUS score above 70.

8.2.5.1.2 Analysis of the thinking aloud questionnaire

The Thinking aloud questionnaire (appendix N) sought to record GPs views on the CDSS ability to support their clinical reasoning, the ease with which GPs could navigate between different sections of the CDSS, the extent with which GPs experienced the CDSS as integrated with the EHR, and overall ease-of-use, by recording ratings of acceptability on a Likert scale of 0-10. GP's mean average ratings across the sample were calculated by the research student.

8.2.5.1.3 Analysis of severity and classification of usability problems

Nielsen's taxonomy (1993), was used to record the severity of any identified usability problem on a scale of 0 -4 (no problem, cosmetic, minor, major or catastrophic problem).

In addition, the coding framework published by Richardson et al., (2017) was used to classify GP's comments in relation to ease of use, visibility, workflow, content appropriateness, understandability, practical utility, and navigation. These criteria have been established as important to CDSS usability testing (Richardson et al., 2017).

8.2.5.1.4 Analysis of GP's qualitative comments

To supplement the quantitative data (GP's ratings of the CDSS on the SUS and brief evaluation questionnaire, and the categorisation of usability severity), GP's qualitative comments were also analysed.

GPs' qualitative comments were recorded in brief field notes created by the research student during the non-live usability test and free text responses on the cognitive walkthrough and brief evaluation questionnaires. Essentialist coding was applied (comments reflect GP's real perceptions of the CDSS), and thematically categorised according to established CDSS development criteria (Richardson et al., 2017).

8.2.5.2 Live usability testing data analysis

GPs were asked to record relevant outcomes on a tally chart (appendix Q) after live use of the CDSS and completion of their clinic session in which usability testing was taking place. Results were tabulated by the research student who then calculated descriptive statistics using Microsoft excel. GPs were also invited to provide any additional qualitative comments as they returned their tally chart to the research student. Any such verbal comments were recorded by the research student as a brief field note. Results were calculated and recorded in relation to the CDSS measure of success outcomes adapted from Kannry et al., (2015)

Table 8-1: CDSS measures of success (adapted from Kannry et al., 2015)

Measure of Success	Definition
Adoption	How frequently the CDSS is used in suicidality consultations
Acceptance	How often or to what degree practitioners follow recommendations generated by the CDSS
Changes in Behaviour	Changes in the form or process of suicidality consultations
Impact on Clinical Outcomes	Demonstrably significant changes in care, such as referral or prescription rates, imputed to use of the CDSS

8.2.6 Sampling Strategy and participant recruitment

8.2.6.1 Consent process

The University of Nottingham health service had consented to host the usability testing study. This mean that all GPs working within the practice were potentially eligible to participate. All the practice's GPs were invited to take part by the research student.

8.2.6.1.1 Non live usability testing consent process and procedure

GP's willing to take part in non-live testing notified the GP within the practice with the remit as the practice's research lead. The research

lead GP then helped the participating GP to install the template onto the PC in their consulting room and to open the dummy template.

The research student was then invited into the consulting room to observe and facilitate the non live usability test. Non live usability testing took place during GP's lunch break between surgeries, or during GP's allotted administration or research time.

8.2.6.1.2 Live usability testing consent process and procedure

GPs taking part were recruited from the same GP practice hosting non-live testing. All 16 GPs were invited, with 4 GPs providing consent to the research student to take part. Live testing involved in-vivo use of the CDSS by the GP during live consultations with patients. GPs were invited to have potential use of the CDSS during specific clinical sessions (regarded as a 4 hour block of activity, such as a morning surgery), in scheduled clinical consultations with patients.

GPs provided same-day appointments on a shift rota over the range of clinic sessions in which live testing was conducted. This enabled all GPs working in the practice to be potentially eligible to participate. In order to provide a minimally satisfactory initial evaluation of the CDSS in live patient consultations, at least 5 uses of the CDSS were desired. Usability testing with up to 5 users is an established convention in usability testing literature, enabling identification of approximately 85% of usability problems (Nielsen, 2000), and represents the optimal benefit to cost ratio.

In appointments where the GP decided to use the CDSS, the GP retained clinical responsibility for the identification of potential suicidality risk and the content and outcomes of the clinical consultation. Since the purpose of the usability testing was to gauge the usability, impact on GP workflow, and overall relevance of the CDSS, no individual patient identifiable data was captured during the usability testing phase of the study beyond patient consent. Such an

approach to patient recruitment was pragmatic, balancing the impact of the study recruitment on patients and the workflow of the GP practice, along with clinical need, ease of recruitment, ethical considerations and adequate processes for obtaining valid-informed consent.

8.2.6.1.3 Patient eligibility for live testing

Eligible patients were those already registered with the GP practice, aged 14 -15 and accompanied to their consultation by parent or guardian, or aged 16 or older (not requiring accompanying parent or guardian), attending the practice for an appointment during the clinical session in which usability testing was taking place.

Opportunistic sampling was used to recruit patients attending an appointment at the practice during the clinic sessions in which live testing was occurring. At the practice test site, registered patients can request same day appointments stating briefly the reason for the appointment. Where same-day consultations were booked, and the reason for the consultation described as depression, anxiety or otherwise in relation to mental health, patients were approached by a member of the GP practice staff to take part in the study.

Patients providing verbal consent for the research student to discuss the study with them were then provided by the research student with a verbal explanation of the study, a brief information sheet (Appendix O) and invited to participate. Verbal and written consent was taken by the research student. It was made clear during this consent process that any prospective use of the CDSS during the patient's GP appointment would be at GP's clinical discretion. Patients agreeing to participate in the usability testing took their signed consent form into the GP appointment. During the ensuing GP appointment, the GP was then able to decide whether or not to use the CDSS with the individual patient. GPs' choosing to use the CDSS during a live patient consultation were asked to supply their patient with the patient debrief sheet (Appendix P) upon completion of the appointment. The

debrief sheet provided further information about the study, the CDSS and contact details for additional sources of support.

8.2.6.1.4 GP Sample Characteristics

In non-live usability testing, all GPs in the practice taking part (n=16) were invited to take-part, but only 4 consented. Basic demographic data and years of GP professional experience were recorded by the research student. The non-live usability testing sample included a mixture of experience with GP partners and salaried GPs, and male (n=3) and female practitioners (n=1) participating.

In live usability testing, 4 GPs consented and 9 patients consented to take part. The 4 GPs used the CDSS with 7 of the 9 consenting patients. The GP sample included 1 GP who had already used the CDSS during none live testing. The remaining 3 GPs had not used the CDSS prior to their clinic. The sample included 2 partner GPs and 2 salaried GPs, and was evenly split with male (n=2) and female (n=2) GPs participating.

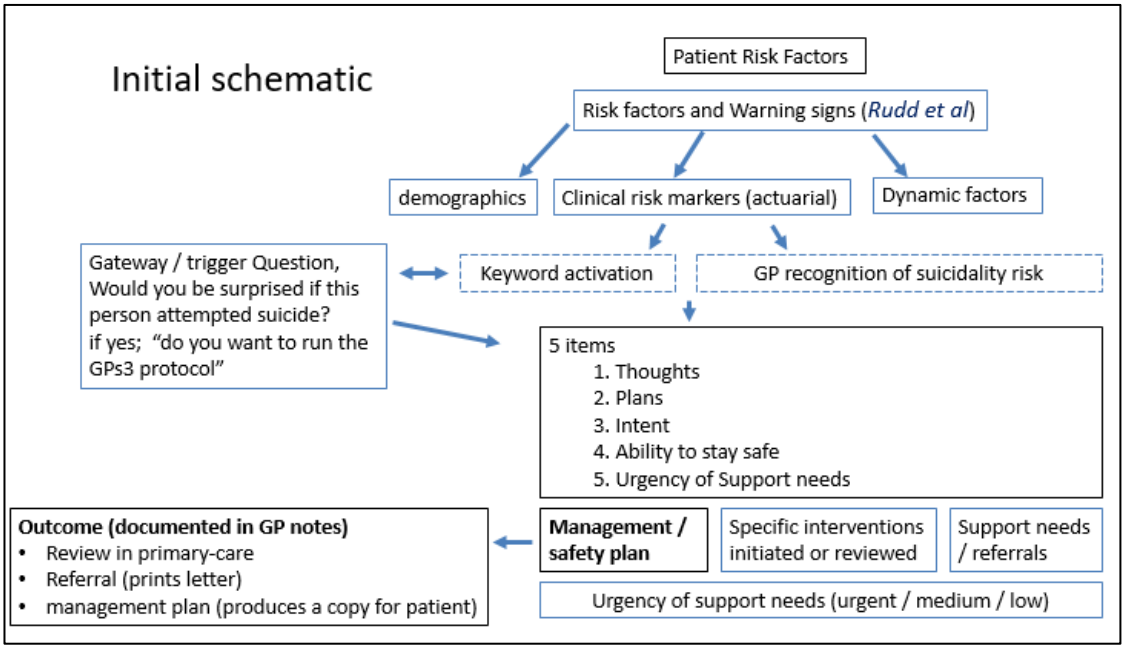
8.2.7 Ethical and Research governance approvals

As per the previous empirical studies within the thesis, the University of Nottingham undertook the role of the research sponsor (Protocol Reference 17053, Appendix A). Ethical and research governance approvals for the study were obtained prior to data collection from the Nottingham 1 NHS Research Ethics Committee, and the Health Research Authority, and local CCG (REC reference: 17/EM/0317 Appendix B-C).

8.3 Prototype Build

The prototype was built, according to the conceptual refinement of the proposed CDSS, emerging from the stakeholder consensus process (chapter 7). The initial schematic of the pre-production prototype is as per figure 8-1 (below)

Figure 8-1: Schematic overview of pre-production prototype



The pre-prototype schematic, refined by the stakeholder consensus study included 5 specific suicidality assessment items, which could be activated by keyword entry into a live consultation within the EHR, or GPs manually opening the CDSS. A gateway question for launching the CDSS could be presented to GPs, when triggered by key-word entry or specific read coded information in relation to patient presentation or history. The CDSS content could be used to help inform GPs clinical decision-making and care-planning. The CDSS could support working with patients to develop a personalised safety-plan, which could printed off for patients or shared with other services as necessary. Finally, the CDSS could document the content and outcome of the consultation in a consistent and systematic way, and record more patient specific information in the EHR, potentially contributing to improved personalisation of care.

PRIMIS, a business unit of the University of Nottingham, were commissioned (with funding obtained from the East Midlands Patient Safety Collaborative by the research student's academic supervisors) to build the prototype CDSS within EMIS web. PRIMIS specialise in primary-care health informatics and designing decision-making support software which extracts, analyses and reviews data from

primary-care patient records. PRIMIS staff are contracted employees within the University of Nottingham, and include current and retired GPs, administrative and technical staff.

The indicative design of the prototype, refined by the stakeholder consensus process, called for the CDSS to be able to highlight evidence-based risk factors (The National Confidential Inquiry into Suicide and Homicide by People with Mental Illness, 2014) recorded in the patient's EHR and support GPs to investigate warning signs of suicide (Rudd et al., 2006). Risk factors included increased frequency of attendance, and people prescribed multiple psychoactive compounds, especially people in receipt of combined benzodiazepines and antidepressant prescriptions. Warning signs included increasing alcohol or drug use, anxiety, or agitation and expressing suicidality related thoughts or engaging in associated behaviour.

Following the stakeholder consensus process (chapter 7) the research student, along with academic supervisors, met with PRIMIS colleagues on several occasions to further refine the prototype content. The prototype was built within EMIS web, using Read codes (Clinical Terms Version 3). Read codes are a clinical classification and coding system used in primary-care (de Lusignan and Chan, 2008), which provide a standardised dictionary of clinical terms and interventions.

8.3.1 Actuarial risk markers

In consultation with PRIMIS, attempts were made to reconcile prospective alerts or triggers for the CDSS identified during the stakeholder consensus process with what could be realistically implemented based on use of Read-coding. The suggested presentations for triggering the CDSS (Table 7-5) were therefore considered in relation to what might be existing Read-coded, actuarial data, within patient records in the EHR.

The suggested trigger presentations (informed by the findings of the stakeholder consensus workshops) were commuted to a list of Read codes denoting clinical risk-markers, identified from the literature (e.g. The National Confidential Inquiry into Suicide and Homicide by People with Mental Illness, 2014).

The presence of specific Read codes related to identified clinical risk factors within the patient's EHR. Existing Read-codes in patient's records in relation to these background clinical risk markers, could function as actuarial risk-markers, triggering the prompt to launch the CDSS.

Actuarial risk markers, coded within the EHR which could trigger the CDSS, included any mental health diagnosis at any time-point (Chesney et al., 2014; Nock et al., 2009), diagnosis of Autistic spectrum disorders, or Attention Deficit Hyperactivity Disorder (Allely, 2014; The National Confidential Inquiry into Suicide and Homicide by People with Mental Illness, 2017; Zahid and Upthegrove, 2017), diagnosis of a long-term health condition (Scott et al., 2010; The National Confidential Inquiry into Suicide and Homicide by People with Mental Illness, 2017) and past self-harm or suicide attempt (O'Connor and Portzky, 2018; Rudd et al., 2006)

8.3.2 Dynamic risk markers

A range of dynamic risk markers had also been identified and informed by the literature and findings from the previous phases of the research, including the stakeholder consensus process. These dynamic risk markers included frequency of attendance over population norms (Hawton et al., 2013b), increasing frequency of attendance (The National Confidential Inquiry into Suicide and Homicide by People with Mental Illness, 2014), recent psychiatric discharge (The National Confidential Inquiry into Suicide and Homicide by People with Mental Illness, 2017) current CRHT contact (The National Confidential Inquiry into Suicide and Homicide by People with Mental Illness, 2016), current alcohol or substance use

problems (Smith et al., 2010; The National Confidential Inquiry into Suicide and Homicide by People with Mental Illness, 2016) and current or recent suicide or self-harm ideation, plans, or intent (Joiner et al., 2003; Jordan et al., 2019; McHugh et al., 2019; Mughal et al., 2019).

8.3.3 Retained triggers

This mixture of actuarial and dynamic risk markers resulted in a broad range of suggested triggering Read codes. This wide range of Read codes was in keeping with a previous study which identified 248 separate Read codes pertinent to suicidality (Thomas et al., 2013).

However, the need to balance targeted alerts for launching the CDSS, against GPs' frustration at CDSS which trigger too easily or for too wide a group of patients, was a recurrent theme in GP interviews (chapter 5) and the co-production process (chapter 7). Such concerns are also noted in the CDSS literature, leading to what has been described as end-user 'alert fatigue' (Sutton et al., 2020; Wulff et al., 2019). Therefore, in consultation with PRIMIS, the following triggers were retained within the prototype build (table 8-1)

Table 8-2: Retained CDSS triggers

Specific diagnostic or condition codes
Depression (current)
Anxiety disorders (current)
ADHD or Autistic Spectrum disorder (current)
Physical health problems, diagnosed by a specialist (within 12 months): Cancer, MS, Ischemic Heart Disease, and Neurological disorders
History of alcohol or substance misuse.
History of suicide ideation, plans, attempts, or self-harm
Prescribed Medication
Anti-depressants, or other psychoactive medication within last 3 months
Current combination of antidepressants and benzodiazepines
Codeine or Methadone

This retained trigger list was a pragmatic attempt to reconcile identified clinical risk factors, information likely to be Read-coded, and end-user alert fatigue.

8.3.4 Changes in the patient's frequency of consultation

Literature highlights changes in consultation frequency are associated with higher suicidality risk (Windfuhr et al., 2016). In particular, i) a doubling of the individual's previous consultation rate, over a 2-3 month period; ii) people consulting more than 15 times within a 12 month period; and iii) those more than 24 times within 12 months are considered at highest risk (odds ratio 12.0 95%CI 8.5-17.5) (The National Confidential Inquiry into Suicide and Homicide by People with Mental Illness, 2014) are considered at higher risk of suicide (OR 6.2 95%CI 5.8-11.0).

In order to calculate doubling of an individual's consultation rate over a 2–3-month period, or people consulting more than 15 times within a 12-month period, a bespoke algorithm calculating patient's individual consultation rate, was considered for incorporation as one of the CDSS triggers. However, a large proportion of the primary care population have more than one significant long-term health condition and such multimorbidity leads to a greater number of consultations per year (Salisbury et al., 2011). Furthermore, frequency of attendance is strongly related to age and sex population norms (Smits et al., 2014). Therefore, 2-year average figures for the number of consultations, stratified by age and sex, were calculated from the published 2007 and 2008 data-sets of the QResearch database (Hippisley-Cox and Vinogradova, 2009). QResearch is an established database which draws anonymised records of patients' age, sex, and consultation rates, from practices using EMIS web nationally. Therefore, the upper quartile of age and sex consultation rates stratified for age groups were incorporated as additional triggers for launching the CDSS (Table 8-2).

Table 8-3: 2-year population average consultation rates, stratfified by age and sex

Age band	Number of annual consultations (upper quartile) : Males	Number of annual consultations (upper quartile): Females
18-24	>2	>5
25-34	>2	>7
35-49	>3	>6
50-64	>5	>7
>65	>13	>13

These upper quartile rates are an attempt to incorporate above average attendance as a clinically important risk marker, balanced against the risk of GP alert fatigue stemming from the CDSS triggering too frequently.

8.3.5 Keyword activation of the CDSS

In addition to the automated triggers codes (actuarial, or dynamic risk markers, and upper-quartile consultation rates), it was also considered important to retain key-word activation of the CDSS. Keywords, can be seen as context sensitive triggers for CDSS activation (Kannry et al., 2015). Therefore, keyword activation of the CDSS was incorporated, in response to GP entry of the keywords 'suicidal' (read code 1B19.), or 'suicidal intent' (EMIS code EMISNQPH1.), or GPs entering a patient's score above 0 on question 9 (thoughts of suicide or self-harm) on the PHQ-9 depression screening tool (Kroenke and Spitzer, 2002).

8.3.6 GP activation of the CDSS

In addition to automated triggers, or keyword entry prompting the GP to launch the CDSS, it was also considered important to retain the ability to manually activate the CDSS. Due to the variation in GPs consultation style, and varying ways in which they have described they might use the CDSS, it was important to enable multiple ways of

accessing the CDSS. Once installed on a GP's computer, the CDSS is stored within EMIS web, as a clinical data template. Templates are pre-designed data-entry forms, which record information in a consistent and standardised way, and which feed in to clinical data reports (EMIS health, 2017).

8.4 Prototype description

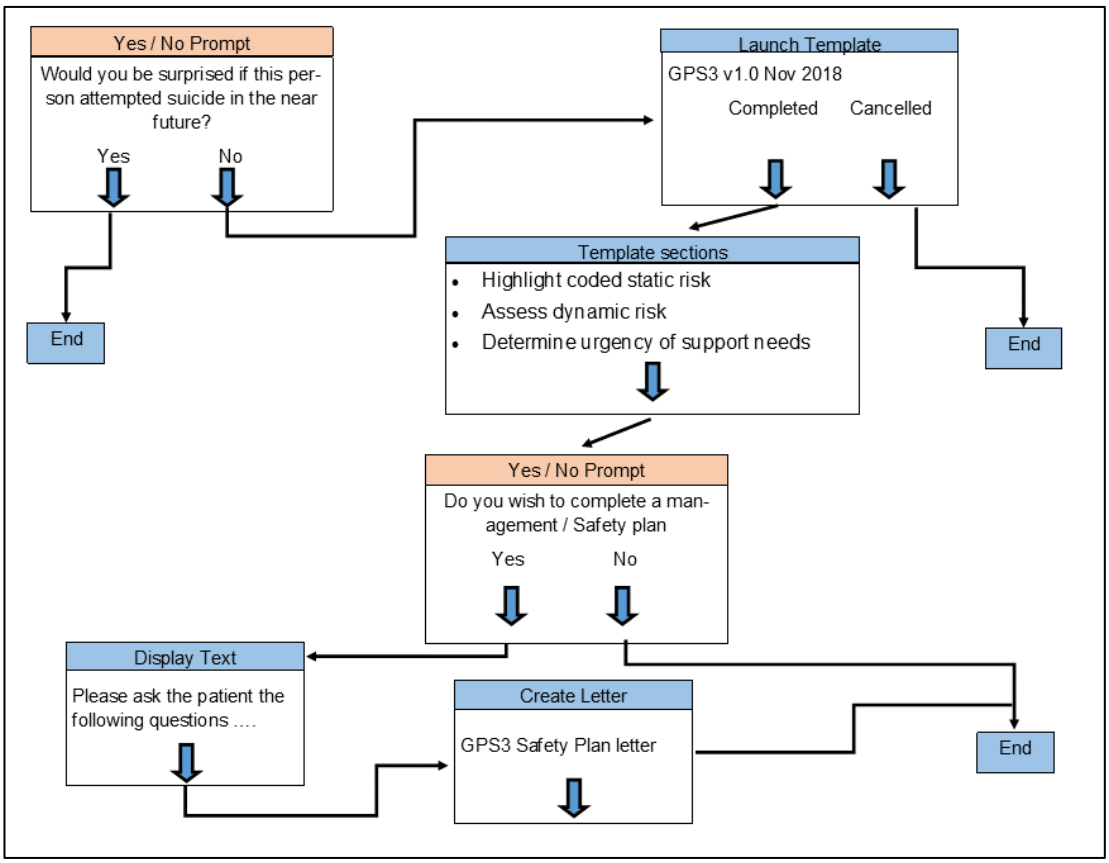
The CDSS is an installable template within EMIS web, comprising a protocol template, a package of bespoke data concepts (the underlying CDSS triggers which can be loaded into EMIS web) and a word file (template clinical management and safety plan).

When installed and operating, the CDSS comprises 4 linked sections: static risk factors, assessment of dynamic risk factors, determination of the urgency of support needs, and safety plan creation. The safety-plan template was adapted from an existing cognitive-behavioural intervention for suicidality (Stanley and Brown, 2012), and further customised through co-production.

In addition, the CDSS also has tabbed pages, including a section on indicated clinical management options, and a resources section with links to internet based educational and clinical information, to further support GPs and their patients.

The end-user flow through the CDSS is as depicted in Figure 8-2.

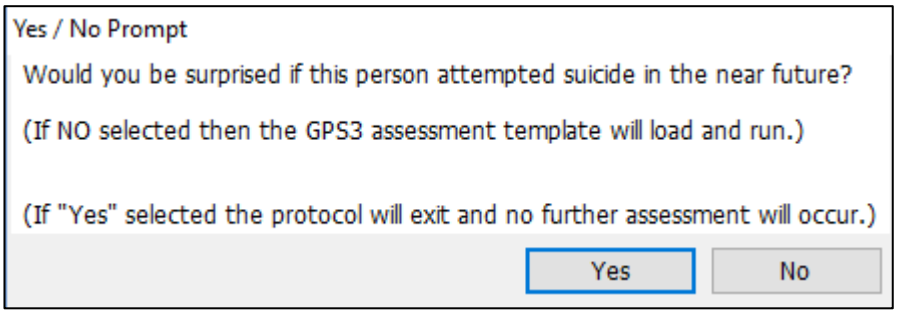
Figure 8-2: End-user workflow through the CDSS



8.4.1 Composition and screen shots

When the CDSS is triggered, the user is offered an introductory dialog, which is the gateway prompt question to the CDSS, intended to help GPs begin to shift from heuristic based, or quick cognition, to more analytical thinking (moving from system one to system two cognition, Croskerry, 2009) (Figure 8-3)

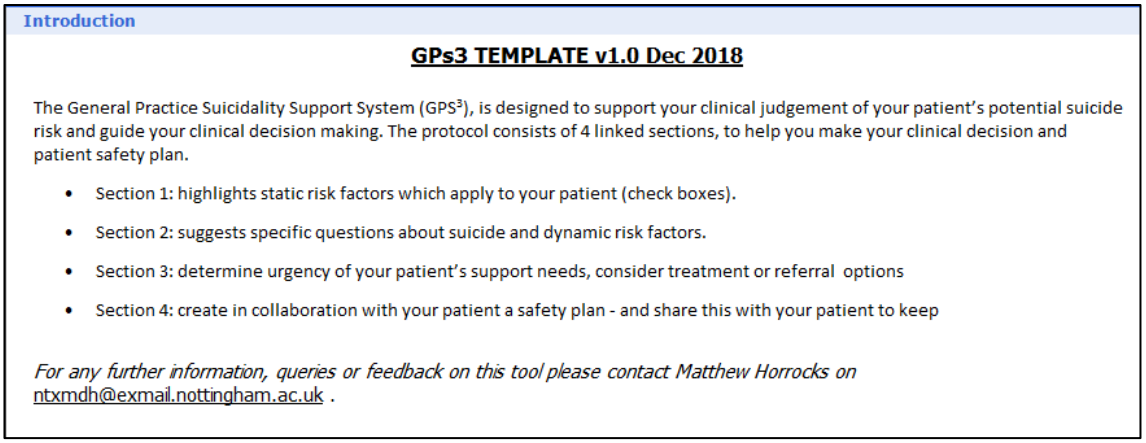
Figure 8-3: CDSS gateway prompt question



If the user selects 'No' the CDSS template opens within EMIS web, which then offers the user the chance to engage in focused analytical thinking about patient specific risk of suicidality.

The main page of the template opens with some introductory guidance (Figure 8-4) to help end users gain familiarity with the template.

Figure 8-4: Template introduction


Introduction

GPs3 TEMPLATE v1.0 Dec 2018

The General Practice Suicidality Support System (GPS³), is designed to support your clinical judgement of your patient's potential suicide risk and guide your clinical decision making. The protocol consists of 4 linked sections, to help you make your clinical decision and patient safety plan.

- Section 1: highlights static risk factors which apply to your patient (check boxes).
- Section 2: suggests specific questions about suicide and dynamic risk factors.
- Section 3: determine urgency of your patient's support needs, consider treatment or referral options
- Section 4: create in collaboration with your patient a safety plan - and share this with your patient to keep

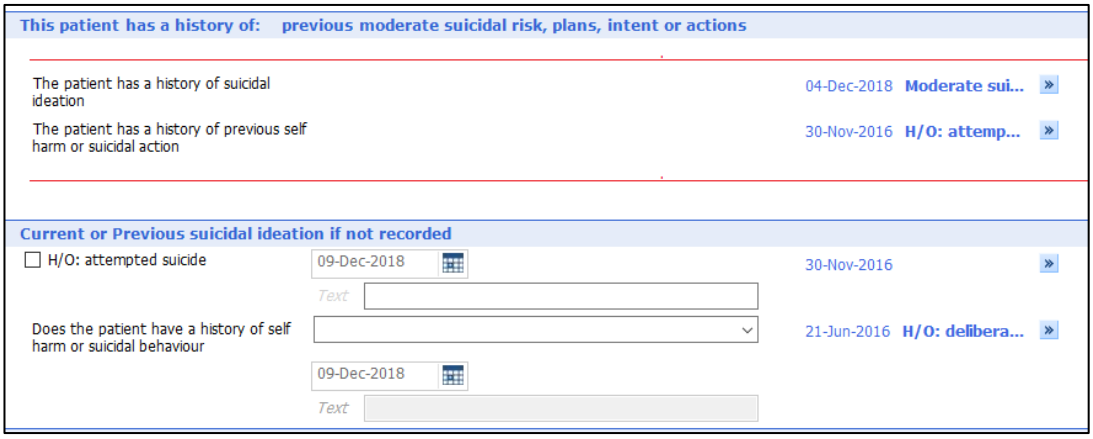
For any further information, queries or feedback on this tool please contact Matthew Horrocks on ntxmdh@exmail.nottingham.ac.uk .

8.4.1.1 Section 1 - Static risk factors

The main page of the template then proceeds with section one, which highlights static risk factors, by drawing out read-coded information in the patient's history.

Codes which filter into this section include identified diagnoses and conditions which increase suicidality risk (table 8-1 – [section 8.2.2.3]), medication prescribed within the last 60 days associated with increased suicidality risk (antipsychotic, antidepressants, antidepressants and benzodiazepines, or methadone), and historical suicide risk (coded history of suicide risk, plans, intent or actions, current or previous ideation). The static risk section is shown in Figure 8-5:

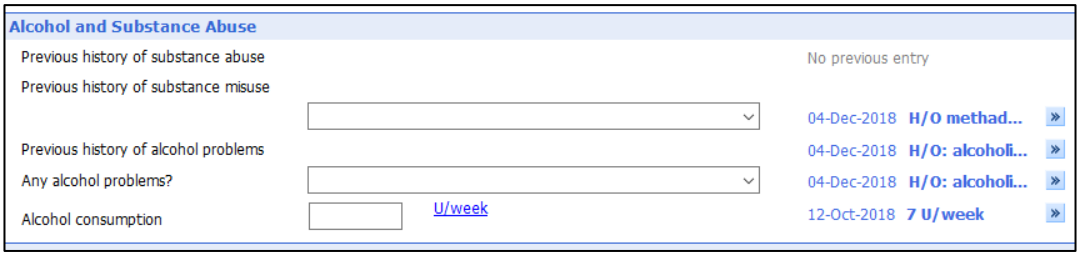
Figure 8-5: Section 1 - Static risk factors



Section 1 also enables the GP to retroactively enter any previously uncoded history of attempted suicide, or suicidal behaviour, by entering brief information if required.

The template then continues, by highlighting any previously coded data relating to alcohol or substance misuse. In addition, the end-user is able to manually enter current alcohol consumption in units per week, generating the code for current alcohol misuse if appropriate (Figure 8-6)

Figure 8-6: Alcohol and substance misuse

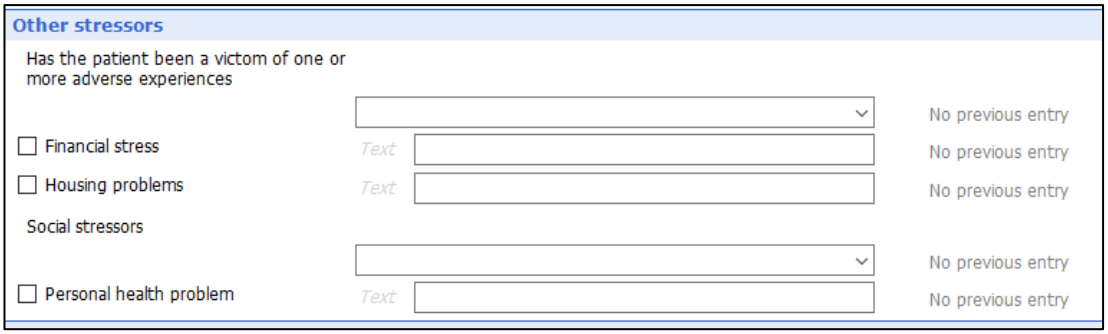


8.4.1.2 Section 2 – Dynamic risk factors

Section 2 of the template then moves beyond alcohol and substance misuse to consider other dynamic risk factors. Previous coded data will display, and again the end-user can enter new data, generating the corresponding EMIS code within the patient EHR. Dynamic risk factors incorporated into the template include financial stress (13k1), housing problems (13EH), social stressors, and long-term health conditions (Zv4). The social-stressors field is an umbrella field drawing on the codes for personal problems (13He), social isolation

(13HL), separation (13H2), martial problems (13H4), and poor family relationship (13HP2). The end-user has again the option of selecting or recording new specific adverse experiences from a pick list containing victim of sexual abuse (14x6), domestic violence (14xb), child sexual exploitation (14xh), and domestic abuse (14xg). The dynamic risk section displays as per Figure 8-7

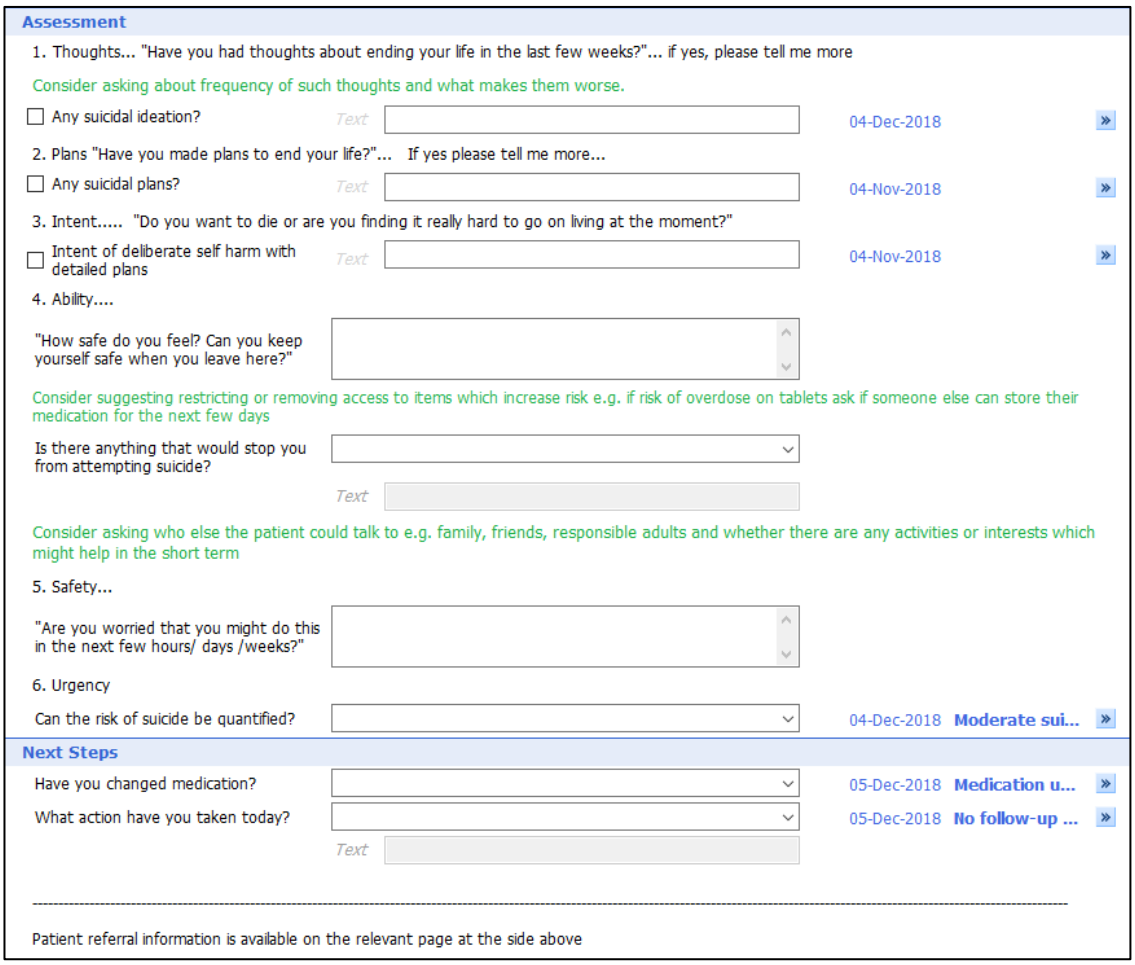
Figure 8-7: Section 2 - Dynamic risk factors



The next part of section 2 is the assessment of suicidality and comprises the 5 items from section 7.3.2.1.3 (Table 7-7), along with determination of the urgency of support needs, selected from a pick list as low, medium or high.

The risk assessment items are displayed in black text, with minimal suggested prompts intended to help GPs think about wording to elicit further risk information displayed in green (Figure 8-8)

Figure 8-8: Assessment of suicdality

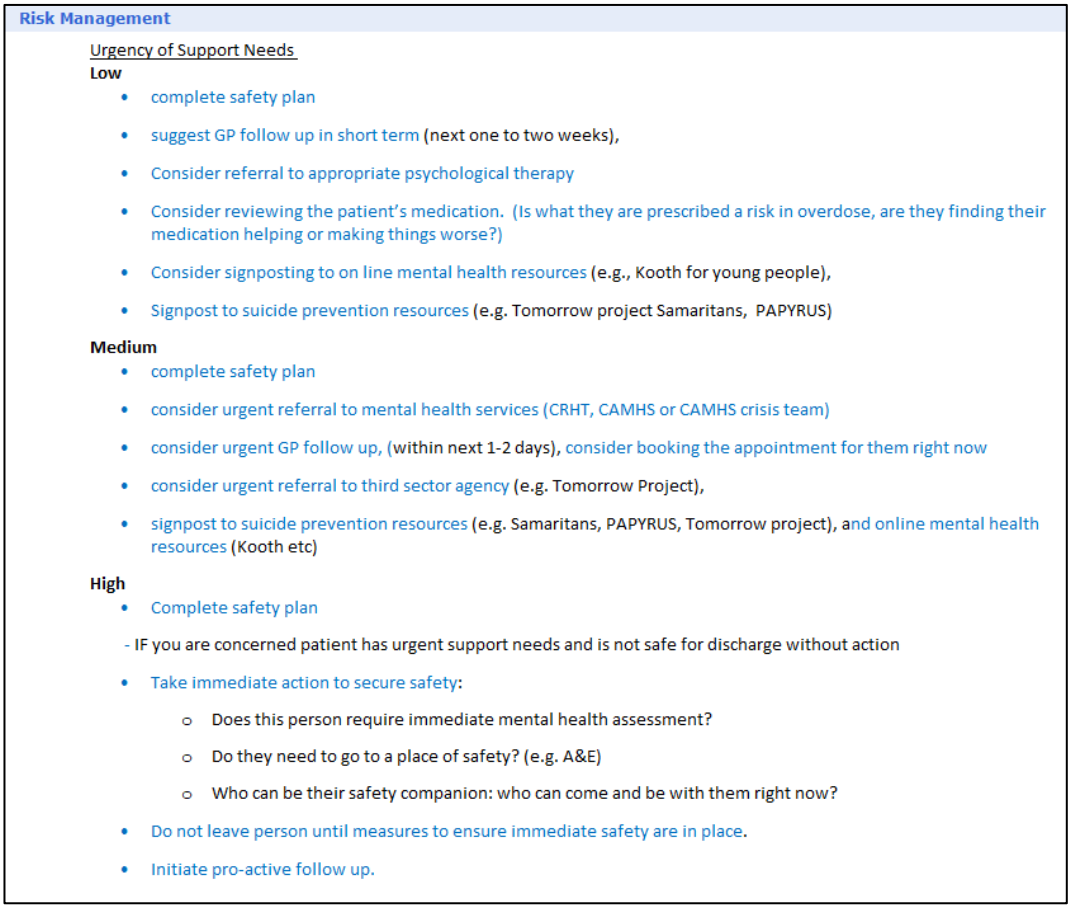


The end of this section, labelled as 'next steps' affords the GP the option to record any new or adjusted prescription medication, and a short summary of clinical outcome, on a pick list containing no follow up (8Ha), return only if necessary (8HA2), follow-up arranged (8H8), referral to psychiatrist declined (8IH54), psychiatric self-referral (8HJ3), psychiatric referral (8H49), refer to Psychologist (8HVi), referral to community mental health team (8Hc0), referral to primary care mental health team (8Hc2), and referral to non NHS mental health community service (8HHn).

8.4.1.3 Section 3 (tabbed page) – risk management information

Section 3 of the template, (risk management information) is contained on a separate tabbed window, and presents indicated clinical-management options corresponding to identified urgency of support needs, [as defined in section 7.3.2.1.5 , Table 7-8] and displays as Figure 8-9.

Figure 8-9: Section 3 - risk management information

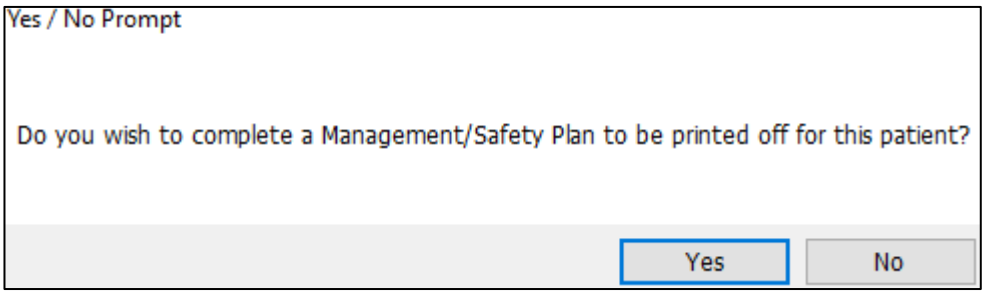


These suggested risk management options are informed by clinical guidance (National Collaborating Centre for Mental Health, 2012), clinical literature (The National Confidential Inquiry into Suicide and Homicide by People with Mental Illness, 2014, and 2017), the findings of chapters 5 to 7 and reflect information coproduced with expert stakeholders (section 7.3.2.1.5)

8.4.1.4 Section 4 – safety plan creation

The safety plan is accessed after completion of the template, or can be accessed manually from the 'documents -create letter' tab within EMIS web. After completing the template, the end user is presented with a following dialogue box prompting creation of a safety-plan (Figure 8-10)

Figure 8-10: Safety-plan dialogue box



If the end user clicks 'yes' they then receive the following guidance, and series of questions to create the safety-plan (Figures 8-11, 8-12)

Figure 8-11: Safety-plan information

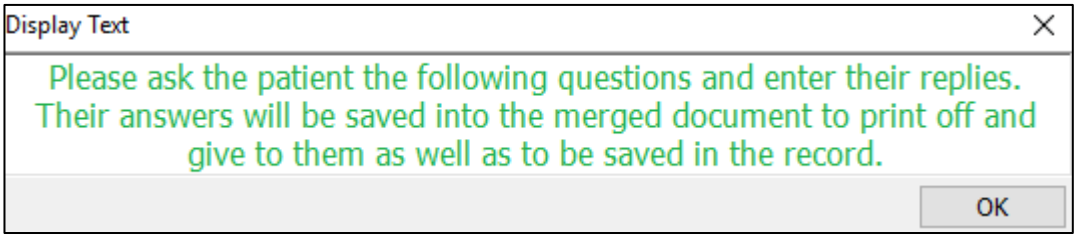
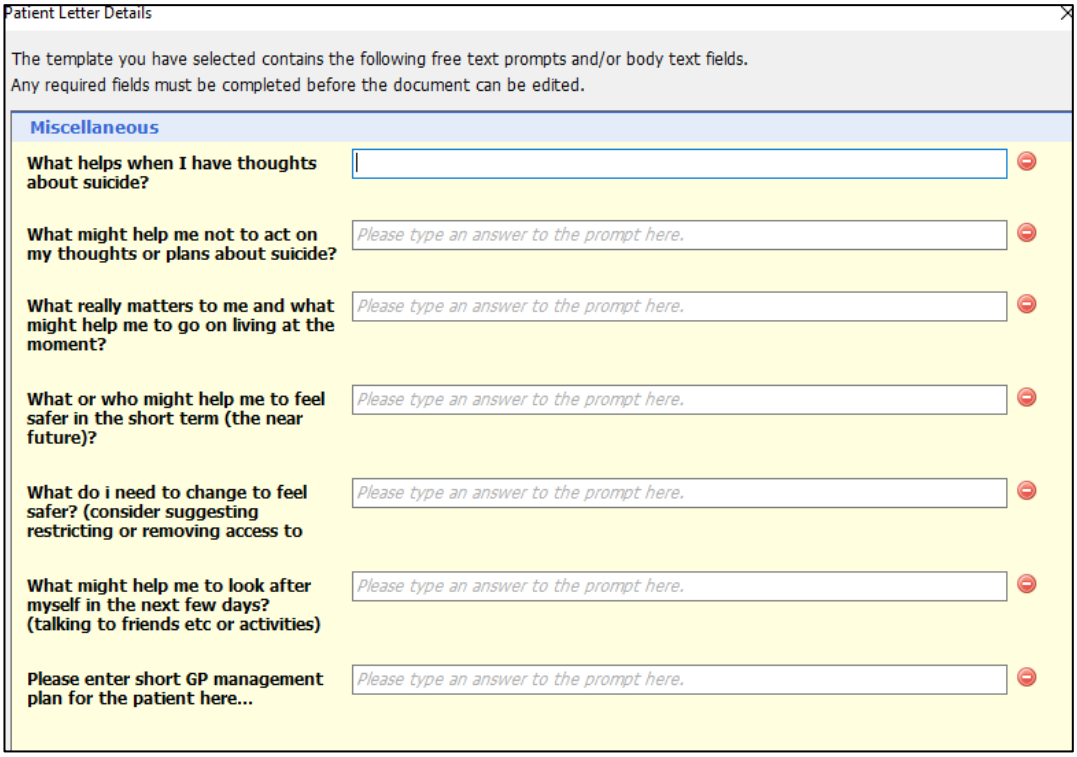


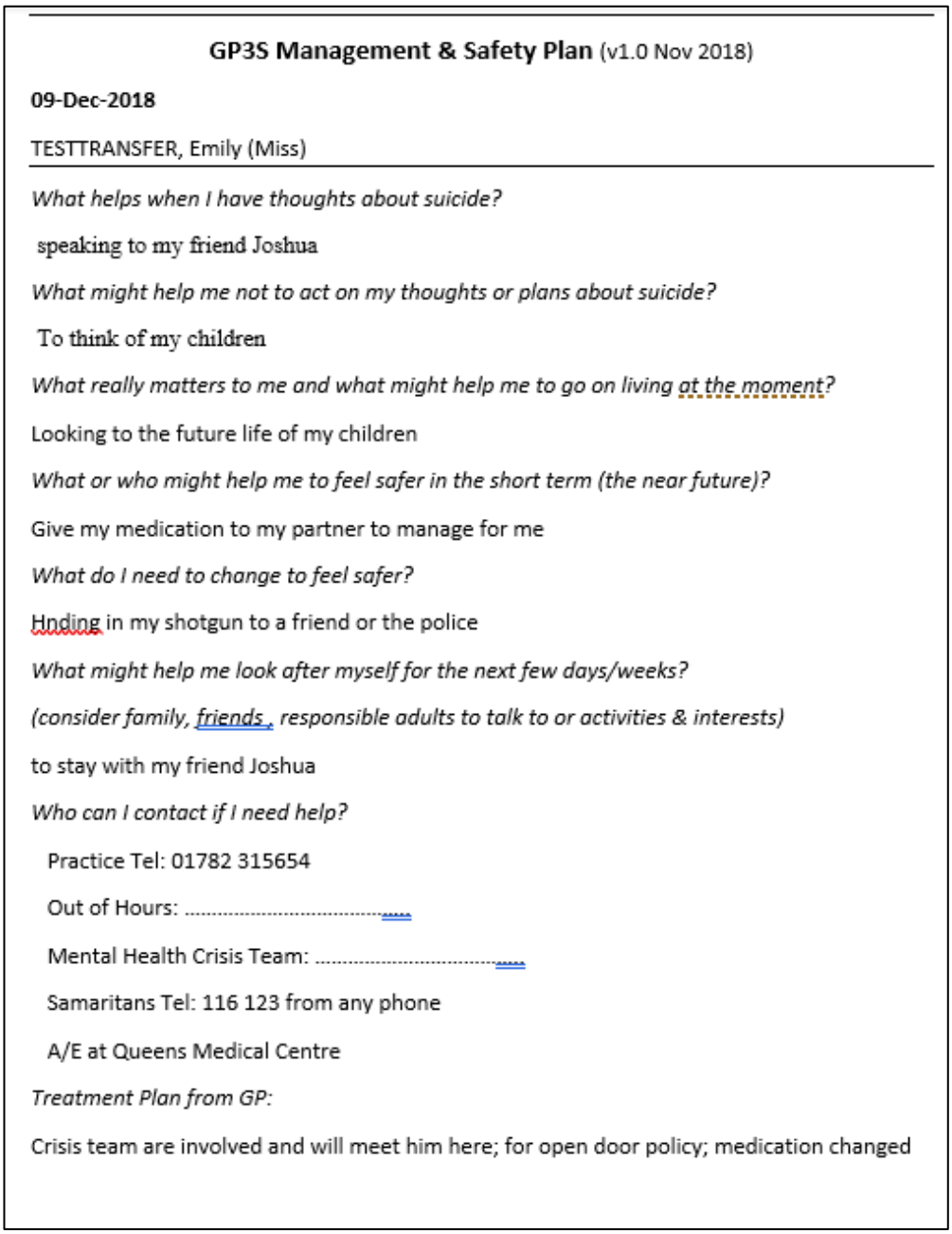
Figure 8-12: Safety-plan questions



The safety plan items are informed by Stanley and Brown (2012), and adapted through the patient advisory groups and co-production process (within this thesis; chapters 6 and 7).

The answers to the fields within this dialogue box are mandatory but can be skipped by entering a "." When completed, the dialogue generates the patient safety-plan, which can be printed off and given to the patient, or shared with other services where appropriate. A completed patient-safety plan displays as Figure 8-13.

Figure 8-13: Completed patient-safety plan



GP3S Management & Safety Plan (v1.0 Nov 2018)

09-Dec-2018

TESTTRANSFER, Emily (Miss)

What helps when I have thoughts about suicide?

speaking to my friend Joshua

What might help me not to act on my thoughts or plans about suicide?

To think of my children

What really matters to me and what might help me to go on living at the moment?

Looking to the future life of my children

What or who might help me to feel safer in the short term (the near future)?

Give my medication to my partner to manage for me

What do I need to change to feel safer?

Hnding in my shotgun to a friend or the police

What might help me look after myself for the next few days/weeks?

(consider family, friends , responsible adults to talk to or activities & interests)

to stay with my friend Joshua

Who can I contact if I need help?

Practice Tel: 01782 315654

Out of Hours: .....

Mental Health Crisis Team: .....

Samaritans Tel: 116 123 from any phone

A/E at Queens Medical Centre

Treatment Plan from GP:

Crisis team are involved and will meet him here; for open door policy; medication changed

8.4.1.5 Section 5 (tabbed page) – educational references

The educational resources section provides links to internet-based resources, to support GPs and their patients. Links included in the

prototype include RCGP resources and toolkits, NICE guidance, GMC and BMA advice on responding to patients enquiring about assisted suicide, and links to a range of important practitioner facing guides, such as Royal College of Psychiatry and British Psychological Society resources. In addition a link is provided to the "it's safe to talk about suicide" leaflet co-produced by researchers, people with lived experience and suicide prevention charities, (Owens and Charles, 2017), which is endorsed for use with patients or carers in local suicide-prevention strategies.

In addition, links are provided to widely used resources for people in suicidality distress, including patient self-help resources published by the Royal College of Psychiatrists for people thinking about suicidality, and the "stay alive" mobile phone application (Grassroots Suicide Prevention, 2016), which is free to download and endorsed by leading suicide prevention experts and evaluated in NHS trusts. Links to the nationally produced suicide bereavement resource "help is at hand" (Hawton and Simkin, 2018), and the locally produced "SAFE from harm" booklet (Nottingham Self Harm Awareness and Resource Project (SHARP), 2018), intended to help carers support people experiencing self-harm and suicidality, are included. Finally, a brief prompt reminds GPs to look after their own emotional and psychological wellbeing, and provides links to GPs' services, including pastoral support provided by the Local Medical Committee, GP peer mentoring services, the GP health service and the BMA counselling and advice service.

The educational resources page displays as Figures 8-14, 8-15.

Figure 8-14: Section 5 -educational resources

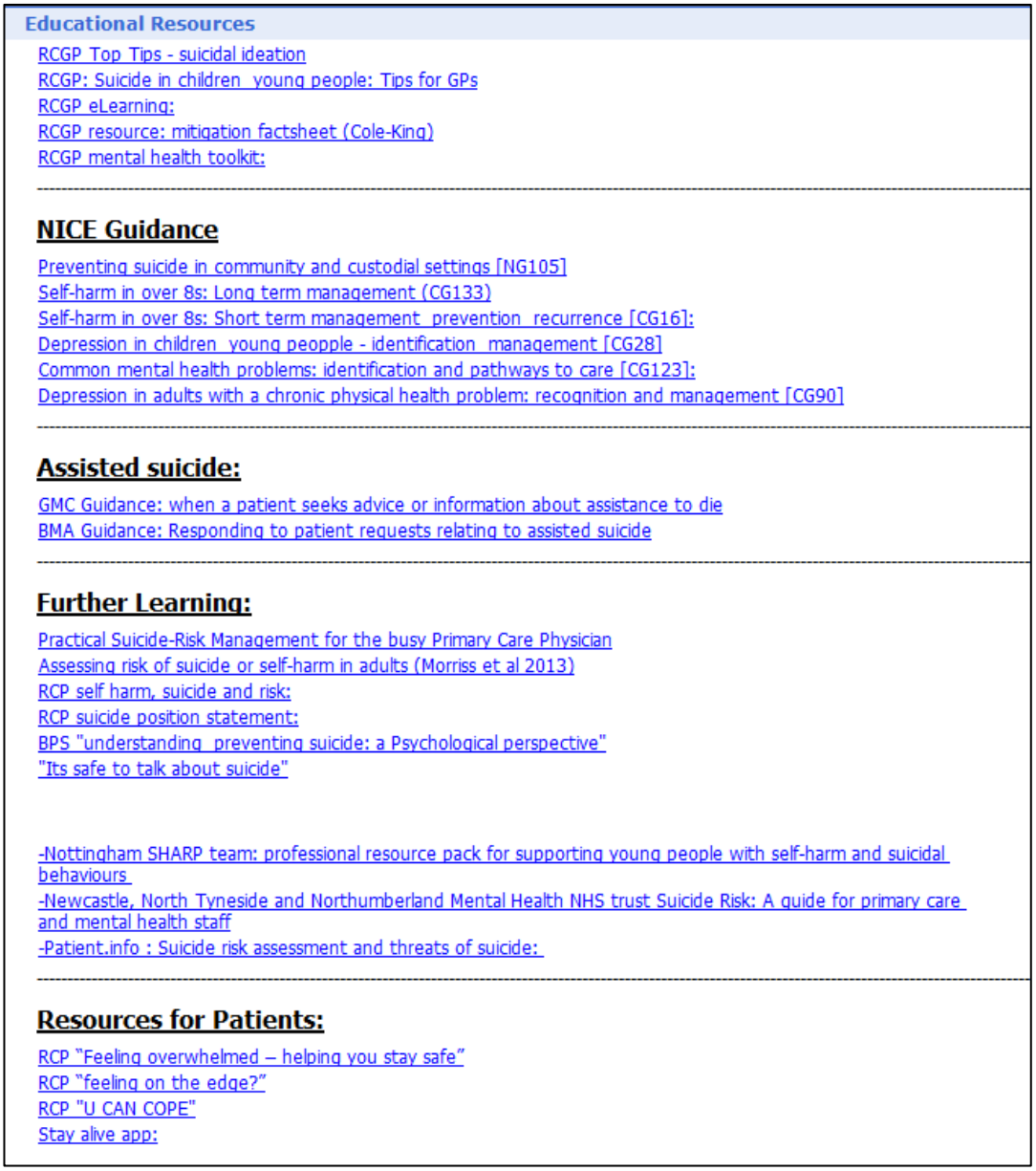
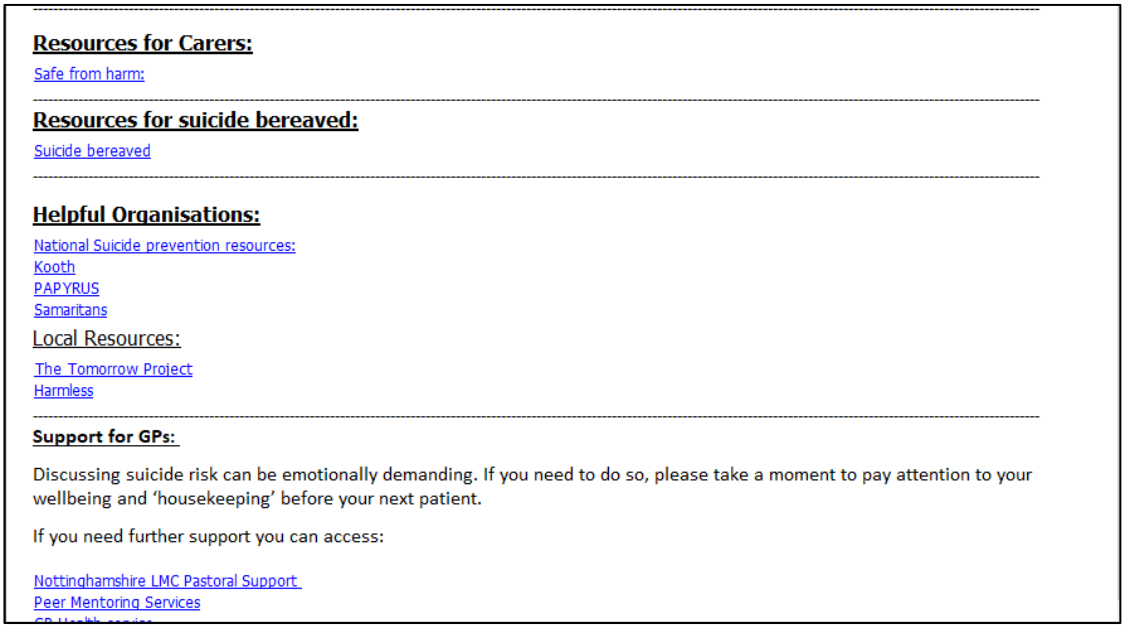


Figure 8-15: Section 5 (continued)



8.5 Findings

This section presents the findings from the non-live and live usability testing study conducted with the prototype CDSS, built within EMIS web.

8.5.1 Findings from non-live usability testing

Non-live testing was conducted between November 2018 and April 2019, with 4 GPs taking part. After completing data entry into the CDSS, in response to 2 patient vignettes selected at random from a sample of 8 possible vignettes, GPs completed the SUS and a brief evaluation questionnaire. GPs then completed a cognitive walkthrough in response to a third vignette, before providing ratings regarding their views of the CDSS with regard to clinical and contextual appropriateness, and its ability to provide actionable decision support.

8.5.1.1 System Usability Scores

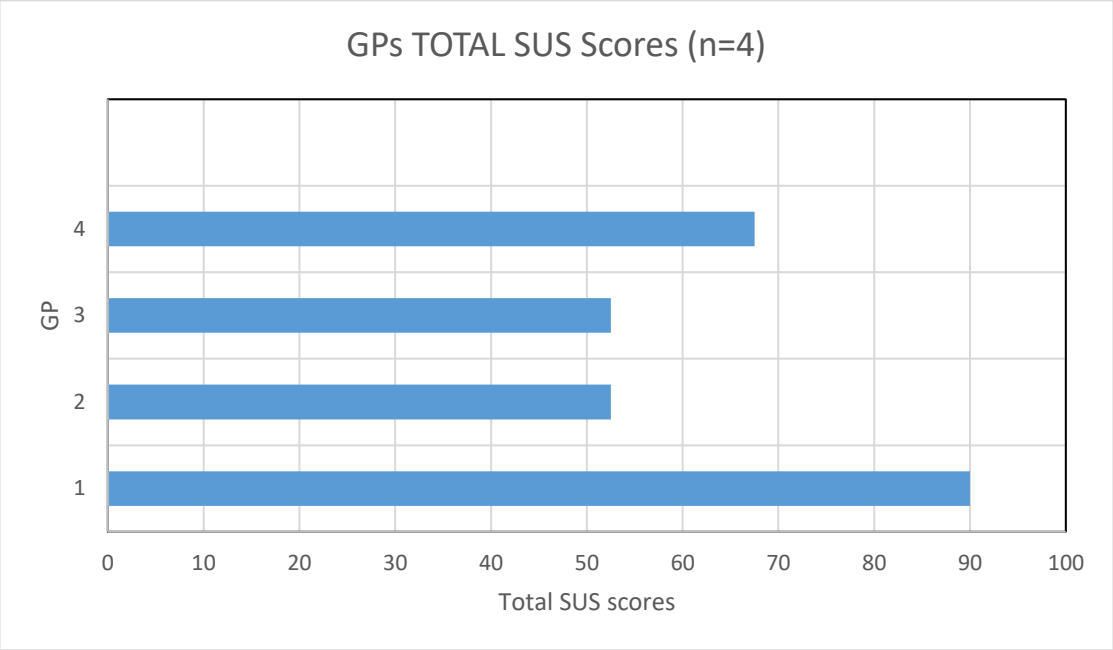
High scores on the SUS indicated GPs agreed with an SUS statement, whereas lower scores indicated disagreement. Scores of '3' are mid-point on the SUS Likert scale suggesting neither agreement nor disagreement (Table 8-3)

Table 8-4: System usability scores

Modified SUS Statements: rated between 1 (strongly disagree) to 5 (strongly agree)	**GP's mean average score**	**range**
I think that I would like to use this product frequently	3.25	3-4
I found the product unnecessarily complex	2.50	1-4
I thought the product was easy to use	3.50	3-4
I think that I would need the support of a technical person to be able to use this product	2.00	1-3
I found that the various functions in this product were well integrated	3.00	2-4
I thought there was too much inconsistency in this product	2.75	2-4
I would imagine that most people would learn to use this product very quickly	4.50	4-5
I found the product very awkward to use	2.50	1-3
I felt very confident using the product	3.50	3-5
I needed to learn a lot of things before I could get going with this product	1.50	1-2

GP's total SUS scores were calculated for each respondent and are presented below (Figure 8-16).

Figure 8-16: GP's total SUS scores

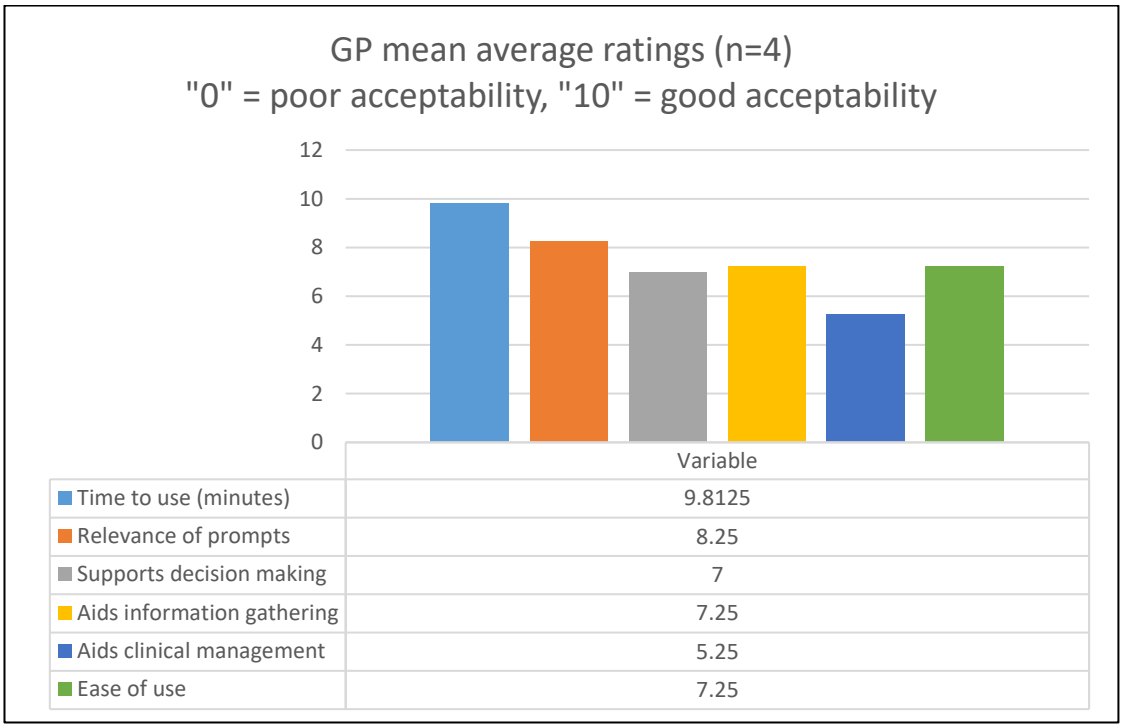


GP's total SUS scores ranged from 52.50 to 90.00 (mean 65.63). These scores were marginally below conventional thresholds for adequate usability as measured by SUS scores (mean 68), suggesting further usability refinement maybe indicated.

8.5.1.2 Evaluation questionnaire

The Evaluation questionnaire was used to gauge GP's views of the usability and acceptability of the CDSS content. GPs provided ratings on a zero to ten Likert scale (Figure 8-17)

Figure 8-17: Evalaution questionnaire - GPs ratings



GPs' ratings suggested the CDSS consisted of relevant prompts, supported information gathering, was easy to use, yet did not score well for aiding clinical management. Reasons for this discrepancy were unclear but may be due to CDSS ultimately leaving decision-making to the GP.

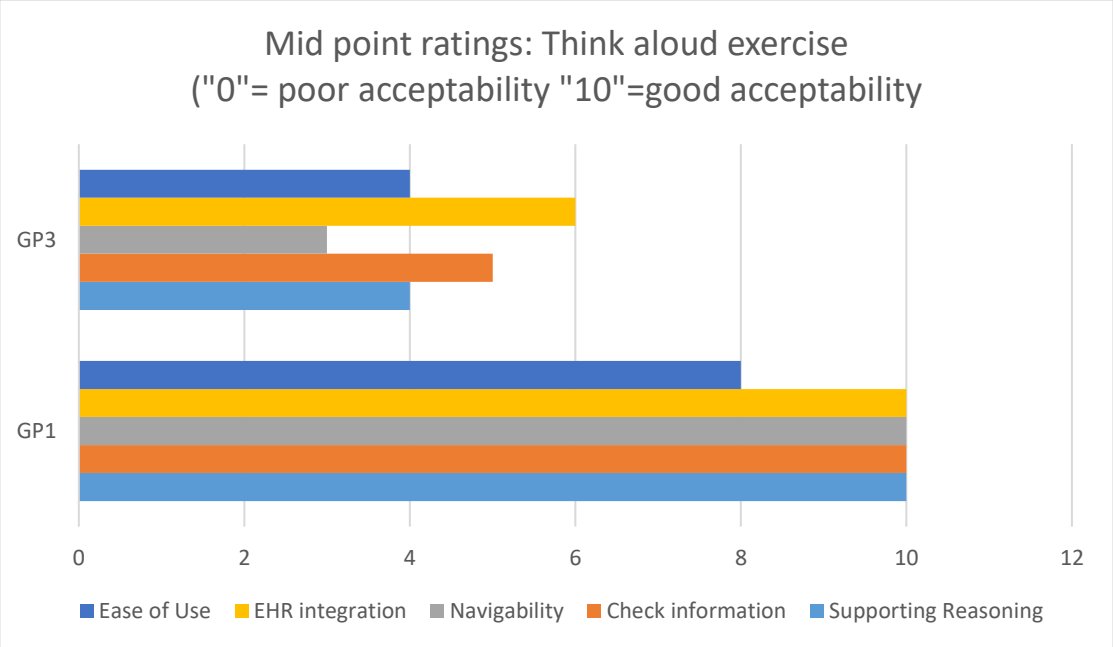
8.5.1.3 Thinking aloud exercise (cognitive walkthrough)

At the mid-way point of the think aloud exercise, between reading the vignette and completing the main page of the CDSS, GPs were asked to rate how well the CDSS was supporting their clinical reasoning, enabling them to check information in support of their reasoning, navigate through the CDSS sections, integrate with the patient's EHR and ease of use.

2 GPs declined to supply ratings mid-way through the process, saying that they would provide detailed feedback at the end. The 2 GPs that

did supply mid-exercise ratings contrasted significantly in their mid-point impressions of the CDSS (Figure 8-18)

Figure 8-18: Thinking aloud exercise -mid point ratings



8.5.1.4 Usability evaluation

An established coding framework (Richardson et al., 2017), was used to classify GP's verbal comments regarding usability as they worked their way through the CDSS in response to the patient vignette. Additionally, Nielsen's taxonomy (1993) was used to record the severity of any identified usability problems on a scale of 0-4, enabling calculation of the proportion of end-users experiencing a problem, and the impact of the problem on the end-user.

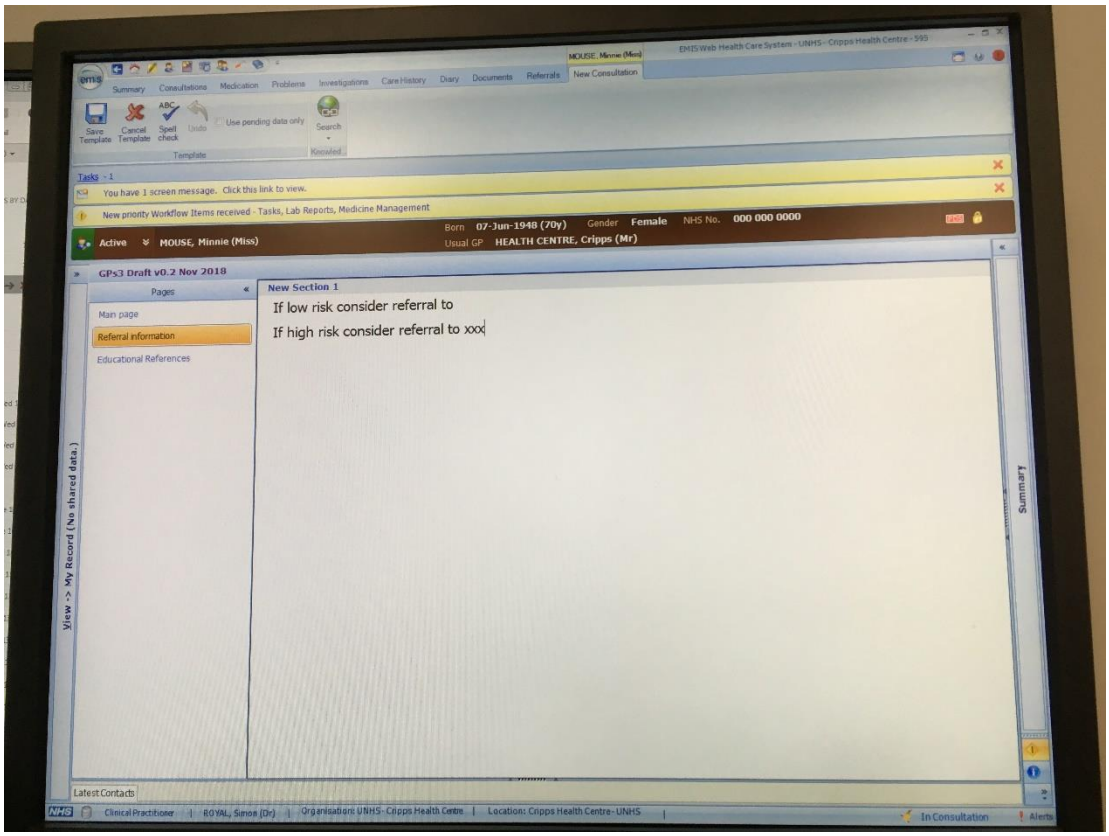
Table 8-5: Usability classification and problem severity (adapted from Richardson et al., 2017 and Nielsen 1993)

GP	Comment	Usability Category (Richardson et al)	Usability problem (Nielsen) 0= no problem, 1= cosmetic, 2=minor, 3 = major, 4 = catastrophic

GP02	Would want to discuss anti-depressants	Workflow	0
GP02	The concept of 'ability' seems a bit ambiguous	Understandability	2
GP03	Would bring back within 7days for review. Needs to link to appointments	Workflow	0
GP01	I can't call up the safety plan.	Navigability	4
GP01	Would like the safety plan prepopulating with more information to make easier to use.	Workflow	2
GP03	Can we add data to the letter dialogue form within the main screen (without having to save the consultation first)	Workflow	2
GP03	When saving the dialogue can it prepopulate the same dialogue box	Workflow	2
GP04	Would like to be able to restructure the tool by plans and risk and then by referral information	Understandability	2
GP04	The phrase 'quantification of risk' is misleading, can you replace with urgency of need?	Understandability	2
GP04	The last item about risk, (started or initiated) this should be re-worded, It is ambiguous how the wording related to risk (high-medium-low)	Understandability	2

A single issue was rated as 4 (usability catastrophe) on Nielsen's taxonomy, concerning navigation between sections of the CDSS. This was in response to the GP being unable to call-up the safety plan creation content. When investigated further, the GP also had an incomplete risk information section which displayed as Figure 8-19.

Figure 8-19: Incomplete installation of the template



This error was due to the GP not installing the version of the template intended for usability testing, and instead had a prior draft version of the template installed which was created to demonstrate the CDSS to the GP team prior to usability testing.

All other issues were rated a '2' (minor usability problem) (n=7), with three comments related to workflow, and four comments related to understandability.

8.5.1.5 Non live testing qualitative feedback

Verbal comments made by GPs relating to their experience of using the CDSS during cognitive walkthrough were noted. GPs comments on their experience of CDSS were a mixture of positive and negative feedback and categorised in relation to Richardson's classification system covering practical utility, ease of use, workflow, content appropriateness, visibility and navigation. No comments were recorded in relation to understandability.

8.5.1.5.1 Practical utility

Positive feedback pertained to the potential clinical utility of a suicidality CDSS, including a comment about the usefulness of the CDSS:

> *"This will be really useful (GP01)"*

This comment evokes practical value that the CDSS could offer in relation to the clinical complexity of working with suicidality in primary care. Another GP provided a slightly more reserved comment:

> "*There are some improvements required on its use, but overall concept is good (GP02)"*

Therefore, 2 of the 4 GPS seemed to endorse the conceptual and practical utility of the CDSS. However, the practical utility of the CDSS was questioned by another GP:

> *"Protocols are a bit awkward, they are not always relevant. I probably wouldn't use it, unless after a consultation in which a significant mental health issue was apparent in the case presentation" (GP03).*

These comments in relation to when this GP might use the CDSS are important relating to the viability of using the CDSS for a suicidality consultation, and its ability to fit with a range of different GP consultation styles. The GP however also seems to hint at a myopic view regarding the possible benefit of CDSS in general.

8.5.1.5.2 Ease of use

Two comments were recorded in relation to the ease of use of the CDSS prototype. These included a comment in relation to the difficulties which GP01 had in accessing the safety-plan.

> *"It needs the safety plan to be easy to get to and available, It's not clear how you access the safety plan" (GP01)*

An additional comment was made in relation to the way in which options are presented within the CDSS:

"You could make more use of drop down boxes to make it easier" (GP04)

This comment was in relation to using more drop down boxes to allow GPS to click through a range of options within the CDSS to support their clinical decision-making process.

8.5.1.5.3 Workflow

The ease of use of the CDSS also has implications for how well the CDSS fits into routine tasks and actions that GPs take. 3 important comments regarding the CDSS ability to integrate with GP workflow were recorded:

"*Reorder the content of the pick list for management options*" (GP04)

This comment was in relation to the item '*what actions have you taken to day*', within the next steps section of the suicidality assessment. The GP suggested booking the patient in for a follow up appointment in primary-care was the most likely course of action and so suggested this should be the first item on the pick-list, opposed to psychiatric referral. Re-ordering the pick list may shave seconds off the time required for that particular item. A further comment in relation to time and workflow was provided by another GP:

"You need to contain this to within 30 minutes total" (GP01)

The GP was referring to both the time taken for the patient appointment, and the workflow of any necessary clinical actions, such as onward referral, and use of the CDSS to record outcomes in the EHR. The time-pressures affecting primary-care consultations are a significant dimension of GP workflow, and therefore a potential generative mechanism influencing use of the CDSS.

An additional comment was made in relation to the order by which options are presented on the picklist for 'what action have you taken today' at the end of the dynamic risk assessment:

> *"Change the next steps drop down - simplify and re-order. Put the one about booking in another appointment in primary care first as that's the one most likely to be used" (GP04)*

At the time of non-live testing the first option on the list was 'no follow-up', followed by various referral options, and then options regarding follow-up in primary-care. Reconfiguring the order with which these options are presented, to fit with what might be the most frequent action taken by GPs, could increase integration with workflow and improve ease of use.

8.5.1.5.4 Content appropriateness

Two comments were made in relation to content appropriateness. The first pertained to customising the content of risk management actions to local contexts.

> *"The referral information page needs populating with the same information that we usually give out when someone talks about suicide. We have a leaflet we use within the practice" (GP01)*

Such customisability is important to enhance the integration of the CDSS into current practice. Furthermore, local customisation to reflect locally appropriate clinical management options would be important should the prototype proceed to wider roll-out. This may be particularly important regarding geographic variation in the commissioning and availability of specialist self-harm and suicidality services.

A second comment was made in relation to perceived over-emphasis on mental-health conditions as content or triggering factors for the CDSS:

> *"It needs to cast its net wider than just mental health presentations, to Increase the scope of it to be relevant to a wider range of presentations, but seek to retain the medico-legal protection afforded by the tool" (GP03)*

A range of non-mental health trigger codes were built into the CDSS, and the language within the display was intended to help GPs consider suicidality as a trans-diagnostic phenomena, not only a consideration with mental-health patients. This GP's association between the CDSS and mental-health may be due to a mental-health emphasis within the suicidality vignettes. It may also bely a wider conflation of mental-health and suicidality in primary-care.

8.5.1.5.5 Visibility

Two GPs provided feedback regarding the visibility of information presented within the CDSS display, one comment suggested the GP perceived poor visibility of information:

> *"It is too busy, there are too many words, it is difficult to see the words for the time that we have" (GP03)*

Such a negative perception of the visibility of information within the CDSS could disincentivise use. However, no other GPs commented on this particular aspect. A second GP suggested improvements in the visibility of links between the sections of the CDSS could be made:

> *"Bolden or highlight the other tabbed pages in the tab selection pain" (GP04)*

This comment referred to the way in which the CDSS is built and displays, with the main page opening as window, with separate tabbed pages for risk management information and educational references. Increasing the visibility of the tabbed pages would help draw attention to their existence, and potentially improve navigability.

8.5.1.5.6 Navigation

One GP commented on specifics of navigability within the tool, which is an important quality of CDSS systems, interacting with other concepts such as ease of use and workflow integration. One GP suggested use increased use of hyperlinks within the CDSS display could help:

"It would be good to put a link after question 4, to the referral information page - that's the question about immediacy / severity of risk" (GP04)

The comment related to adding a hyperlink to the risk management information tab, after question 4 of the dynamic risk assessment section, which relates to patient's sense of ability to keep themselves safe after the consultation. Linking to referral information at this point, suggests for this GP, patient responses suggesting inability to maintain personal safety might be a threshold for onward referral. No other comments were received in this regard.

8.5.1.6 Overall impression of the CDSS

At the end of the thinking-aloud exercise, GPs were asked to provide Likert scale responses of their views of the CDSS, with regard to clinical and contextual appropriateness, its ability to provide actionable decision support, and satisfaction with the CDSS ability to support patient specific risk decisions in suicidality consultations.

Table 8-6: Overall impressions of the CDSS; GPs mean average ratings (n=4)

	GPs overall impressions	Total Score (maximum possible 40)	GPs Mean average rating	Range
Clinical Appropriateness	Meets patient needs	27	6.75	4-9
	Meets GPs needs	31	7.75	5-10
	Takes into account all relevant information	29	7.25	4-9
Contextual Appropriateness	Time efficiency	24	6.00	4-8
	Integrates with workflow	26	6.50	4-9
	Integrates with EHR	30	7.50	5-9
Actionable decision support	Adds confidence to clinical decision	31	7.75	3-10
	Guides decision making	29	7.25	4-9
	Adds value to the consultation	30	7.50	4-10
patient specific risk decisions	encouraged analysis of patient specific risk	28	7.00	4-9
	Appropriate prompts and items	28	7.00	4-9
	Supported patient centred decision making	27	6.75	4-8

Highest total scores and mean ratings were in relation to the CDSS meeting GP's clinical needs, adding confidence to their clinical decision-making process, integrating with the patient's wider electronic health record, and adding value to the consultation. Lowest ratings were in relation to time efficiency and workflow integration. This suggests the GPs found the CDSS time consuming and potentially not well integrated with their consultation or workflow. However, studies suggest that time taken to use CDSS systems, and integration with workflow, improves with repeated use (Chaudhry et al., 2006).

8.5.2 Findings from live usability testing

Live usability testing took place with 4 GPs taking part. In total, 9 patients consulted, and the 4 GPs used the CDSS in 7 consultations. Outcomes were Adoption, Acceptance, Changes in Behaviour and Impact on Clinical Outcomes (derived from Kannry et al., 2015).

8.5.2.1 Adoption

The opportunistic sampling approach led to 9 patients providing consent who were attending a same day appointment, where the reason given for the consultation was in relation to mental health. Repeat use of the CDSS by GPs was variable, influenced by the opportunistic sampling approach, with 2 GPS using the CDSS 3 times each, and 1 GP using it on just once. The fourth GP did not return their record of use meaning it is unknown if they used the CDSS.

Use of the CDSS in 7 of 9 patient consultations, represents an adoption rate of 77.78%. This adoption rate is in keeping with US data, suggesting the frequency of CDSS use within primary-care appointments ranges between 68.5% to 100% (Jing et al., 2019). The study by Jing and colleagues only included CDSS which highlighted drug interaction and preventive screening reminders.

Such CDSS maybe conceived as relatively passive systems, requiring the least active involvement of the GP and maybe preferred by GPs due to lower workflow interactions (Trinkley et al., 2019). The current, knowledge-based CDSS can require a greater degree of active involvement from the GP to utilise features within the system, such as conducting the suicidality assessment, or constructing a suicidality safety-plan with the patient. CDSS systems which go beyond alerts and reminders to focus on decision support and treatment planning are the least frequently available CDSS systems which likely requiring greater demands of the clinician's time (Wright et al., 2011). Therefore, an adoption rate of 77.78% can be seen as exceeding expectation.

8.5.2.2 Acceptance

Acceptance was measured by GPs confirming that they had complied with the indicated clinical risk management actions suggested within the CDSS. GPs recorded that they had accepted the care planning recommendations within the CDSS for 6 of the 7 consultations (85.7%) This exceeds published data on acceptance rates for CDSS systems, which typically range between 10-42.4% (Kannry et al., 2015).

8.5.2.3 Changes in behaviour

Changes in behaviour was adapted within this study to infer possible changes in the process of care as a result of GPs' use of the CDSS. Whilst it is impossible to know how GPs might have assessed risk or formulated risk prior to using the CDSS, GPs reported that using the CDSS appears to have contributed to them considering a range of static and dynamic risk factors, within their assessment and formulation of suicidality risk (table 8-7)

Table 8-7: Components of risk considered during consultations (n=7)

	Consultation							
Changes in the process of care	1	2	3	4	5	6	7	%
Reviewed prescribed medication	✓	✓	✓	✓	✓	✓	✓	100.00
Review of existing mental-health diagnosis	✓	✓	✓	✓	✓	✓	✓	100.00
Explored alcohol or substance use	✓	✓	×	×	✓	✓	✓	71.40
Discussed aspects of patient's interpersonal relationships	×	✓	✓	×	✓	✓	✓	71.40
Enquired about financial stressors	×	×	×	✓	✓	✓	✓	57.14

It is not possible to know if GPs might have asked about factors such as alcohol and substance misuse, financial stress, or strained interpersonal relationships without use of the CDSS. However, these findings suggest that use of the CDSS supported GPs to ask about intimate and sensitive areas of patient's lives, which are known to be important suicidality risk factors (Barr et al., 2015; Ness et al., 2015; Smith et al., 2010; Van Orden et al., 2010)

8.5.2.4 Impact on clinical outcomes

The impact of use of the CDSS on clinical outcomes was measured by GP's record of referral and actions taken during live testing. As can be seen (Table 8-8), the CDSS supported GP clinical decision making with a range of clinical outcomes.

Table 8-8: Impact on clinical outcomes

	Consultation							
Clinical outcome	1	2	3	4	5	6	7	%
Follow on consultation in primary care	✓	✓	✓	✓	✓	✓	✓	100.00

Psychiatric /CRHT referral	×	✓	×	×	×	×	×	14.29
Substance use referral	×	×	×	×	×	×	×	0.00
Talking therapy referral	×	×	×	×	×	×	×	0.00
Self-harm / suicide support service referral	×	×	×	×	✓	✓	×	28.57
Other support agency/service referral	×	×	×	×	×	×	✓	14.29
Safety-plan created within the CDSS	×	✓	✓	×	✓	✓	✓	71.43

All 7 of the patients whose consultation featured use of the CDSS were offered a follow consultation in primary care. This may not be resultant from use of the CDSS, as the GP interview study (chapter 5), highlighted that booking a follow-up appointment and holding patient risk in primary-care were frequent risk management outcomes reported by GPs.

A small proportion of patients were referred to psychiatric, specialist self-harm or suicide prevention services or other support agencies. The details of the other support agencies were not recorded, but retrospectively the GP suggested it had been referral to a housing tenancy support service.

These results show that CDSS appears to possess ability to support GPs clinical decision-making and referral decisions to psychiatric, suicidality prevention and other support agencies. This apparent variation in clinical outcomes may suggest the CDSS can usefully support patient-centred preventative care, such as referral to housing support services, as well as specialist psychiatric or suicidality prevention services.

The safety plan creation feature within the CDSS was used in 71.43% of consultations. Construction of a suicide safety-plan is a process leading to a collaboratively devised, personalised plan for the patient

to take-away from the consultation, which includes practical ways to help keep the patient safe during times of distress, and which can be shared with others involved in the patient's care (Health Education England, 2018). Suicidality safety-planning amounts to a brief-cognitive behavioural intervention intended to mitigate suicidality (Stanley and Brown, 2012). It may also be considered a suicidality specific form of 'safety-netting' which is a trans-diagnostic strategy used in primary-care to reduce clinical uncertainty and to highlight circumstances in which patient's might need to seek further medical help (Edwards et al., 2019). Safety-netting was first introduced as one aspect of Neighbour's consultation model (Neighbour, 1987) and is now considered an important element of GPs practice to help patients' and carer's understanding of ways to reduce risk and how and when to seek further medical help (Royal College of General Practitioners, 2020). Recently, safety-netting has been described as a key-skill in primary-care (Jones et al., 2019). Completion of the safety-plan within the CDSS, requires additional patient interaction and data-entry beyond the risk assessment within the CDSS, taking additional time and impacting GP workflow. Utilisation of the CDSS' safety-planning facility within 71.43% of consultations, suggests that GPs found this facility useful in complementing their established safety-netting skills.

8.5.2.5 Qualitative comments on the CDSS

At the conclusion of the specific GP clinic session in which live-testing had taken place, GPs who had used the CDSS were invited to provide additional feedback on using the CDSS or its refinement.

The additional time-impact of the CDSS on GP workflow, and ease of using the system within the consultation was raised by one GP:

> "*I'm sure use of this would get easier, but if felt quite 'clunky' in an already time-consuming consultation*" (GP06)

This GP had not used the CDSS before and was reporting on use of the system within a patient consultation in which suicidality has been

discussed. Such consultations are known to be challenging, and time-consuming, requiring a lot of GPs mentally and emotionally. That the GP was willing persist with using the CDSS, even if experiencing it as 'quite clunky' is cautiously encouraging, since studies suggest repeated use of CDSS may reduce the time taken for future use of the system (Meulendijk et al., 2016). Reduced time and cognitive load required for using CDSS, as a result of increased familiarity with the CDSS, may increase perception of ease-of-use. Ease of use has been identified as a key determinant of CDSS adoption and acceptance of CDSS (Kannry et al., 2015). Therefore, further usability testing of the CDSS including repeat use by GPs is indicated, to investigate if perceptions of ease-of-use and time requirements and impact on GP workflow alter with familiarity with the CDSS.

One of the key additional benefits of the CDSS, may be in helping GPs and people in suicidality distress to talk about the experience of suicidality, as well as distal and proximal risk factors. The CDSS deliberately seeks to draw on medical and social models of suicidality, by incorporating items related to the patient's social and interpersonal functioning. One GP commented specifically upon this aspect of the CDSS:

> "*It prompts you to ask about some of the difficult things like interpersonal problems or abuse*" (GP05)

The ability of the CDSS to support GPs to have conversations with patients about interpersonal problems or abuse may constitute an important added benefit of using the CDSS, which may sometimes be overlooked in clinical risk assessment processes.

Balancing an assessment of suicidality, informed by medical, psychological and social models of suicidality within the time-constraints of a primary-care suicidality consultation is a challenge. Moreover, for the CDSS to be able to guide the GP through the assessment process in a clear and structured way, it's ease of use and ease of navigability are important concerns influencing GPs

overall sense of the benefit of the CDSS. One GP commented in this regard:

> "*Overall it is very good and self-explanatory*" (GP02)

This comment suggests that the format, ease of use and navigability were experienced as very-good by this GP, inferring that the content, lay-out and extent of end-user interaction with the system is appropriate for the demands of the primary care context.

However, this thesis has suggested that an important generative mechanism influencing GPs prospective use of the CDSS is the degree with which it supports, rather than countermand GPs' autonomy of clinical decision-making. One comment was made in this regard:

> "*It's really helpful, I appreciate the decision is still mine, but this makes it easier to review*" (GP01)

This feedback suggests that the CDSS may succeed in helping GPs to retain autonomy of clinical decision-making supported by the CDSS. Furthermore, it appears that the CDSS also succeeds in helping GPs to assess suicidality, and changes in the patient's medical, social or interpersonal risk factors, whilst facilitating patient-centred and clinically appropriate management options.

8.6 Discussion and implications

This section discusses the findings of the prototype development and usability testing study, along with important implications for CDSS development and use, as well as the clinical management of suicidality in primary care.

In non-live testing, the prototype CDSS demonstrated adequate usability and acceptability to GPs. Changes were suggested by GPs for iterative development of the tool and incorporated where possible. Subsequent live usability-testing of the CDSS showed that it possesses good clinical acceptability and is able to guide and support GP clinical-decision making in primary-care suicidality consultations.

8.6.1 Implications for CDSS development

Previously, a typology of CDSS systems was suggested consisting of classic CDSS (alerts, reminders, or prompts with regard to specific actions such as medication prescription, or ordering specific clinical investigations), information retrieval tools (to aid in the search and retrieval of clinical information based on patient specific information), and knowledge resources which provide a summary of the evidence base with regard to distinctive clinical issues pertinent to a specific care situation (Bright et al., 2012).

More complex CDSS, are referred to as "knowledge-based" CDSS (Berner, 2009), which provide layered clinical-knowledge at the point of patient contact. The suicidality CDSS (referred to here-after as the General Practice Suicidality Decision Support System, or GPS^3), can be seen as a knowledge-based CDSS which is an amalgamation of the 3 types identified in Bright et al.'s review (2012).

The GPS^3 aims to provide layered clinical knowledge, drawing on medical, social and psychological understandings of suicidality to support GP's decision-making at the point of use. Functions contained within the GPS^3 include consideration of patient specific distal and proximal suicidality risk factors, precise suicidality clinical management guidance, general references to support GPs knowledge acquisition, and a patient safety-planning utility. This combination of features matches the description of what was described as 'next generation clinical decision support' (Wu et al., 2002) deliberately seeking to link evidence and best practice.

However, knowledge-based CDSS are thought to be the least commonly encountered type of CDSS systems in clinical use (Wright et al., 2011), owing to their wider range of component features, and their comparative complexity blending 'front-end tools' (such as alerts and reminders) and 'back-end capabilities' (such as intervention planning and referral features). It is possible that knowledge based CDSS might be the least preferred CDSS among GPs owing to

perceived complexity and impact on workflow. Nevertheless, GPs in this usability study have indicated that the GPS^3 possesses adequate usability, with good adoption and acceptance rates.

These positive findings may be due to the GPS^3 integrating seamlessly into the EHR in which the prototype was built (EMIS-web), once installed properly. This integration with the EHR enabled GPs to move with ease between the GPS^3 and the patient's wider medical record.

Prior to live-testing revisions to EMIS web degraded the ability of the GPS^3 to alert GPs to the presence of read coded suicidality risk in the patient's record. These EMIS upgrades were referred to as the roll-out of EMIS "resource publisher", which replaced the module within the software for developing data-entry templates, documents and protocols. Due to technical issues occurring as a result of the upgrade, the in-built trigger Read codes, which would have prompted GPs to launch the protocol no-longer worked. All other functionality of the CDSS was not-impacted, and manual activation of the GPS^3 template resulted in display of relevant coded information, enabling GPs to appraise distal as well as proximal risk. Fortunately, the loss of trigger codes alerting GPs to consider launching the GPS^3 was mitigated by the procedure implemented in live usability testing; to only allow use of the CDSS with same-day appointments, where patients had cited mental health as the reason for the consultation.

It is possible that the loss of 'alert' features presented to GPs during live-testing (resultant from the EMIS-web upgrade) may have beneficially influenced GPs perceptions of the CDSS, since CDSS 'alert fatigue' appears to be increasingly reported by GPs (Sutton et al., 2020).

A future update of the EMIS web system may rectify the problems with the GPS^3 trigger alerts, but this had not occurred during the period of live-testing. Therefore, further research may be required to ascertain GP's perception of the trigger alerts within the GPS^3. This

may be important since it is considered that CDSS tools are likely to be easier to use when alerts intrude minimally into GPs workflow (Richardson et al., 2017).

Overall, the ease of use, acceptance, and navigability of the GPS^3 appears to be experienced as appropriate by GPs. In keeping with currently established best practice in CDSS development (Richardson et al., 2017), the GPS^3 attempts to provide obvious workflow through the different sections of the CDSS, using clear and easy to understand wording, and altering the appearance of important text to draw GPs attention to specific features. The data obtained from the GP end-users is encouraging, since CDSS development must maintain a focus on the end-user experience if CDSS systems are to be implemented in practice (Ash et al., 2010). The usability data suggests that the GPS^3 can contribute to clinician's clinical decision-making processes by assisting GPs with clinically appropriate assessment, estimating the urgency of risk, selecting optimal interventions and working with the patient to mitigate risk and create a safety plan.

The usability study has shown that the framework for CDSS development and initial evaluation proposed by Kannry and colleagues (2015) is applicable to complex knowledge based CDSS. The CDSS development framework (Kannry et al., 2015) was conceived in-relation to the development of a more simplistic CDSS, a clinical prediction rule which functioned as a medication prescription aid (McGinn et al., 2013b). This current study supports and extends Kannry and colleagues CDSS development framework, to show how it may be used to iteratively develop and evaluate complex knowledge based CDSS.

The iterative approach underpinning the development of the GPS^3, has featured robust co-production processes, with service-users, GPs and key stakeholders. The high level of GP involvement in the development of the GPS^3 has been key, since physician input is vital

for adoption of CDSS in practice (Katz, 2013). This is necessary to enhance the perceived legitimacy of the CDSS, and to ensure its characteristics fit as best possible, with the demands of GP practice and the primary-care context.

The pragmatic inter-weaving of top-down and bottom-up processes underpinning the GPS^3 design, development and evaluation, has sought to be guided by the meta-theoretical perspective of critical realism, and application of Bhaskar's trinity of ontological realism, epistemological relativism, and judgemental rationality. The flexibility provided by the meta-theoretical perspective, allows abduction and retroduction to explore generative mechanisms, powers and potentials influencing prospective use of the suicidality CDSS. The relative fluency with which the CDSS supports GPs and patients to work together during suicidality consultations may be one such transfactual mechanism, which has been highlighted as a result of the underpinning theoretical and trans-disciplinary insights afforded by critical realism.

8.6.2 Implications for suicidality prevention in primary care

The usability study has highlighted important considerations for the clinical practice of suicidality assessment and management in primary care. Clinical assessment of suicidality requires a comprehensive and holistic assessment to identify modifiable risk factors (Clibbens, 2019). Comprehensive assessment, requires structured professional investigation and judgement, of actuarial and dynamic risk factors (Bouch and Marshall, 2005). This usability study suggests that the GPS^3 offers potential to assist GPs with the known clinical, emotional, and practical challenges of identifying, assessing and managing suicidality in primary care.

An important impact of the GPS^3 may be on GP referral decisions and referral pathways. Typically, suicidality referral decisions might involve consideration of referral to crisis resolution and home

treatment teams, or other secondary mental-health services (Michail and Tait, 2016; Saini et al., 2015). However, studies highlight sometimes referral pathways can be difficult and time-consuming for GPs (Michail and Tait, 2016; Saini et al., 2015). This difficulty referring patients at risk may interact with GPs experiences of high workloads and the emotional intensity of their role (Riley et al., 2018), along with the economic and resource pressures on the NHS which potentially influence GPs gate-keeping decisions (Majeed, 2013). Thus, there is the possibility that appropriate referrals are dissuaded by these contextual challenges which GPs face. The benefits of using the GPS^3 are multifaceted but include consideration of distal and proximal risk in relation to indicated clinical management and referral options. These features may support and encourage GPs to persevere with referral to specialist mental-health services or crisis teams when indicated, even if the referral process has previously been experienced negatively, such as the GP in chapter four who described CRHT referral processes as *'a game of hot potato as to who takes responsibility'* for suicidality patients.

In addition to its possible impact on referral pathways, and medicalised understandings of suicidality, the data at hand suggests that to a small but important degree, the GPS^3 may support and enable GPs and patients to discuss and understand suicidality from different conceptual standpoints including medical, social and psychological perspectives.

Furthermore, the GPS^3 appears to exhibit appropriate acceptability within the primary-context, and a degree of fit with the hidden processes' characteristic of a primary-care consultation. These include the switching of linguistic codes, with reference to the Habermasian concepts of the medical linguistic register belonging to the systems world, and the patient's natural or life-world language (Woods, 2006, Barry et al., 2001). This linguistic switching occurs as the GP moves between appraisal of the patient's suicidality risk and their internal

calibration of that risk with external reference data, such as population norms, and statistical knowledge about risk factors. This is the process referred to as striving to balance the narrative and normative aspects of primary-care consultation (Launer, 2019). This process may also reflect the GP's proposed movement between system 1 and system 2 cognitive styles of clinical reasoning (Croskerry, 2009) proposed as key aspects of GPs clinical reasoning when working with uncertainty (Silvério Rodrigues et al., 2019). This complex balancing act of interpersonal and intrapersonal processes is required so that patients can feel that their experience has been heard and validated, and at the same time, GPs can fulfil their duties to both the patient and their role within the wider healthcare system.

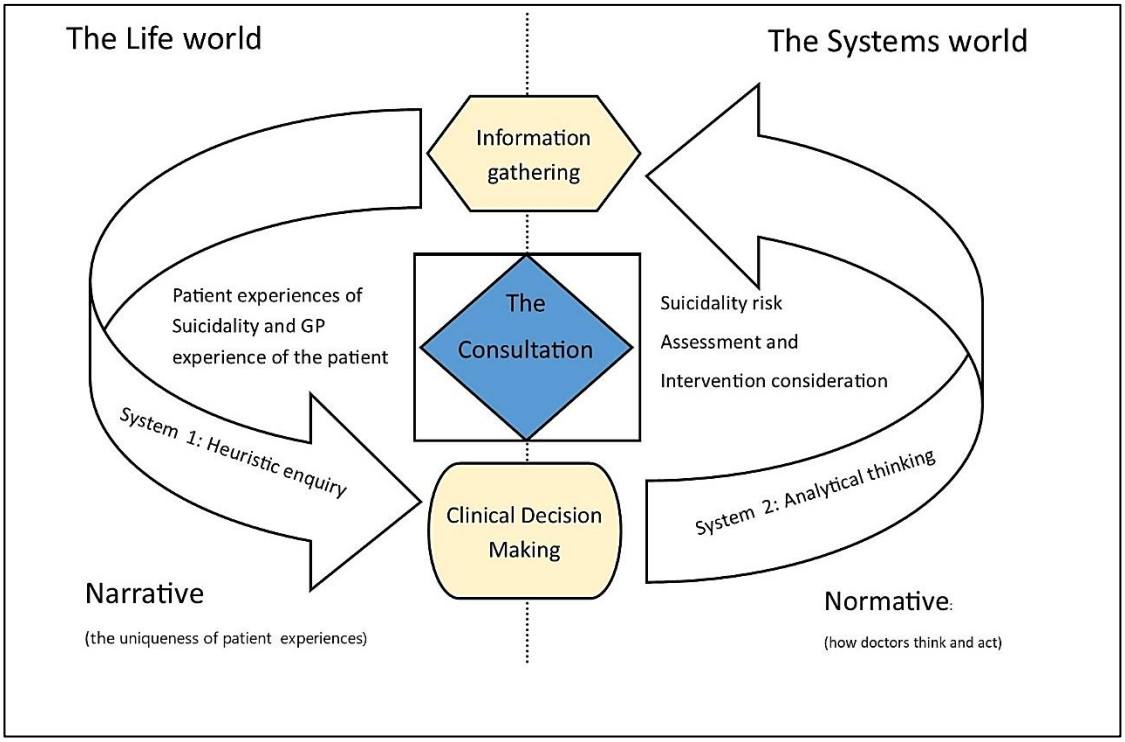
Thus, it is suggested that there are a number of facets of a suicidality consultation in which risk is openly discussed and appropriately managed, so that patient's perceive their experience of suicidality has been heard and witnessed, and GPs can be reassured that they have fulfilled their role appropriately. These facets include

- the mediation of life-world and systems-world considerations
- A reconciliation between normative and narrative process
- GPs balancing quick and analytical cognition, allowing appraisal of suicidality risk

Such a suicidality consultation, where GPs and patients are interpersonally engaged, where risk is openly discussed, and the risk-assessment demands of the system-world satisfied, moves beyond the GP attending to the life-world of the patient and empathising. Though the experience of being heard and receiving empathy is a well-established factor within clinical consultation literature (Bowie et al., 2014), a consultation meeting the needs of patients, GPs and the systemworld requires more than empathy. It also requires shared decision-making in relation to suicidality risk.

Beyond the concept of empathy, the idea of 'co-bearing' the emotional strain of suicidality consultations has been proposed (Dunkley et al., 2017). Co-bearing suggests doctors and patients can work together as a team, to share the emotional load experienced by discussing and assessing suicidality. Though a theoretical construct, co-bearing may define consultations in which genuine shared decision-making takes place, with risk and emotional strain shared between GPs and patients. The potential role of the GPS^3 may therefore be both facilitative and supportive of shared decision-making and the process of co-bearing suicidality consultations. Such a proposed process may be depicted as Figure 8-21

Figure 8-20: Consultation featuring use of the GPS3, (adapted from Dunkley et al.,2017, Launer, 2019, Brown & Gale, 2018)



This postulated view of the GPS^3 as possessing practical and theoretical value in assisting GPs and patients to reconcile normative and narrative demands, and to navigate the demands of both life-world and system-world considerations is hinted at in GP's endorsement that use of the GPS^3 enabled discussion "*of the difficult things like interpersonal problems or abuse*"

The potential of CDSS systems, to help GPs and patients to discuss and to manage the emotional toll of discussing sensitive and emotionally charged experiences, such as suicidality, is under-explored in the literature. Further research is required to investigate this facet of CDSS use in more depth, and follow-on research is planned with patients and GPs, to determine the processes or mechanisms which might be most facilitative in this regard.

8.6.3 Strengths and limitations

8.6.3.1 Strengths

The key strength of this study is that the prototype GPS^3 was created through a rigorous stakeholder consensus process grounded in the realities of general practice and reflecting the lived experience of patients and GPs. The prototype was subjected to non-live and live usability testing, presenting real-world data relevant to its evaluation. The under-pinning meta-theoretical perspective of CR has helped elucidate generative mechanisms influencing use of the CDSS, and provide a trans-disciplinary framework for its initial evaluation.

8.6.3.2 Limitations

The methodology used in the usability study does have limitations, including a small sample size, and restrictive use of a single test-site GP practice, where the GP medical team frequently encounter suicidality. The existing expertise of the GP team may introduce bias into their evaluation of the CDSS, as they may be comparing it against well-established norms and processes in their practice.

The limitations of small sample and single test-site practice are typical in CDSS usability studies (Richardson et al., 2017), but are offset by the importance of live-testing providing insights regarding the CDSS' ease of use, utility and extent to which it impacts on the healthcare consultation (Richardson et al., 2019). It has been argued that relatively small sample sizes are sufficient to elicit the most

commonly occurring usability problems; whereas a fairly large number of end-users would be needed to reliably measure the frequency and impact of rarer usability problems (Nielsen 1993, p104).

A further limitation refers to the GP suggesting use of the GPS^3 was experienced as time-consuming and 'clunky'. Such experiences might improve with repetition of use, since it has been argued repeated use of CDSS systems is likely to reduce the total time taken to complete constituent tasks within a system (Meulendijk et al., 2016). Further research is required to extend and expand upon the usability testing conducted to date, and is discussed in the next section

8.6.3.3 Implications for further research

This study has important implications for further research.

Firstly, further longitudinal research would be required to map the impact of the GPS^3 on referral rates and pathways, but the combination of structured risk assessment and indicated clinical management options may usefully assist GPs with referral decisions.

Part of the process of clinical decision-making, including referral decisions, involves the calibration of system one and two clinical reasoning styles (Croskerry, 2009). The extent to which the GPS^3 may help or hinder GPs clinical reasoning could also be explored in relation to suicidality assessment and clinical management. This is important since it is suspected that the main flaws in clinical decision-making result from the way in which doctors think, rather than deficits in clinical knowledge (Silvério Rodrigues et al., 2019). Thus, the ability of the GPS^3 to help GPs discern which patients are suitable for maintaining in primary care, from those more obviously requiring referral to specialist services may be an important aspect for future research.

Secondly, future usability testing could include multiple GP practices, especially those where GPs are less frequently exposed to suicidality, or GP practices in varying geographic locations, and with higher variation in patient demographics.

Thirdly, future research could also seek to gain a greater understanding of patients' experience of consultations in which the GPS^3 was used. This is important because patient satisfaction with consultations featuring use of the CDSS could mediate GPs adoption of the CDSS. However, the current study captured no patient identifiable data, and no direct feedback from patients, about their experience of the CDSS.

8.7 Conclusion

This chapter has reported a prototype build and usability testing study of a suicidality CDSS for use in primary care consultations. Mixed but encouraging data has been obtained on GPs' experience of using the GPS^3 in supporting clinical decision-making in relation to patient suicidality in primary care. Further research is warranted to gain a more complete insight into the way in which the GPS^3 might be used and experienced by a wider range of doctors and primary care health professionals, and the patients in their clinics. Whilst further work is indicated, the GPS^3 may represent an important contribution to the discussion regarding ways in which to support GPs ability to work with patient suicidality, and improving primary care suicidality consultations.

Chapter 9: Discussion and Conclusion

9.1 Introduction

This thesis aimed to develop an electronic Clinical-decision Support System (CDSS) to assist GPs with the identification, assessment and management of suicidality in primary care consultations. The content, format, design and prospective use of the CDSS was informed by the extant literature across the disciplines of psychology, psychiatry, public health and implementation science; but crucially grounded in the realities of general practice and shaped by the experiential knowledge of patients. This is the first CDSS for use in primary care consultations for the improved assessment and management of suicidality. Findings from an initial usability testing evaluation suggest that the CDSS has the potential to be a clinically useful tool for assessing suicide risk in primary care by supporting GPs' clinical decision-making process whilst facilitating difficult conversations about suicide during a consultation.

9.1.1 Key findings

Interviews with GPs (Chapter 5) exploring their perspectives on the format, content and use of a suicidality CDSS, and generative mechanisms which might influence their practice, demonstrated the following key issues:

i) There is great variability in how GPs understand and conceptualise suicide risk, which subsequently impacts on their clinical decision-making process.

ii) Whilst some GPs use existing suicide risk assessment scales or tools, or abridge content from such tools to inform their practice, there is currently no standardised way of assessing, working with, or recording suicidality in the EHR. This introduces significant variability in practice, which could potentially have medico-legal consequences, whilst preventing GPs from offering personalised care.

iii) An evidence-based CDSS, informed by practitioner expertise could provide a standardised method of recording risk history or risk factors and support GP decision-making when working with patients experiencing suicidality.

iv) The CDSS must be able to be used flexibly so as to fit with various consultation styles, and to minimise the potential of the CDSS intruding on the inter-personal aspect of the consultation.

The potential for a suicidality CDSS to help improve quality of care was also explored with 2 patient advisory groups (Chapter 6). Findings from 6 consultations with the groups demonstrated that:

i) Involving patients in embedded consultation groups enabled co-production of CDSS content, and highlighted potential generative mechanisms influencing use of the CDSS in consultations.

ii) Participants reported difficulties raising suicidality as the reason for GP consultation at the point of booking. Similarly, during some consultations talking about suicide was experienced as difficult for both patients and GPs.

iii) GPs likely vary in their attitudes and skills in relation to working with patient experiences of suicidality. GPs who were able to offer a collaborative, inter-personal interaction, were experienced as more emotionally supportive and more helpful than GPs who were more emotionally distant in their approach.

iv) Participants recognised that GP's role is partly to assess risk and refer onwards, but the difficulties providing continuity of care meant that personalised assessment of

risk and personalised suggestions for managing risk were often lacking.

v) The CDSS could have important contribution to improving access to care, easing the process of talking about suicidality in consultation for both GPs and patients, and improving personalised care-planning.

Building on the insights of GPs and patients with lived experience of suicidality consultations, an expert panel was recruited, and a modified Delphi expert consensus study conducted (Chapter 7), for the purposes of refining and tailoring the content of the CDSS. Findings from this study demonstrated that:

i) A modified Delphi process was acceptable to agree face and content validity of CDSS items, and when supplemented by a theory-led qualitative workshop, led to refinement of CDSS content, format and prospective use, leading to a co-produced CDSS.

ii) Content of the CDSS must be relevant to the needs of GPs and patients in primary-care suicidality consultations, and take into account contextual factors such as time-pressures.

iii) Data entry into the CDSS must be brief, and limited, so as not to detract from the inter-personal aspects of the consultation.

iv) Contextual generative mechanisms may influence GPs use of the CDSS, and any future implementation of the CDSS will need to take into account the dynamic nature of generative mechanisms, some of which may occur across domains of established implementation theories.

In the final empirical study (Chapter 8), a prototype version of the CDSS was developed within EMIS web in collaboration with PRIMIS. The CDSS was built in and fully integrated into the EHR with the purpose of facilitating assessment and management of suicidality in primary care consultations.

The CDSS used Read coding to present clinically significant distal risk factors in the patients' history and guide the end-user through a brief assessment of patient suicidality, whilst offering the ability to record additional read codes into the patient's record. Codes that can be added during the consultation include items such as interpersonal relationship problem, financial stressor or substance use. This ability to add new codes during a consultation is important as some patients reveal information at different time points, in different consultations, or with different GPs. The safety-plan creation function allows for personal coping strategies and resources to be recorded. The safety-plans are retrievable as documents linked to a dated consultation, meaning they can be retrieved at a future date.

An initial usability testing evaluation was subsequently carried out with GPs from the University of Nottingham practice. The usability study highlighted that the following:

i) GPs rated that the CDSS in its prototype form possesses adequate usability, and is acceptable to GPs, particularly in terms of its ease of use, content, and navigability between sections of the CDSS.

ii) The CDSS demonstrated good adoption rates (frequency of use 77.8%) and acceptance rates (compliance with care-planning recommendations 85.7%) and appears to effectively support GPs clinical-decision making, across patients who may have variable risk-profiles.

iii) Use of the CDSS may beneficially impact on care-decisions, by supporting GPs to assess urgency of support needs and

make tailored care-planning decisions, such as determining when patients might need referral to appropriate services.

iv) In contrast with GPs' fears about the CDSS detracting from patient interactions during consultation, GPs reported that using the CDSS facilitated conversations about "*some of the difficult things*", such as interpersonal relationships, or abuse histories, and usefully supported their clinical decision-making.

v) The findings from the usability study suggest that the CDSS warrants further consideration as a quality-improvement initiative within primary care.

9.2 Suicide prevention in primary care: the unique contribution of the CDSS

This research has shown that the GPS[3], as a prototype knowledge based CDSS, has potential to improve the assessment and clinical management of suicidality in primary care.

Suicide prevention in healthcare falls somewhere between psychiatric, public health and primary care specialities. Within the suicidality prevention literature, psychiatry has been proposed as the primary medical speciality in suicidality prevention (Bertolote, 2004). In contrast, others have argued, that primary care has an important, yet too often unrealised, potential to mitigate suicidality (Haste et al., 1998; Milton et al., 1999; Mughal et al., 2019; Schulberg et al., 2004). This thesis argues that primary care has a key role to play, in mitigating suicidality, alongside public health and psychiatry, since suicide prevention often requires a multi-faceted approach with primary care as the bedrock of the health system (Michail et al., 2020).

The prominence of primary care as a key setting for suicidality prevention is underlined by NICE guidance, which states that primary

care has an important role in the assessment and treatment of suicidality (National Institute for Health and Social Care Excellence, 2004). However, historically GPs have reported that systematic training for working with suicidality has rarely been provided, with fewer than half of GPs reporting any formal training on working with suicidality (Bajaj et al., 2008). Whilst specific suicidality training could help GPs to more consistently identify warning signs and risk factors (Michail et al., 2017), myriad barriers exist making it difficult for GPs to access such training, including time constraints and lack of perceived need among the specific GPs who might most benefit from such training (Appleby et al., 2000; Morriss et al., 2005). Moreover, when GPs are able to access suicidality prevention training, the impact on reducing mortality, suicidality attempts or improving patient care is difficult to ascertain due to conflicting findings and significant methodological heterogeneity in the research (Milner et al., 2017). The wide scale training of GPs is therefore not supported by the existing research evidence, posing a need for an alternative approach. This is particularly evident since studies show some GPs fail to assess suicidality when patients present with established risk factors (Bajaj et al., 2008; Feldman et al., 2007; Hooper et al., 2012).

As an evidence-based alternative to GP training, the CDSS is a targeted initiative to improve suicide prevention in primary care by transforming GPs ability to assess and manage suicidality.

CDSSs have shown important abilities to improve preventative and ambulatory care (Sutton et al., 2020), where they may be particularly useful in promoting preventative care-planning, supporting prescribing decisions, and ordering clinical investigations (Bright et al., 2012).

CDSSs have been successfully used in primary-care in relation to a range of clinical presentations, including asthma (Bousquet, 2019) cardiovascular disease (Groenhof et al., 2019), and depression care

management (Fortney et al., 2010), as well as assisting GPs with risk of medication prescription error (Avery et al., 2012), and diagnostic reasoning in relation to chest-pain and shortness of breath (Kostopoulou et al., 2017). However, there has been a lack of an evidence-based CDSS to assist GPs with their indentation, assessment and care-planning, in relation to patients who may be at risk of suicidality.

The value of such a tool has been highlighted in the NHS Long Term Plan (NHS England, 2019b), which called for a suicidality specific CDSS to improve GPs ability to deliver more personalised care for people at suicidality risk.

The CDSS developed in this research (the GPS^3) therefore has significant implementation potential. The GPS^3 is the first suicidality specific CDSS which is evidence-based, designed for use in primary-care and which was co-produced with expert stakeholders, GPs and primary care patients.

The prototype has demonstrated its ability to support GPs clinical-decision making when assessing and care-planning with patients at risk of suicidality.

The GPS^3 is an optimal solution for improving suicidality prevention in primary care and supporting GPs ability to identify, assess and care-plan with patients who may be at risk of suicidality within the primary care context.

9.3 Decision-making: the interactions of structure and agency

Decision-making in the primary care context is subject to a dynamic inter-weaving of contextual generative mechanisms, agential actions on the part of patients and GPs, and structural entities influencing the consultation.

Generative mechanisms, such as suicide stigma, and time pressures born of healthcare rationing in a capitalist society, may come-together with variation in GPs knowledge, skills and personal characteristics, as well as patients decision to disclose or withhold suicidality related information, to lead some GPs and patients to engage in tacit collusion, to not ask about, or disclose suicidality during consultations (Quinnett, 2019).

The GPS^3 may go someway towards addressing these intransitive aspects of the consultation, by alerting GPs toward evidence based risk factors read-coded in the patient's record, by providing suggested prompts GPs could ask patients within a structured assessment of suicidality and providing a standardised way of recording the outcome of the consultation in the EHR.

Patients have also suggested that should the GPS^3 be implemented, it may ease the process of raising suicidality within consultation, potentially improving access to care, and supporting more personalised care-planning.

Therefore, the GPS^3 may have important characteristics enabling GPs and patients to talk about suicidality, including any underpinning factors potentially mediating risk, such as issues and disruptions in patient's inter-personal lives, or personal histories of trauma and abuse. Such underpinning factors might be topic areas which GPs sometimes find difficult to ask patients about.

The GPS^3 may then navigate some of the often-unacknowledged contextual generative mechanisms pertinent to healthcare consultations, whilst being shaped by structural entities in primary care, and attempting to account for agential actions on the part of GPs and patients. The CDSS may achieve some of this by encouraging and guiding a more-personalised consultation about suicidality risk within the patient's life-world, and promoting personalised care-planning. The evidence within this research suggests the CDSS can support doctors and patients working

collaboratively, in discussing and assessing suicidality. The CDSS therefore may demonstrate relative fluency in supporting GPs and patients to share the emotional load within suicidality consultations, (Co-bearing, Dunkley et al.,2017). Co-bearing, or openly discussing suicidality, within the interpersonal aspect of the consultation, appears supported by the GPS^3. Moreover, the GPS^3 may also enable GPs and patients to reconcile normative and narrative aspects of the consultation and to navigate the interacting elements of both life-world and system-world considerations. Such considerations may be viewed as often hidden, but real aspects of primary-care suicidality consultations. The GPS^3 therefore may support decision-making amongst the complex interweaving of context, structural entities, agential actions, and underpinning generative mechanisms.

9.4 A computer mediated consultation

It has been suggested that assessing patient suicidality requires consideration of evidence-based risk factors, with individual patient factors, in a process of structured professional judgement (Bouch and Marshall, 2005). Such a process should consider both distal and proximal risk (Rudd et al., 2006) and recognise the complex, multifaceted nature of suicidality which can occur across biological, psychological, social, and contextual domains (McClure, 2000; Wasserman, 2016). It is the assessing clinician's synthesis of information and judgement of risk which is the final arbiter of the outcome of the suicidality assessment (Sequeira et al., 2019). Given the noted limitations of suicidality predication and risk assessment research (Franklin et al., 2017), supporting GPs' synthesis of patient's personal risk information is important.

The CDSS can promote such a synthesis by enabling structured decision making informed by patient's distal risk factors, warning signs, and psychosocial circumstances.

However, studies reporting on the implementation of new EHRs or CDSSs, suggest at time use of such systems may lead to inaccurate diagnosis, incorrectly prescribed medication or inappropriate treatment plans (Campbell et al., 2006; Weiner et al., 2007). Conversely, other studies suggest that CDSS use may contribute to improved doctor-patient communication and collaboration (Doyle et al., 2012) whilst enhancing preventive care, adherence to clinical guidelines and reducing medication prescription errors (Kawamoto et al., 2005).

It has long been feared that the increasing use of computers within GP consultations runs the risk of the computer system becoming a de-facto third party in the consultation, negatively impacting the reciprocal patterns of communication and patients' experience of personalised care (Pearce et al., 2011). This fear may be particularly pertinent to suicidality consultations, given their interpersonal, emotional and psychological complexity. For example, when clinicians are perceived as attending more to computerised risk assessment, undertaken for the benefit of 'the system', rather than the patient, some patients may choose to conceal risk information (Ganzini et al., 2013). Critics of CDSSs may therefore continue to see them as devices which turn clinicians into administrative bureaucrats and patients into a standardised digital entity lacking a personal narrative (Hunt et al., 2017). Such fears may stem from doctor's fear of losing professional autonomy and freedom of choice (Khairat et al., 2018) which can lead to a sense of demotivation and professional devaluation (Vashitz et al., 2009). From such a perspective, CDSSs seem unlikely to be of benefit in emotive and complex, 'high stakes' suicidality consultations. However, there is no evidence that the suicidality CDSS exerted a negative impact on consultations during usability testing in this thesis. Conversely, one GP reported that the way the CDSS guided the assessment and presented information for consideration yet left the GP to make their own clinical decision was "*really helpful*" as "*the decision is still mine, but this makes it easier*

to review". This finding contrasts somewhat with existing literature, which suggests automatically produced clinical recommendations, not requiring clinician engagement with the CDSS, may be more likely to be accepted by doctors (Kawamoto et al., 2005). However, it is possible that the high stakes nature of suicidality consultations means GPs would not feel comfortable leaving decision-making to automated processes. Medico-legal concerns and RCGP guidance to engage the patient in a structured and collaborative assessment likely further dissuade GPs from devolving responsibility for clinical decisions regarding patient suicidality to the computer.

Active engagement of GPs with CDSS systems may promote development of enhanced mental models of assessing and care-planning for a given presentation (Greenes et al., 2018). In this way active use of a CDSS may assist the development of clinical reasoning, leading to the use of a hybrid intelligence of the clinician and the CDSS (van Baalen et al., 2021). The CDSS therefore potentially possess an educational value for GPs who do not have a well-developed or accurate heuristic of suicidality risk. The educational value of CDSS use is under-explored in the literature; however, it is likely that if GPs engage with CDSS systems they may gain improved clinical reasoning regarding the conditions targeted by a CDSS. Engagement with the conceptualisation of suicidality contained within the CDSS could prove corrective to erroneous heuristics, which feature in some GPs mental-models of suicidality, such as lack of eye-contact signifying suicidality. Direct eye contact may denote a patients level of comfort and engagement in a consultation (Wachter, 2015). Conversely, direct eye contact or avoidance thereof, is also a culturally determined behaviour reflecting cultural norms and values (Akechi et al., 2013), irrespective of engagement in a consultation.

Furthermore, the impact of the CDSS in recording more personally specific information may be another important aspect of the CDSS. Patients' specific coping strategies can be retained and reviewed in

the safety plan document, whilst the suicidality assessment section allows for more of the patient's psychosocial circumstances to be quickly and easily read-coded. The CDSS thus enables the capture of more of patients' personal experiences and psychosocial circumstances alongside more static or distal risk factors. These aspects of the CDSS amount to improved recording of patients' specific mediators of their experience of suicidality.

Retaining more of a patients' specific experience of suicidality may improve the ability of primary care to offer a patient-centred consultation, potentially over-coming some of the known difficulties in many practices with seeing the same GP for repeat appointments, due to patient demand, workforce shortages, resource limitations and bureaucratic requirements (Hobbs et al., 2016; Riley et al., 2018).

However, the extent to which the CDSS can truly facilitate a patient-centred consultation may depend on the way in which it is used within a consultation. It has been argued that patient-centred use of EHR systems is possible, a 'triangle of trust' can be created between the patient, the health professional and the computer (Lee et al., 2017). Clinicians ability to create the triangle of trust and deliver a patient-centred consultation whilst using the EHR or an embedded CDSS may be modifiable through training and repeated practice (Alkureishi et al., 2018). Proponents of such a view argue that patient-centred use of technology should be incorporated into medical school curricula (Simpkin et al., 2017) in order to deliver optimal patient-centred and humanistic care. The extent to which the suicidality CDSS enables or constrains a patient-centred consultation is not yet fully known and warrants further investigation. Similarly, development of a training package for GPs on reconciling use of the CDSS and patient-centred care may be warranted. Nevertheless, it is possible that the CDSS may have some potential to improve the personalised aspect of primary-care practice, capturing more of the patient's personal experience, as well as considerations the GP needs to be thinking about such as risk recording and management. This

potential dichotomy between a patients personal experience, and the things which make clinical sense to a GP, has been described as the narrative and normative realities within a consultation (Launer, 2019). According to Launer (2019), an effective consultation is one in which the GP can engage with and track the patients narrative, yet adapting it for the GPs normative purposes.

This contrast between the way in which patients might present their experience of suicidality, and the way in which GPs are required to make sense of them could also reflect the theoretical dualism between the concerns of the lifeworld and the systemworld (Habermas, 1985). This dualism has been suggested as observable in primary care practice (Mishler, 1984) with GP interactions taking place at the crossroads of the lifeworld and systemworld (Greenhalgh, 2014). This difference between patients ways of communicating their experiences of suicidality and clinicians' conceptualisation of suicidality risk has also been suggested as characterising suicidality consultations (Dunkley et al., 2017). Greenhalgh (2014) reminds us that within the consultation, the voice of technology is a third mediator of communication within and between doctors and patients. The degree to which the suicidality CDSS enables or constrains GPs and patients' conversations about suicidality, is therefore a particularly important consideration. The CDSS may possess capability to help GPs engage in conversations about lifeworld, such as the GP who found the CDSS helped "*to ask about some of the difficult things like interpersonal problems or abuse*". The CDSS may also simultaneously possess the capacity to turn patient's personal experiences into artefacts of the system world, such as read-codes, risk histories, referral actions and depersonalised patient histories, reflecting Habermas' (1985) notion of the systemworld corrupting the lifeworld. In order to explore how the CDSS enables or restrains communication about suicidality within consultation further research may be warranted. GPs and patients experience of the CDSS and its impact on the consultation may be illuminating in this regard. At

present the evidence is limited, but the CDSS appears to have some merit in mediating the competing demands of narrative or lifeworld and normative or systemworld, concerns within suicidality consultations. As such, the CDSS can therefore be seen as a potential quality improvement solution intended to help GPs navigate the challenges of suicidality prevention in primary-care.

9.5 The implementation of the CDSS in primary care

Quality Improvement (QI) programmes in healthcare have been defined as attempts to make healthcare safer, more effective, more equitable and more efficient (The Health Foundation, 2013). The end result of QI should lead to improved patient experiences of care, better outcomes, and enhanced clinician development (Batalden and Davidoff, 2007).

The GPS^3 is a targeted initiative designed for use in primary care, informed by QI principles, and based on experiences of GPs, patients and expert stakeholders. The GPS3 has been designed to be used flexibly within consultations, and to account for the demands of the primary care culture and context. Such concerns reflect established theoretical considerations of the CFIR (Damschroeder et al., 2009), and the Achieving Change in Primary-Care model (ACiPC) (Lau et al., 2016) which highlight socioecological complexity.

Consideration of context and culture is also increasingly embraced within advances in patient safety research which is moving away from its historical focus on adverse events, toward exploring what promotes safer care in routine practice (Braithwaite et al., 2015). From such a perspective, research ought to place an increased emphasis on what helps mitigate and, not just what might precipitate, suicidality. The prospective contribution of suicidality consultations featuring the CDSS is inconclusive; however, it is possible that CDSSs may have an important contribution toward improving patient safety in routine practice (Khairat et al., 2018). It

has been argued that effective suicidality prevention requires a confluence of patient safety, suicidality prevention and public health perspectives (Quinlivan et al., 2020). The suicidality CDSS may be seen as a step towards bringing together these contrasting perspectives, as a targeted primary-care QI development.

However, successful implementation of CDSSs is known to be difficult, and requires such systems to be perceived as useful and pragmatic (Kawamoto et al., 2005), whilst scaffolding clinicians knowledge and decision-making capacities yet not reducing clinicians professional autonomy (Khairat et al., 2018).

Furthermore, successful technology based QI in primary care requires an enabling organisational culture, facilitative workflows and processes within GP practices, existing high functioning IT systems, and end-user familiarity with using such systems (Higgins et al., 2015). The primary care context therefore offers particular challenges pertinent to the development of the suicidality CDSS.

Successful CDSS systems aspire to balance acceptability to clinicians and patients, with high performance in providing actionable decision support during a consultation, whilst also improving adherence to guideline based care (Richard et al., 2020). The evidence from this thesis is inconclusive, yet suggests that a moderate degree of success has been achieved and the suicidality CDSS is a novel attempt at QI in primary care.

9.5.1 The implication of the Covid-19 context

Since the empirical studies within this thesis were conducted, the primary care context has been faced with significant challenges stemming from the SARS-C0V-2 covid-19 pandemic and its consequences.

In the early stages of the pandemic, in order to mitigate against possible contagion, primary care across England made a rapid change with a massive increase in the number of GP consultations

undertaken as remote consultations using telephone, or online video consultation platforms. The pace and scale of this change to remote consultation, has been described as possibly the fastest and most extensive scale up of a major service innovation since the NHS was created (Wherton et al., 2020).

Studies show that in a number of locations, greater than 90% of GP consultations were switched from face to face, to remote consultation (Murphy et al., 2021). Moreover, it has been suggested that the growth in remote consultations has allowed for a substantial increase in the overall number of GP consultations (Green et al., 2022).

At the same time, the pandemic and its consequences have created an unprecedented demand for GP consultations. The increased demand may relate to physical illness after covid-19 infection, or consequences of the pandemic affecting economic, psychological and interpersonal wellbeing. A pooled analysis of cohort studies suggests deterioration in mental health occurred at population level, as a result of living through the pandemic, and which might be sustained and maintained by increased financial stress and disruptions to daily life and social relationships (Patel et al., 2022). Globally, the pandemic has been associated with increased levels of mental health distress across population groups, with increased reporting of symptoms associated with depression, anxiety, sleep disturbance and psychological trauma (Dragioti et al., 2022).

The increased prevalence of symptoms associated with mental health distress may also increase suicidality (Mughal et al., 2021). Fortunately, initial data has not confirmed a significant rise in suicidality across England, despite greater reported psychological distress (Appleby et al., 2021). However, the pandemic's impact on suicidality is complex and may continue to evolve over time (Sinyor et al., 2022). Against this backdrop of potential rising suicidality, GPs are advised to watch for heightened suicidality risk amongst their patients, to discuss safety plans, signpost to self-care and other

resources, follow up with active surveillance of increasing risk, and to consider onward referral to mental health services (Mughal et al., 2021). These indicated actions could be supported by the GPS^3, with its ability to support identification, clinical assessment, care planning and safety planning in relation to patient suicidality.

Working with risky presentations on a remote basis in primary care is challenging and complex, but current research is ongoing to explore the best way to sustain safe remote working in primary care (Rosen and Greenhalgh, 2022). It is likely that a range of strategies will be needed to increase the safety of remote consultations, including careful triage of presenting problems and patient's documented history in the EHR, attention to active listening and eliciting information, checking patient's understandings and using video consultation as opposed to telephone calls (Rosen and Greenhalgh, 2022). Templates, such as the GPS^3, which are integrated within the patient's EHR, which possess ease of use and which can highlight risk information whilst guiding triage and assessment, may be particularly valuable in supporting remote consultation, but further research will be required.

9.6 Strengths and limitations

This section provides a critical synthesis of the strengths and limitations of the work undertaken as part of this thesis.

9.6.1 Strengths

This real-world research seeks to address a challenging clinical practice issue, where patients' lives, and GP wellbeing, maybe at stake. The gravitas of the topic area, and the attempt to support GPs in their work via the novel solution of a suicidality CDSS amounts to an important original contribution to knowledge.

As far as the research student is aware, there is no other co-produced and empirically evaluated suicidality CDSS in use, and none built purposefully to integrate with EHR systems in primary care.

The CDSS is a novel attempt at overcoming the known challenges of improving suicidality prevention in primary care. The CDSS aims to overcome these challenges and support more personalised risk assessment and care-planning, which may contribute to enhanced patient safety.

The CDSS has demonstrated encouraging potential to help GPs identify, assess and care-plan with patients who may be at risk of suicidality and represents a novel contribution to the evidence-base in this area. The CDSS has real implementation potential informed by the wider policy context including the NHS Long Term Plan (NHS England, 2019b), which recently called for a suicidality specific CDSS to improve healthcare professionals' ability to deliver more personalised care for people at suicidality risk.

Given the complexity of suicidality, neither quantitative, nor qualitative research alone enables sufficiently adequate explanatory research in this area (Goldney, 2002). From this perspective, a mixed-methods study underpinned by critical realism was particularly suited to the task of trying to develop domain specific theory relating to the potential use of the CDSS, as well as guiding and enabling and the development and usability evaluation of the CDSS.

9.6.2 Limitations

Methodological problems are common to much of the existing research in suicidality prevention, and studies in this area often suffer from small sample sizes, short follow-up, biases in design, and inadequate control groups (De Leo, 2002). These problems are often inherent in suicidality research (De Leo, 2002) and doctoral research projects (Mason, 2010).

These criticisms may all be levelled at this body of work, such as small sample sizes and purposive recruitment strategies for the GP interview, patient advisory groups and co-production studies. Similarly, small sample size and purposive recruitment were also characteristics of the usability study; however, small sample size is

typical for usability studies, yet considered adequate to elicit the majority of usability problems (Richardson et al., 2019). Methodologically, the limitations of small sample size and purposive sampling confer limited generalisability of the findings and may reduce confidence with which the CDSS might be seen to be applicable to other GP practices and primary-care organisations.

However, the low base rates of suicidality make it difficult to find clinicians and patients who have salient first-hand experience to share, therefore the participants within this thesis amount to an important purposive sample of people with experience of suicidality consultations, able to inform the development of the CDSS and provide some answers to the research questions guiding this thesis. The importance of the thesis' findings to GPs and patients who may experience suicidality, partially off-set the methodological limitations, since the lived experience of GPs, patients and topic experts is valid knowledge to underpin the CDSS.

Despite this thesis' methodological limitations, this work has resulted in the development of a prototype CDSS informed by the lived experience of GPs, patients and expert stakeholders. It can be argued therefore that the findings of the thesis and the CDSS may be transferable to analogous primary care contexts.

9.7 Impact of the research student's clinical role

As the research student, my clinical role must also be considered reflexively. I did not know any of the participants prior to their involvement in this body of research. As a clinician and a member of the local suicide prevention steering groups, it is possible that participants may have had some awareness of my clinical work or my thesis research.

I took care to describe myself as a research student and not a clinician when liaising with potential participants, however as a clinician with more than 20 years' experience of working in primary care and mental health services, the way in which I approached GPs,

patients and expert stakeholders may have influenced participant's responses. It is possible that my years of clinical experience amount to something of an 'insider position' in relation to GP's clinical encounter with suicidality, and this may have influenced both what data was collected, and how I analysed and interpreted that data, recursively influencing the development of the CDSS.

In attempt to manage reflexivity and guard against my own experience and perspectives overly shaping the process, I sought to balance my perspective with iterative feedback from participants. Such as process is necessary in critical realist informed research, since development of my theories, informed by Bhaskar et al's (2010) schema for identifying mechanisms and structures is, at heart an interpretive process. I therefore asked participants to comment upon potential generative mechanism and structures relevant to the development, use and implementation of the GPS[3]. The pathway to development of the CDSS has sought to balance my interpretation of prior theory and research with participants lived experience and stakeholder expertise. In attempt to help maintain reflexivity I relied upon my research journal, along with regular discussion of my sense making and perspective in research supervision. Whilst my own perspectives will have necessarily influenced this body of research, the methods used are well suited to developing new healthcare interventions, since a pragmatic blending of interpretations of published evidence along with participants experience and stakeholder expertise allows triangulation of data and an explanation informed by the critical realist tenants of ontological realism, epistemological relativism and judgemental rationality.

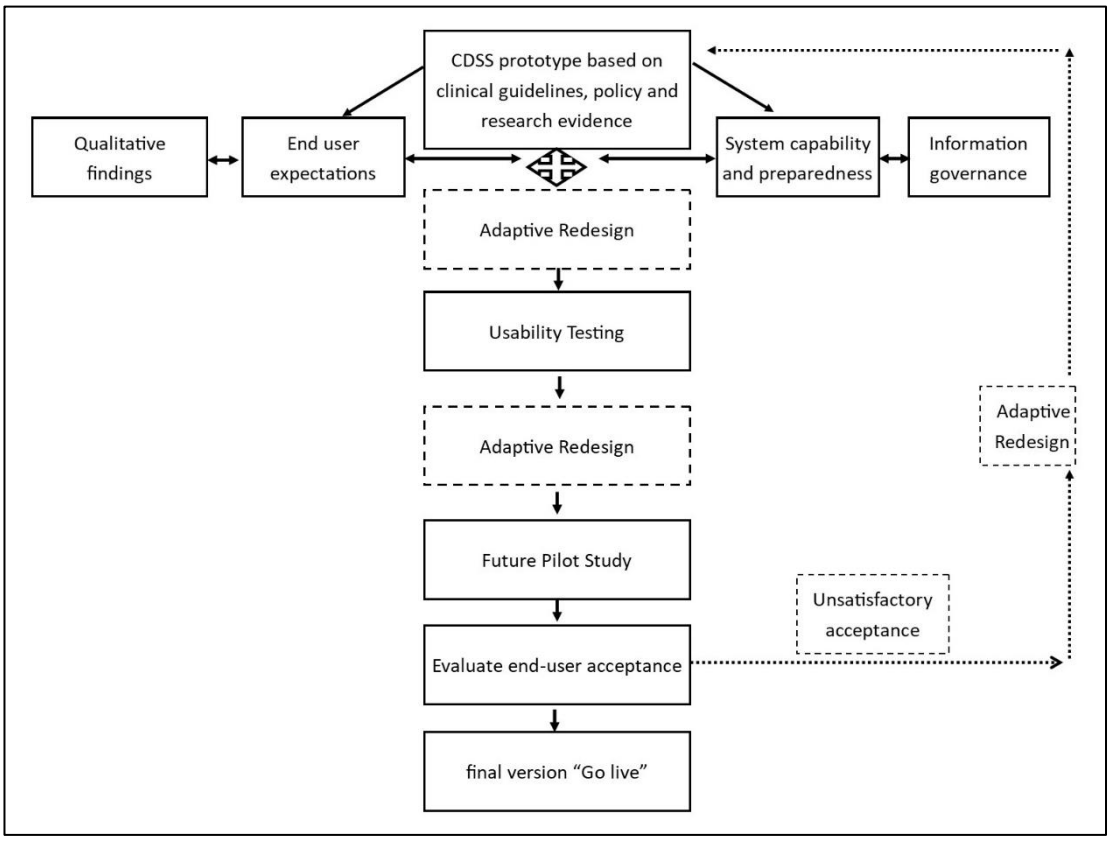
9.8 Future directions

The suicidality CDSS prototype developed through this thesis demonstrates adequate usability and acceptability to GPs. Similar complex knowledge-based CDSS systems are often the least well adopted and implemented in practice (Wright et al., 2011). Therefore, the feedback from GPs in relation to the CDSS' ability to help them in suicidality consultations can be seen as endorsement that the CDSS possesses encouraging potential. The positive feedback obtained from GPs regarding their experience of the CDSS is attributable to the early involvement of clinicians and patients in determining the scope and content of the CDSS and iterative development and usability testing. Such aspects of CDSS development have been proposed as the most likely way to maximise end-user acceptance of CDSSs (Khairat et al., 2018). However, encouraging results at the usability testing phase of CDSS development is only part of the process necessary for developing CDSSs which maximise end-user acceptance. This thesis has brought together qualitative findings to gauge end-user expectations, created the prototype and conducted an initial usability evaluation, yet further research is required to more fully evaluate the CDSS.

9.8.1 Recommendation 1: Research - continued iterative development.

Additional research could be undertaken to continue iterative development of the CDSS. Future research should feature adaptive re-design in response to research findings, and ongoing evaluation of end-user acceptance. Such research could be guided by the user acceptance and system adaptation design (UASAD) model (Khairat et al., 2018), depicted below:

Figure 9-1 User Acceptance and System Adaptation Design, (adapted from Khairat et al., 2018)



Firstly, building on the initial usability evaluation a pilot-study of the CDSS should be undertaken. To gain a greater understanding of the CDSS' acceptance in practice, the pilot study should extend over a longer period of time, with multiple and repeated end-users. Such research should incorporate GPs as the end-users of the CDSS, but also include patients as co participants in a consultation in which the CDSS is used. The impact of the CDSS use on the experience of the consultation may further elucidate important generative mechanisms influencing its acceptance and use.

However, a definitive cluster-randomised controlled trial of the CDSS versus GPs usual care may be required to establish the effectiveness of the CDSS, prior to wider implementation.

9.8.2 Recommendation 2: Clinical practice - consultation outcomes and referral pathways

Future work could examine the impact of the CDSS on clinical practice, in relation to consultation outcomes and referrals processes, and the impact of the CDSS on referral acceptance, or rejection, would be an imperative consideration.

The influence of the CDSS on referrals to secondary crisis mental health services maybe a particularly important area of consideration in this regard. The perspectives of staff working in such crisis services could be explored, to see how such professionals might view and respond to referrals from primary care in which the CDSS has been used.

Additionally, it would be important to explore GPs' perspectives of the referral process after using the CDSS to see if using it reduces known difficulties in referring patients (Michail and Tait, 2016; Saini et al., 2015). Recent policy initiatives enacted through NHS Sustainability and Transformation Plans (STPs) are seeking to redesign referral pathways between primary care networks and secondary care services (Turner and Newbigging, 2017). The importance of exploring the CDSS impact on referral processes and outcomes is therefore very timely and may illuminate important facilitators and barriers within the redeveloping referral pathways.

Similarly, the impact of the CDSS on patient safety from the perspective of improved preventative care could be usefully explored. This work could be informed by new advances in patient safety research (Braithwaite et al., 2015), which seek to highlight factors (e.g. psychosocial circumstances) which promote safety in contrast to factors which increase risk. Should the CDSS improve patients' experiences of personalised assessment and care-planning, it may improve perceptions of care-providers being able to provide patient-centred humanistic care (Simpkin et al., 2017). Experiences of receiving patient centred care may potentially impact on a range of secondary outcomes, including patients' consultation satisfaction,

sense of empowerment, perception of quality of life and wider health prognosis (Derksen et al., 2013). Tracing the impact of suicidality consultations beyond the consulting room would be therefore useful to gauge the extent to which the suicidality CDSS might contribute to preventative care and patient's wider quality of life.

9.8.3 Recommendation 3: Policy development

Should further work, such as a pilot-study, demonstrate appropriate acceptability, the impact of the CDSS on suicide prevention policy and primary care service delivery could be significant.

NHS policy has highlighted a suicidality CDSS is required to enhance patients' experiences of personalised risk assessment and care (NHS England, 2019b). Increasing primary care's ability to work with patients experiencing suicidality is therefore an important practice development, in keeping with national suicide prevention policies (Department of Health, 2012; NHS England, 2016b). Improving referral pathways for suicidality is also likely to be a high priority within STPs, which seek to develop new models of care, and co-ordinated care-pathways between primary and secondary-care (The King's Fund, 2017). Furthermore, supporting GPs to manage complex presentations in primary care fits with the evolution of primary care organisations, from CCGs to primary care networks (PCNs), which will focus on localised proactive case-management (Nottingham and Nottinghamshire Clinical Commissioning Group 2020). Supporting GPs' skills and capacity to manage suicidality in primary care is therefore a likely policy advance in the near-future.

9.9 Conclusion

Suicide prevention in primary care is a major challenge. This thesis makes a significant contribution to understanding, conceptualising, assessing and managing suicidality in primary care through a novel, knowledge-based clinical decision-making tool. The GPS^3 has the potential to transform primary care service delivery thereby improving quality of care and patient experience of that care. The

GPS^3 is a unique tool which enables GPs to engage with and record patients' narrative experiences of suicidality, whilst also translating those experiences back into Read-codes and GPs' normative clinical rationality (c.f. Launer, 2019). This has important implications for enhancing shared decision-making and patient-centred care, the pinnacle of care respecting patients autonomy, values, preferences and expressed needs (Barry and Edgman-Levitan 2012), alongside GPs' clinical, professional, and moral obligations to protect patient safety.

Appendix A: Sponsor confirmation

University of Nottingham

Our reference: RGS 17053
IRAS Project ID:

0115 8467906
sponsor@nottingham.ac.uk

Health Research Authority
Research Ethics Committee

Research, Enterprise and Graduate Services
University of Nottingham
King's Meadow Campus
Lenton Lane Nottingham
NG7 2NR

Dr. Maria Michail
Senior Research Fellow in Youth Mental Health
School of Health Sciences, Room D17
Institute of Mental Health
University of Nottingham Innovation Park
Triumph Road, Nottingham
NG7 2TU

20th July 2017

Dear Sir or Madam,

Sponsorship Statement

Re: The development of an electronic Clinical Decision Support System to assist GPs with their identification, assessment and management of suicidal presentations in primary care

I can confirm that this research proposal has been discussed with the Chief Investigator and agreement to sponsor the research is in place.

An appropriate process of scientific critique has demonstrated that this research proposal is worthwhile and of high scientific quality.*

Any necessary indemnity or insurance arrangements will be in place before this research starts. Arrangements will be in place before the study starts for the research team to access resources and support to deliver the research as proposed.

Arrangements to allocate responsibilities for the management, monitoring and reporting of the research will be in place before the research starts.

The duties of sponsors set out in the NHS Research Governance Framework for Health and Social Care will be undertaken in relation to this research.**

* Not applicable to student research (except doctoral research).
** Not applicable to research outside the scope of the Research Governance Framework.

Yours faithfully

Angela Shone
Head of Research Governance
University of Nottingham

world-changing research
from The University of Nottingham

Appendix B: NHS Research ethics approval

NHS
Health Research Authority
East Midlands - Nottingham 1 Research Ethics Committee
The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

21 September 2017

Dr Maria Michail
Senior Research Fellow in Youth Mental Health,
University of Nottingham
Room D17, Institute of Mental Health
University of Nottingham Innovation Park, Jubilee Campus,
Triumph Road, Nottingham
NG7 2TU

Dear Dr Michail,

Study title:	**The development of an electronic clinical decision support system to assist GPs with their identification, assessment and management of suicidal presentations in primary care**
REC reference:	**17/EM/0317**
Protocol number:	**17053**
IRAS project ID:	**226469**

Thank you for your letter of 20 September 2017, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact hra.studyregistration@nhs.net outlining the reasons for your request.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Copies of advertisement materials for research participants [Recruitment advert]	1.1	20 September 2017
Copies of advertisement materials for research participants [Recruitment Leaflet]	1.1	20 September 2017
Covering letter on headed paper [Cover letter]	final version 1.0	21 July 2017
Covering letter on headed paper [Cover letter]	1.1	20 September 2017
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Sponsor insurance confirmation]	final version 1.0	20 July 2017
GP/consultant information sheets or letters [GP notification letter]	final version 1.0	19 July 2017
Interview schedules or topic guides for participants [Interview topic guide]	final version 1.0	19 July 2017
IRAS Application Form [IRAS_Form_27072017]		27 July 2017
Letter from funder [confirmation of PhD funding]	1.0	13 August 2015
Letter from sponsor [Sponsor Letter]	final version 1.0	20 July 2017
Letters of invitation to participant [GP / Cluster lead invitation]	final version 1.0	19 July 2017
Letters of invitation to participant [service user invitation letter]	1.1	20 September 2017
Non-validated questionnaire [Usability Testing - additional questions]	final version 1.0	19 July 2017
Non-validated questionnaire [Usability Testing - Live patients]	final version 1.0	19 July 2017
Participant consent form [Consent Form (GP interviews)]	final version 1.0	19 July 2017
Participant consent form [Consent Form - SUAG]	final version 1.0	19 July 2017
Participant consent form [Consent Form - SUAG (parents/guardians)]	final version 1.0	19 July 2017
Participant consent form [Consent Form - Usability testing (GPs)]	final version 1.0	19 July 2017
Participant consent form [Consent Form - Usability testing (service users)]	final version 1.0	19 July 2017
Participant consent form [Consent Form - Usability testing (parents/guardians)]	final version 1.0	19 July 2017

Participant consent form [Assent Form - SUAG (young people)]	1.0	20 September 2017
Participant information sheet (PIS) [Info Sheet - GP interviews]	1.1	13 September 2017
Participant information sheet (PIS) [Info Sheet - Service User Advisory Group]	1.1	13 September 2017
Participant information sheet (PIS) [Info Sheet - Service User Advisory Group (young people)]	1.1	13 September 2017
Participant information sheet (PIS) [Info Sheet - Service User Advisory Group (parents/gaurdians)]	1.1	13 September 2017
Participant information sheet (PIS) [Info Sheet - Usability Testing (GPs)]	1.1	13 September 2017
Participant information sheet (PIS) [Info Sheet - Usability Testing (service users)]	1.1	13 September 2017
Participant information sheet (PIS) [Info Sheet - Usability testing (young people)]	1.1	13 September 2017
Participant information sheet (PIS) [Info Sheet - Usability Testing (parents/guardians)]	1.1	13 September 2017
Research protocol or project proposal [Protocol - Suicidal presentations e-CDSS]	1.1	13 September 2017
Summary CV for Chief Investigator (CI) [CV - Dr. Maria Michail]	final version 1.0	19 July 2017
Summary CV for student [CV - Matthew Horrocks]	final version 1.0	19 July 2017
Summary CV for supervisor (student research) [CV - Dr Aimee Aubeeluck]	1.0	21 July 2017
Summary CV for supervisor (student research) [CV - Professor Patrick Callaghan]	final version 1.0	19 July 2017
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Summary of Protocol]	final version 1.0	21 July 2017
Validated questionnaire [Usability Testing - SUS]	final version 1.0	19 July 2017

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

17/EM/0317	Please quote this number on all correspondence

With the Committee's best wishes for the success of this project.

Yours sincerely,



Mr John Aldridge
Chair

Email:NRESCommittee.EastMidlands-Nottingham1@nhs.net

Enclosures: "After ethical review – guidance for researchers"

Copy to: *Ms Angela Shone*
Mrs Shirley Mitchell, Head of Research and Innovation

Appendix C: HRA approval

NHS
Health Research Authority

Dr Maria Michail
Senior Research Fellow in Youth Mental Health,
University of Nottingham
Room D17, Institute of Mental Health
University of Nottingham Innovation Park, Jubilee Campus,
Triumph Road, Nottingham
NG7 2TU

Email: hra.approval@nhs.net

05 October 2017

Dear Dr Michail

Letter of HRA Approval

Study title:	**The development of an electronic clinical decision support system to assist GPs with their identification, assessment and management of suicidal presentations in primary care**
IRAS project ID:	**226469**
Protocol number:	**17053**
REC reference:	**17/EM/0317**
Sponsor	**University of Nottingham**

I am pleased to confirm that **HRA Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Participation of NHS Organisations in England

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. **Please read *Appendix B* carefully**, in particular the following sections:

- *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
- *Confirmation of capacity and capability* - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.
- *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

IRAS project ID	226469

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

It is critical that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details and further information about working with the research management function for each organisation can be accessed from www.hra.nhs.uk/hra-approval.

Appendices

The HRA Approval letter contains the following appendices:

- A – List of documents reviewed during HRA assessment
- B – Summary of HRA assessment

After HRA Approval

The document *"After Ethical Review – guidance for sponsors and investigators",* issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

In addition to the guidance in the above, please note the following:

- HRA Approval applies for the duration of your REC favourable opinion, unless otherwise notified in writing by the HRA.
- Substantial amendments should be submitted directly to the Research Ethics Committee, as detailed in the *After Ethical Review* document. Non-substantial amendments should be submitted for review by the HRA using the form provided on the HRA website, and emailed to hra.amendments@nhs.net.
- The HRA will categorise amendments (substantial and non-substantial) and issue confirmation of continued HRA Approval. Further details can be found on the HRA website.

Scope

HRA Approval provides an approval for research involving patients or staff in NHS organisations in England.

If your study involves NHS organisations in other countries in the UK, please contact the relevant national coordinating functions for support and advice. Further information can be found at http://www.hra.nhs.uk/resources/applying-for-reviews/nhs-hsc-rd-review/.

If there are participating non-NHS organisations, local agreement should be obtained in accordance with the procedures of the local participating non-NHS organisation.

IRAS project ID	226469

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/.

HRA Training

We are pleased to welcome researchers and research management staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

Your IRAS project ID is **226469**. Please quote this on all correspondence.

Yours sincerely,

Natalie Wilson
Assessor

Email: hra.approval@nhs.net

Copy to: *Mr Matthew Horrocks, University of Nottingham, Student contact*
Ms Angela Shone, University of Nottingham, Sponsor contact
Mrs Shirley Mitchell, Nottinghamshire Healthcare NHS Trust, Lead NHS R&D contact

IRAS project ID	226469

Appendix A - List of Documents

The final document set assessed and approved by HRA Approval is listed below.

Document	*Version*	*Date*
Contract/Study Agreement template	v1.0	22 September 2017
Copies of advertisement materials for research participants [Recruitment advert]	1.1	20 September 2017
Copies of advertisement materials for research participants [Recruitment Leaflet]	1.1	20 September 2017
Covering letter on headed paper [Cover letter]	final version 1.0	21 July 2017
Covering letter on headed paper [Cover letter]	1.1	20 September 2017
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Clinical Trials Insurance]		25 July 2017
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Liability Insurance]		26 July 2017
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Sponsor insurance confirmation]	final version 1.0	20 July 2017
GP/consultant information sheets or letters [GP notification letter]	final version 1.0	19 July 2017
HRA Schedule of Events [Recruiting Sites]	1	05 October 2017
HRA Schedule of Events [Other]	1	05 October 2017
HRA Statement of Activities [Other]	1	05 October 2017
HRA Statement of Activities [Recruiting Sites]	1	05 October 2017
Interview schedules or topic guides for participants [Interview topic guide]	final version 1.0	19 July 2017
IRAS Application Form [IRAS_Form_27072017]		27 July 2017
Letter from funder [confirmation of PhD funding]	1.0	13 August 2015
Letter from sponsor [Sponsor Letter]	final version 1.0	20 July 2017
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Non-validated questionnaire [Usability Testing - Live patients]	final version 1.0	19 July 2017
Participant consent form [Assent Form - SUAG (young people)]	1.0	20 September 2017
Participant consent form [Consent Form - Usability testing (service users)]	final version 1.0	19 July 2017
Participant consent form [Consent Form - Usability testing (parents/guardians)]	final version 1.0	19 July 2017
Participant consent form [Consent Form (GP interviews)]	final version 1.0	19 July 2017
Participant consent form [Consent Form - SUAG]	final version 1.0	19 July 2017
Participant consent form [Consent Form - SUAG (parents/guardians)]	final version 1.0	19 July 2017
Participant consent form [Consent Form - Usability testing (GPs)]	final version 1.0	19 July 2017
Participant information sheet (PIS) [Info Sheet - GP interviews]	1.1	13 September 2017

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Participant information sheet (PIS) [Info Sheet - Service User Advisory Group]	1.1	13 September 2017
Participant information sheet (PIS) [Info Sheet - Usability Testing (GPs)]	1.1	13 September 2017
Participant information sheet (PIS) [Info sheet - SUAG (young people)]	1.2	04 October 2017
Participant information sheet (PIS) [Info sheet - SUAG (Parents/guardians)]	1.2	04 October 2017
Participant information sheet (PIS) [Info sheet - Usability testing (Service Users)]	1.2	04 October 2017
Participant information sheet (PIS) [Info sheet - Usability Testing (young people)]	1.2	04 October 2017
Participant information sheet (PIS) [Info sheet - Usability Testing (Parents/guardians)]	1.2	04 October 2017
Research protocol or project proposal [Protocol - Suicidal presentations e-CDSS]	1.1	13 September 2017
Summary CV for Chief Investigator (CI) [CV - Dr. Maria Michail]	final version 1.0	19 July 2017
Summary CV for student [CV - Matthew Horrocks]	final version 1.0	19 July 2017
Summary CV for supervisor (student research) [CV - Dr Aimee Aubeeluck]	1.0	21 July 2017
Summary CV for supervisor (student research) [CV - Professor Patrick Callaghan]	final version 1.0	19 July 2017
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Summary of Protocol]	final version 1.0	21 July 2017
Validated questionnaire [Usability Testing - SUS]	final version 1.0	19 July 2017

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Appendix B - Summary of HRA Assessment

This appendix provides assurance to you, the sponsor and the NHS in England that the study, as reviewed for HRA Approval, is compliant with relevant standards. It also provides information and clarification, where appropriate, to participating NHS organisations in England to assist in assessing and arranging capacity and capability.

For information on how the sponsor should be working with participating NHS organisations in England, please refer to the, *participating NHS organisations, capacity and capability* and *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* sections in this appendix.

The following person is the sponsor contact for the purpose of addressing participating organisation questions relating to the study:

Name: Matt Horrocks
Email: ntxmdh@nottingham.ac.uk

HRA assessment criteria

Section	HRA Assessment Criteria	Compliant with Standards	Comments
1.1	IRAS application completed correctly	Yes	No comments
2.1	Participant information/consent documents and consent process	Yes	Minor amendments have been made to relevant PIS documentation post-REC to ensure conformity to HRA standards (please see appendix A for current PIS documents).
3.1	Protocol assessment	Yes	No comments
4.1	Allocation of responsibilities and rights are agreed and documented	Yes	This is a non-commercial, multicentre study taking place in the NHS. Two Statement of Activities have been submitted. The relevant Statement of Activities will act as the agreement between Sponsor and 'Recruiting Sites' Sponsor has submitted a bespoke agreement. This will be used as the agreement between Sponsor and

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Section	HRA Assessment Criteria	Compliant with Standards	Comments
			'Other' sites.
4.2	Insurance/indemnity arrangements assessed	Yes	Where applicable, independent contractors (e.g. General Practitioners) should ensure that the professional indemnity provided by their medical defence organisation covers the activities expected of them for this research study
4.3	Financial arrangements assessed	Yes	Sponsor has confirmed that funding is not being provided to 'Recruiting Sites' or 'Other' sites.
5.1	Compliance with the Data Protection Act and data security issues assessed	Yes	Please see section 2.1.
5.2	CTIMPS – Arrangements for compliance with the Clinical Trials Regulations assessed	Not Applicable	
5.3	Compliance with any applicable laws or regulations	Yes	No comments
6.1	NHS Research Ethics Committee favourable opinion received for applicable studies	Yes	No comments
6.2	CTIMPS – Clinical Trials Authorisation (CTA) letter received	Not Applicable	
6.3	Devices – MHRA notice of no objection received	Not Applicable	
6.4	Other regulatory approvals and authorisations received	Not Applicable	

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Participating NHS Organisations in England

This provides detail on the types of participating NHS organisations in the study and a statement as to whether the activities at all organisations are the same or different.
This is a non-commercial, multicentre study. There are two site-types involved in the research. Activity at 'recruiting' sites will involve the identification of participants, obtaining informed consent from GP and service users, interviews with GPs, service user advisory group meetings and co-production meeting with both service users and GPs. Activities at 'other' sites will include the identification of participants, obtaining consent and two stages of the usability testing. The Chief Investigator or sponsor should share relevant study documents with participating NHS organisations in England in order to put arrangements in place to deliver the study. The documents should be sent to both the local study team, where applicable, and the office providing the research management function at the participating organisation. For NIHR CRN Portfolio studies, the Local LCRN contact should also be copied into this correspondence. For further guidance on working with participating NHS organisations please see the HRA website. If Chief Investigators, sponsors or Principal Investigators are asked to complete site level forms for participating NHS organisations in England which are not provided in IRAS or on the HRA website, the Chief Investigator, sponsor or Principal Investigator should notify the HRA immediately at hra.approval@nhs.net. The HRA will work with these organisations to achieve a consistent approach to information provision.

Confirmation of Capacity and Capability

This describes whether formal confirmation of capacity and capability is expected from participating NHS organisations in England.
Participating NHS organisations in England **will be expected to formally confirm their capacity and capability to host this research**. • Following issue of this letter, participating NHS organisations in England may now confirm to the sponsor their capacity and capability to host this research, when ready to do so. How capacity and capacity will be confirmed is detailed in the *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* section of this appendix. • The Assessing, Arranging, and Confirming document on the HRA website provides further information for the sponsor and NHS organisations on assessing, arranging and confirming capacity and capability.

Principal Investigator Suitability

This confirms whether the sponsor position on whether a PI, LC or neither should be in place is correct for each type of participating NHS organisation in England and the minimum expectations for education, training and experience that PIs should meet (where applicable).
Neither a Principal Investigator (PI) nor a Local Collaborator (LC) is expected at participating NHS organisations. Sponsor does not expect research staff to undertake specific or additional training for

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the research.

GCP training is not a generic training expectation, in line with the HRA statement on training expectations.

HR Good Practice Resource Pack Expectations

This confirms the HR Good Practice Resource Pack expectations for the study and the pre-engagement checks that should and should not be undertaken

As this study is taking place in GP practices we expect you contact the primary care management function to follow their local process. Where arrangements are not already in place, network staff employed by another Trust or University (or similar) undertaking any of the research activities listed in A18 or A19 of the IRAS form (except for administration of questionnaires or surveys), would be expected to obtain an honorary research contract from one NHS organisation (if university employed), followed by Letters of Access for subsequent organisations. This would be on the basis of a Research Passport (if university employed) or an NHS to NHS confirmation of pre-engagement checks letter (if NHS employed). These should confirm enhanced DBS checks, including appropriate barred list checks, and occupational health clearance. For research team members only administering questionnaires or surveys, a Letter of Access based on standard DBS checks and occupational health clearance would be appropriate.

Other Information to Aid Study Set-up

This details any other information that may be helpful to sponsors and participating NHS organisations in England to aid study set-up.

The applicant has indicated that they do not intend to apply for inclusion on the NIHR CRN Portfolio.

Appendix D: Interview topic guide

Topic guide: suicidal presentations e-CDSS. Final version 1.0 19.07.2017

Topic Guide

Individual Interviews will be carried out with GPs, at times and locations convenient to them.

The topic guide will piloted and refined in response to participant's responses. Iterative development of interview topic guides is methodologically acceptable in research informed by a critical realist perspective, where initial theories are developed as the research progresses and are subject to continual modification and refinement (Fletcher ,2016).

Topics areas covered will include:

1) Typical flow and content of a consultation where suicidal thoughts, feelings or behaviours are discussed.
2) Clinical reasoning and decision making processes in relation to consultations where suicidal thoughts, feelings or behaviours are discussed.
3) GPs understanding of suicide risk
4) GP attitudes toward and current use of electronic prompts / electronic clinical decision support systems in practice.
5) Factors which help or hinder engagement with electronic tools / electronic clinical decision support system
6) Barriers and facilitators to routine implementation.

Appendix E: Information sheet – GP interviews

The University of Nottingham
UNITED KINGDOM · CHINA · MALAYSIA

Local Letterhead to be added

Participant Information Sheet: GP interviews
(Final Version 1.1 / 13.09.2017)

IRAS Project ID: 226469

Title of Study: The development of an electronic clinical decision support system to assist GPs with their identification, assessment and management of suicidal presentations in primary care

Name of Researcher(s): Mr M Horrocks (PhD Student)

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you have. Talk to others about the study if you wish. Ask us if there is anything that is not clear.

What is the purpose of the study?

The aim of the proposed study is to develop and evaluate an electronic clinical decision support system (e-CDSS) to support GPs in consultations with potentially suicidal patients. In order to create this tool, we would like to conduct interviews with GPs to find out about their clinical decision making process when they assess patients at suicide risk; and explore what the challenges are, how these can be managed or circumvented. Findings from GP interviews would feed into development of the electronic clinical decision support system. The study is being conducted in fulfilment of the requirements for a PhD. at the University of Nottingham.

Why have I been invited?

You are being invited to take part because you are a GP practicing within an NHS primary care practice in Nottingham or Nottinghamshire. We are inviting 30 participants like you to take part. Participants are being recruited in accordance with a sampling frame to provide a range of GP participants, stratified by gender, and years of post-qualification experience. This means that not everyone agreeing to take part in the study will definitely by interviewed.

Do I have to take part?

No you do not have to take part. It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. This would not affect your legal rights.

What will happen to me if I take part?

If you decide to take part, and you are selected for interview, in accordance with the sampling frame, you will be asked to will take part in a single interview, of approximately 60 minutes length. The interview will be carried out at times and locations convenient to you.

Before asking you to take part in the interview, we will need to obtain your consent to take part. You will be given a copy of the consent form to keep, and you should also keep this information sheet.

The interview will seek to gain an understanding of your perceptions of previous patient's suicide risk and accounts of your decision making and clinical reasoning in consultations where you have openly enquired about patient's suicidal thoughts or feelings.

Interviews will be audio-recorded and transcribed. The audio-recording will be deleted once the interview is transcribed. Transcripts will be anonymised to protect your confidentiality.

Later we may ask if you are happy to take-part in a follow up meeting between members of the research team, colleagues from PRIMIS (a business unit of the University of Nottingham specialising in primary care IT systems), primary care service-users and fellow GPs from Nottingham and Nottinghamshire. The follow up meeting will aim to agree final items for inclusion in the e-CDSS and to focus on the steps required to maximise the chances of the e-CDSS being used in local NHS GP practices. If you agree to take part in this follow-up meeting, we would ask you to attend the University of Nottingham or other appropriate NHS / community location. The follow up meeting is expected to take approximately 3 to 4 hours.

Expenses and payments

Participants will not be paid an inconvenience allowance to participate in the study.

What are the possible disadvantages and risks of taking part?

No risks or disadvantages of taking part are expected

What are the possible benefits of taking part?

We cannot promise the study will help you but the information we get from this study will be used to develop an e-CDSS to support GPs in the assessment and management of suicidal presentations in primary care. Whilst there are no direct benefits from taking part, you may find it helpful to be involved in the development of the e-CDSS which in the future could be integrated in primary care IT systems. Such activities could also go towards your CPD portfolios.

What happens when the research study stops?

At the end of the study there is no guarantee that the e-CDSS will be available for use in local practices in the future. At this early stage in development of the e-CDSS prototype it is impossible to specify the final intended purposes or use of the tool.

We will send you a summary of the research findings unless you advise us that you do not wish to be contacted.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. The researchers contact details are given at the end of this information sheet. If you remain unhappy and wish to complain formally, you can do this by contacting the Research Director at the University of Nottingham's School of Health Sciences, by emailing shs-enquiries@nottingham.ac.uk or telephoning (0115) 823 0850.

Will my taking part in the study be kept confidential?

We will follow ethical and legal practice and all information about you will be handled in confidence.

Interviews will be audio-recorded and transcribed. The audio-recording will be deleted once the interview is transcribed. Transcripts will be anonymised to protect your confidentiality.

If you join the study; data collected for the study will be looked at by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

All information which is collected about you during the course of the research will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database. Any information about you which leaves the practice will have your name and address removed (anonymised) and a unique code will be used so that you cannot be recognised from it.

However, if during the course of this study any suspected malpractice is disclosed by you or GP colleagues, the researcher will advise that they may be required to raise a concern with the GMC and /or NHS England.

Your personal data (address, telephone number) will be kept for less than 3 months after the end of the study so that we are able to contact you about the findings of the (unless you advise us that you do not wish to be contacted). All other data (research data) will be kept securely for 7 years. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team will have access to your personal data.

What will happen if I don't want to carry on with the study?

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw then the information collected so far cannot be erased and this information may still be used in the project analysis.

What will happen to the results of the research study?

The study results will be published in peer reviewed scientific journals, presented at scientific conferences and disseminated via service-user forums both locally and nationally by presenting to local groups and writing lay summaries of the findings. Furthermore, educational outreach visits to interested parties/stakeholder groups will be offered and meetings will be sought with opinion leaders in the local health and social care communities. Additionally the study will also be written up for an educational qualification (PhD) with University of Nottingham. Participants will not be identified in any publications.

Who is organising and funding the research?

This research is being organised as a PhD project at the University of Nottingham and is being funded by the National Institute for Health Research's Collaboration for Leadership in Applied Health Research and Care – East Midlands.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the Nottingham 1 Research Ethics Committee.

Further information and contact details

Matthew D. Horrocks
PhD Student
School of Health Sciences
University of Nottingham
Tel: (to be confirmed)
matthew.horrocks@nottingham.ac.uk

Dr. Maria Michail
Chief Investigator
School of Health Sciences
University of Nottingham
Tel: (to be confirmed)
maria.michail@nottingham.ac.uk

Dr. Aimee Aubeeluck
Academic Supervisor
School of Health Sciences
University of Nottingham
Tel: (to be confirmed)
aimee.aubeeluck@nottingham.ac.uk

Appendix F: Consent form – GP interviews

University of Nottingham
UK | CHINA | MALAYSIA

(Form to be printed on local headed paper)

CONSENT FORM: GP interviews
(Final Version 1.0 / 19.07.2017)

Title of Study: The development of an electronic clinical decision support system to assist GPs with their identification, assessment and management of suicidal presentations in primary care

IRAS Project ID: 226469

Name of Researcher: Mr. Matthew Horrocks

Name of Participant: **Please initial box**

1. I confirm that I have read and understand the information sheet version number XXX dated XXX for the above study and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my medical care or legal rights being affected. I understand that should I withdraw then the information collected so far cannot be erased and that this information may still be used in the project analysis. ☐
3. I understand that relevant sections of my data collected in the study may be looked at by authorised individuals from the University of Nottingham, the research group and regulatory authorities where it is relevant to my taking part in this study. I give permission for these individuals to have access to these records and to collect, store, analyse and publish information obtained from my participation in this study. I understand that my personal details will be kept confidential. ☐
4. I understand that the interview will be recorded and that anonymous direct quotes from the interview may be used in the study reports. ☐
5. I understand the study will also involve a half-day workshop, I am interested in receiving further information (please circle) Yes or NO ☐
6. I agree to take part in the above study. ☐

Name of Participant	Date	Signature
Name of Person taking consent	Date	Signature

2 copies: 1 for participant, 1 for the project notes

Clinical decision support for potential suicide risk in primary care
Consent form GP interviews Final version 1.0 19.07.2017

Appendix G: Advert – patient advisory groups

Advert: suicidal presentations e-CDSS. Final version 1.1 20.09.2017

Discussing suicidal thoughts and feelings in primary care

The University of Nottingham



Could you help us with a study to improve the way in which suicide is discussed during GP consultations?

We are looking for participants to form a discussion group (known as service user advisory group).

The group will discuss how and when GPs might best raise questions about suicidal thoughts and feelings.

Please get in touch if you:

- ✓ **Are aged more than 14 years old.**
- ✓ **and you have in the past discussed suicidal thoughts and/or feelings with a GP during an appointment.**

The group will meet 4 times between November 2017 and October 2018, at the University of Nottingham.

If you would like to find out more please contact:
Matthew Horrocks
PhD Student
School of Health Sciences
University of Nottingham
Tel: (to be confirmed)
matthew.horrocks@nottingham.ac.uk

Appendix H: Information sheet – patient advisory groups

The University of Nottingham
UNITED KINGDOM · CHINA · MALAYSIA

Local Letterhead to be added

Participant Information Sheet: Service User Advisory Group
(Final Version 1.1 / 13.09.2017)

IRAS Project ID: 226469

Title of Study:
The development of an electronic clinical decision support system to assist GPs with their identification, assessment and management of suicidal presentations in primary care.

Name of Researcher: Mr M Horrocks (PhD Student)

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through this information sheet with you and answer any questions you have. Talk to others about the study if you wish. Ask us if there is anything that is not clear.

What is the purpose of the study?

The study is being conducted as part of a degree at the University of Nottingham. The aim of the study is to develop and evaluate a computer programme (known as an electronic clinical decision support system or e-CDSS) to support GPs to ask patients about suicidal thoughts, feelings or behaviours. Helping GPs to think and ask about people's possible suicide risk is important because up to 45% of people who die by suicide have a GP appointment in the month before their death.. However, how and when GPs ask patients about suicidal thoughts, feelings or behaviour may influence what patients tell their GP. . e-CDSS are online programmes on the GPs computers, which the GP could use during the patient's appointment, which prompt the GP to ask certain questions, consider specific information, and make a decision about treatment options. Introduction of an e-CDSS, could help GPs to support people who might be at risk of suicide. In order to create this e-CDSS, we would like to form a group of service users who have relevant experience, to discuss with us, how GPs might phrase potential questions and to help us write the content included in the e-CDSS so that GPs might best help people at risk of suicide..

Why have I been invited?

This research is taking place with the support of your GP practice, and this study might be relevant to you. . People with lived experience of using GP services can help us to think about when and how GPs might ask other service-users about suicidal thoughts and feelings. We are inviting 20 people across Nottingham and Nottinghamshire to take part.

Do I have to take part?

No you do not have to take part. It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. This would not affect your legal rights.

What will happen to me if I take part?

You will be invited to join an advisory group of people aged either 14-25, or 26 and older. There will be up to 10 participants in each group. The groups will discuss how and when GPs ask people about suicidal thoughts or behaviours, and how we might word potential questions for inclusion in the e-CDSS..

Before asking you to take part in the group discussions for the first time we will need to obtain your consent to take part. You will be given a copy of the consent form to keep, and you should also keep this information sheet.

The group will meet for a total four times between 2017 and 2018. Each meeting is expected to be of about two hour's duration. Meeting will take place at the University of Nottingham, or appropriate NHS premises or other community locations.

Fellow group members will be other primary care patients who also have relevant experience.

The service-user advisory group will include participants aged greater than 25 years of age who are registered with a GP practice in Nottingham or Nottinghamshire.

Later we may ask if you are happy to take-part in a follow up meeting between members of the research team, colleagues from PRIMIS (a business unit of the University of Nottingham specialising in primary care IT systems), GPs from Nottingham and Nottinghamshire and fellow primary care service-users. In this follow up meeting we will agree final questions for inclusion in the e-CDSS and the steps required to maximise the chances of the e-CDSS being used in local NHS GP practices. If you agree to take part in this follow-up meeting, we would ask you to re-attend the University of Nottingham or other appropriate NHS / community location. The follow up meeting is expected to take about half a day (3 and a half hours).

Expenses and payments

You will not be paid an inconvenience allowance to participate in the study. However reasonable travel expenses will be offered, in line with the School of Health Science's existing policies, to support participants with the cost of attendance at advisory group meetings, incurred as a result of participation.

What are the possible disadvantages and risks of taking part?

We do not anticipate any risks from taking part in this study.
Discussing questions about suicide risk is a potentially sensitive issue. Although talking about suicide risk could be upsetting, there is no evidence that discussing suicide risk leads to higher risk or harm, and studies show that talking about suicide risk is acceptable to service-users and may be perceived as helpful.

However, if group meetings cause anyone in the group to report distress or discomfort, the meeting will be immediately stopped and only reconvened if and when appropriate.

If you decide to take part in the discussion group, you will be provided with contract details for NHS and third sector organisations that could support you, if required after participating in the study.

The group is not a therapy group and it is not expected that discussing the phrasing of potential questions in the e-CDSS will necessitate detailed disclosure of your past personal experiences. Group members will however be encouraged to share their views on how other patients might react to the phrasing of possible questions intended for use in the e-CDSS.

What are the possible benefits of taking part?

We cannot promise the study will help you, but the information we get from this study may help GPs to explore service-user's suicide risk more appropriately. Taking part in research intended to result in changes to clinical practice and future healthcare provision maybe experienced as helpful and empowering.

What happens when the research study stops?

When the study ends, you will continue with your usual care from your GP.

At the end of the study there is no guarantee that the e-CDSS will be available for use in local GP practices in the future. At this early stage in development of the e-CDSS prototype it is impossible to specify the final intended purposes or use of the tool.

We will send you a summary of the research findings unless you advise us that you do not wish to be contacted.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. The researchers contact details are given at the end of this information sheet. If you remain unhappy and wish to complain formally, you can do this by contacting the Patient Advice and Liaison services within either the Nottingham city or county Clinical Commissioning group areas. For GP surgeries based in the City of Nottingham please contact 0800 1830456 or email PALS@nottinghamcity.nhs.uk; for GP surgeries based in Nottinghamshire please contact 0800 0283693 or email PALS@nottspct.nhs.uk

Will my taking part in the study be kept confidential?

We will follow ethical and legal practice and all information about you will be handled in confidence.

If you join the study, the data collected for the study will be looked at by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

All information which is collected about you during the course of the research will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database. Any information about you which leaves the NHS will have your name and address removed (anonymised) and a unique code will be used so that you cannot be recognised from it.

Your personal data (address, telephone number) will be kept for less than 3 months after the end of the study so that we are able to contact you about the findings of the study a*nd possible follow-up studies* unless you advise us that you do not wish to be contacted. All other data (research data) will be kept securely for 7 years. After this time your data will be disposed of securely. During this time all

precautions will be taken by all those involved to maintain your confidentiality, only members of the research team will have access to your personal data.

Although what you say in the group meetings is confidential, should you disclose anything to us which we feel puts you or anyone else at any risk, we may feel it necessary to report this to the appropriate persons, including your GP.

What will happen if I don't want to carry on with the study?

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw then the information collected so far cannot be erased and this information may still be used in the project analysis.

Involvement of the General Practitioner/Family doctor (GP)

We will ask for your permission to notify your GP if you agree to participate in the study. This is to ensure that your GP is aware that you have agreed to participate in case of the unlikely event that taking part in the group discussion causes you to experience distress or discomfort, or that you need to see the GP in relation to any activities associated with taking part in the advisory group discussions.

What will happen to the results of the research study?

The study results will be published in peer reviewed scientific journals, presented at scientific conferences and disseminated via service-user forums both locally and nationally by presenting to local groups and writing lay summaries of the findings. Furthermore, educational outreach visits to interested parties/stakeholder groups will be offered and meetings will be sought with opinion leaders in the local health and social care communities. Additionally the study will also be written up for an educational qualification (PhD) with University of Nottingham. Participants will not be identified in any publications.

Who is organising and funding the research?

This research is being organised as a PhD project at the University of Nottingham and is being funded by the National Institute for Health Research's Collaboration for Leadership in Applied Health Research and Care – East Midlands.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the Nottingham 1 Research Ethics Committee.

Further information and contact details

Matthew D. Horrocks
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Dr. Maria Michail
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Dr. Aimee Aubeeluck
Academic Supervisor
School of Health Sciences
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Appendix I: Consent form -patient advisory groups

University of Nottingham
UK | CHINA | MALAYSIA

(Form to be printed on local headed paper)

CONSENT FORM: Service User Advisory Group
(Final Version 1.0 / 19.07.2017)

Title of Study: The development of an electronic clinical decision support system to assist GPs with their identification, assessment and management of suicidal presentations in primary care

IRAS Project ID: 226469

Name of Researcher: Mr. Matthew Horrocks

Name of Participant: **Please initial box**

1. I confirm that I have read and understand the information sheet version number XXX dated XXX for the above study and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my medical care or legal rights being affected. I understand that should I withdraw then the information collected so far cannot be erased and that this information may still be used in the project analysis. ☐
3. I understand that relevant sections of my medical notes and data collected in the study may be looked at by authorised individuals from the University of Nottingham, the research group and regulatory authorities where it is relevant to my taking part in this study. I give permission for these individuals to have access to these records and to collect, store, analyse and publish information obtained from my participation in this study. I understand that my personal details will be kept confidential. ☐
4. I agree to my GP being informed of my participation in this study ☐
5. I understand that I may also be invited to participate in a half-day workshop. I confirm that I am interested to receive further information (please circle Yes or NO) ☐
6.. I agree to take part in the above study. ☐

_____	_____	_____
Name of Participant	Date	Signature

_____	_____	_____
Name of Person taking consent	Date	Signature

3 copies: 1 for participant, 1 for the project notes, 1 for the GP notes

Appendix J: List of items

Item Number	Item Content	Not relevant -1-	Somewhat relevant -2-	Quite relevant -3-	Highly relevant -4-	**Notes:** please use this space to record any additional comments on the relevance of the specific item
	e.g. how often do you feel life is hopeless?				✓	
1	Has something very stressful happened to you in the past few weeks?					
2	Has anything especially stressful happened to you recently?					
3	Do you know if anything has changed in your personal circumstances?					
4	Are you aware of anything that might be contributing to how you are feeling?					
5	Have you started finished or changed medication recently?					
6	Have you changed how you are taking your medication?					
7	Have you suffered a significant loss?					
8	Are you experiencing any financial or legal problems?					
9	Many times when people feel [describe patient's symptoms or complaints] they also think about death or have thoughts about suicide. Do you ever wish you were dead or think about killing yourself					
10	Sometimes people, when they're feeling like this, may feel like taking their life, have you thought about that at all?",					
11	Have you thought about ending your life? Please tell me about what you have been thinking					
12	Do you know how long you have been feeling this way					
13	How long have you had these thoughts?					
14	Have you had any wishes to be dead?					
15	How distressed have you been by thoughts of ending your own life over the last two weeks?					
16	What are your reasons for dying? Why do you want to kill yourself? Do you have any intention of acting on those thoughts?					
17	Tell me what do you think will happen when you die / kill your self					
18	What would suicide mean for you? And the people closest to you?					
19	Have you had thoughts sometimes that you feel you may harm yourself or life's not worth living?					

20	"people who are feeling low in mood, have sometimes told me that they are so sad that they don't want to be here anymore and they've even had thoughts about hurting themselves or even doing things so that they wouldn't be here anymore. Are you having any of those type of thoughts, have you ever done anything like that".					
21	Have you thought you might be better off not here anymore?					
22	Are you finding it hard to carry on living?					
23	Sometimes people think the people close to them would be better off if I was gone – do you think that?					
24	When you think about suicide do you feel afraid?					
25	"Is it something you can imagine yourself doing?", and if not, why not?					
26	Have you made any plans to end your life? Please tell me more about your plans					
27	Have you ever thought about how you might end your life?					
28	Have you got a plan of how you might kill yourself?					
29	Have you made any plans to end your life?					
30	Would you carry out these plans?					
31	Do you have a plan? Have you thought about how you might do it?					
32	Do you have a time in mind?					
33	Are you worried that you might do this in the next few hours / days / weeks?					
34	Do you know when you might attempt suicide?					
35	"If you were going to kill yourself, how would you possibly be thinking of doing it?"					
36	How ready to kill yourself are you? Have you got plans? How well thought out are they?					
37	Have you ever planned to do anything?" "Have you prepared anything"? Have you made any preparations for a suicide attempt?					
38	Do you have access to [method], have you taken steps to get access?					
39	Have you done anything to prepare for ending your life? E.g. writing a will, or suicide note					

40	Have you practiced [method] in any way, or have you done anything to prepare for your death?					
41	Do you have the means and opportunity to kill yourself / suicide?					
42	Do you want to be dead, or do you want to not feel like this					
43	Is it that you don't want to be here or is it that you don't want to be in this situation?					
44	How strong it your intent to kill yourself on a 0-10 scale?					
45	Do you want to die, or are you finding it really difficult to go on living at the moment?					
46	Have you thought you would be better off dead or wished you were dead?					
47	Sometimes people who feel down can start to feel hopeless about the future. Has this happened to you?					
48	Do you feel hopeless or have thoughts of death?					
49	It is not unusual for someone who is feeling depressed / agitated / lonely to feel hopeless. Do you ever feel hopeless about life or feel that things are never going to get any better					

50	Have you ever cut yourself, burned yourself, held a gun to your head, taken more pills than you should, or tried to kill yourself in any other way?					
51	Let's talk a little bit about the worst time you attempted suicide, the time you were most suicidal and tried to kill yourself ➢ When did this occur ➢ What did you do ➢ Where were you when did this ➢ Did you hope you would die, or did you hope something else would happen? ➢ Afterwards, were you glad to be alive or were you disappointed you weren't dead					
52	Did you write a note? Did you lock the door? Was there any chance that anybody could find you?"					
53	Let's talk a little bit about the first time you tried to kill yourself ➢ When did this occur ➢ What did you do ➢ Where were you when did this ➢ Did you hope you would die, or did you hope something else would happen? Afterwards, were you glad to be alive or were you disappointed you weren't dead					
54	How often are you feeling distress and despair					
55	How sensitive to criticism from others are you feeling at the moment?					
56	Recently are you able to stay in contact with other people ?					
57	How are you coping with your emotions?					

58	What makes how you are feeling better or worse?					
59	In the past when you've had these thoughts, or felt like this, what happened?					
60	"Have you felt desperate at times, sometimes you can feel like life's not worth living, have you had thoughts like that?"					
61	Do you feel like you are burden to others?					
62	What are you most hopeless about?					
63	Do you feel isolated from other people					
64	How do you see the future?					
65	Have you ever intentionally injured yourself in any way before?					
66	Have you ever tried to harm yourself in any way?					
67	have you ever tried to hurt yourself [eg cutting] to calm down or feel better?					
68	How much do you hate yourself on a scale of 1-5?					

69	What do you hate most about yourself?					
70	Do you ever do anything impulsive to make you feel better?					
71	When you are feeling low how do you cope?					
72	Is substance use part of this problem?					
73	Have you started using alcohol or drugs to help you relax, calm down or feel better?					
74	Are you having relationship problems?					
75	Are you experiencing any physical pain?					
76	Is life worth living?					
77	With all that has been going on, what is keeping you alive right now?					
78	What reasons do you have for living					
79	What prevents you from killing yourself?					

80	What matters most to you in life?					
81	How much do you trust your own decisions and judgement at the moment?					
82	How often are you able to feel relaxed?					
83	How do you feel about your physical health?					
84	How often do you act on the spur of the moment?					
85	How would you describe your self-confidence / how self-confident are you?					
86	Is this a process you recognise from the past?					
87	How safe do you feel? Can you keep yourself safe when you leave here?					
88	When you are feeling low how do you cope?					
89	Is there anything that you are ashamed of?					
90	How can I be sure that you will keep yourself alive until …?"					
91	What are you going to do when you leave this room?".					

	"Can I see you again tomorrow/three days' time/a week					
92	Im not sure where we go from here, but let's meet again [at identified time slot]					
93	It's impossible for me to take away what you are dealing with - I can't fix it – these ideas might seem insignificant, but if it gets you through the next few hours / days, then it's worth it. here are some ideas that might help a little bit ➢ Mindfulness ➢ Exercise ➢ Have a bath ➢ See friends ➢ Make or play music ➢ Engage in something creative.. writing.. knitting.. making something ➢ Do something you are good at ➢ Be productive, do little jobs / chores ➢ Call a friend ➢ Walk / get some fresh air ➢ Paly with pets ➢ Internet – safe sites only [ones that are unlikely to be related to suicidality] ➢ Create and stick to a daily routine					

Appendix K: Usability testing agreement

University of Nottingham
UK | CHINA | MALAYSIA

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Email: shs-enquiries@nottingham.ac.uk

Our Ref: RGS[TBC]
Sponsor Ref: 17053
REC Ref: 17/EM/0317
Date: [Insert date] 26 JUN 2018

[Insert partner organisation name] UNIVERSITY OF NOTTINGHAM HEALTH SERVICE
[Insert partner organisation address] CRIPPS HEALTH CENTRE
UNIVERSITY PARK
NOTTINGHAM
NG7 2QW

For the attention of [insert name]
Mr Daniel Tomlinson

Dear Sirs

Electronic Clinical Decision Support for potential suicide risk in primary care – usability study (the "Study")

We refer to the recent conversations between Dr. Maria Michail, Dr. Aimee Aubeeluck, (the investigators) or Matthew Horrocks (research student) and [NAME] and thank you for agreeing to participate in the Study.

We have designed the Study to evaluate the usability and effectiveness of a prototype electronic Clinical Decision Support System (the "**e-CDSS**") developed at the University of Nottingham. Your collaboration on the Study is greatly appreciated.

The purpose of this letter is to explain our respective responsibilities in respect to the Study and set out the terms on which we agree to collaborate on the Study.

Our responsibilities

The University of Nottingham is the Sponsor of the Study under the Department of Health's Research Governance Framework for Health and Social Care. This means that we are responsible for initiating, managing and financing the Project. We confirm that we have obtained all relevant ethics approvals and opinions for conducting the Study.

We have supplied you with the current version of the study protocol (the "**Protocol**"). The Protocol is the manual for the Study and explains how the Study should be conducted. We will keep you updated if the Protocol is amended during the course of the Project.

Page **1** of **4** GP site agreement v1.0 22.9.17

We will supply you with the format of the evaluation questionnaires that we need you to complete in order to collect the data we need from you for the Study.

We will supply you with access to the e-CDSS at the Practice and provide training on its use. If you have any technical problems or queries with the e-CDSS, please let us know by contacting Matthew Horrocks and we will try to resolve them.

The intellectual property in the e-CDSS, and in any improvements we make to the e-CDSS as in the course of or as a result of the Study, belongs to The University of Nottingham. We hereby grant you a licence to use the e-CDSS for the purposes of the Study and for the duration of the Study.

We will advise you promptly if we need to discontinue the Study for any reason.

Your responsibilities

You will:

- participate in the non-live usability testing of the e-CDSS and subsequent evaluation, as described in the Protocol;
- make the initial approach to service users, who are attending the surgery for an appointment, to gain their permission to discuss participation in in the study with the researcher [Matthew Horrocks];
- pass confirmation to Matthew Horrocks of those service users who provided verbal consent to being approached by Matthew Horrocks regarding participating in the Study, so that we can obtain their written consent to participating;
- use (at your discretion) the e-CDSS in appointments with the consented service users, and supply them with a copy of the patient support sheet specified in the Protocol;
- complete the relevant evaluation questionnaire following each service user appointment where you have used the e-CDSS, and send to us the completed questionnaire.

Please note that, where you do decide to use the e-CDSS, you will retain clinical responsibility for both the identification of potential suicide risk and the content and outcomes of the clinical consultation. Supply of the e-CDSS does not constitute clinical advice nor does the University of Nottingham accept any liability for clinical decisions made using the e-CDSS.

You acknowledge that the data that we collect from you using our evaluation questionnaires will vest in and be the property of The University of Nottingham.

Data protection, confidentiality and publication

This letter is supplemental to the HRA Statement of Activities that we have agreed with East Midlands CRN, and we have supplied you with a copy of that document. The confidentiality, data protection and freedom of information rules set out in that document apply to both your role and our role in the conduct of the Study.

For the avoidance of doubt, we will comply with our obligations under the Data Protection Act 1998 (and, when it comes into force, the General Data Protection Regulation) in respect of

any personal data that you transfer to us in connection with the Study (in particular, names and contact details for service users who agree to participate in the Study).

Please do not include any identifiable data of service users when you complete the evaluation questionnaires. If we acquire any medical information from service users who agree to participate in the Study, we will keep that information confidential and secure, and only disclose it in the circumstances described in the Protocol.

The Study is being conducted in the furtherance of our charitable objective to advance education through teaching and research. Consequently we intend to publish and disseminate the results of the Study through various forums for wider public benefit, in accordance with the publication policy set out in the Protocol. We will not publish any personal data that we have acquired from you or from any service users in the course of the Study. We will acknowledge your support of the Study in any publication of the Study results, unless you advise us that you do not wish to be acknowledged.

General

This agreement commences on the date that it has been signed by you and will terminate on completion of the Study, which we anticipate to be [DATE].

Nothing in this agreement shall create, imply or evidence any partnership or joint venture between us, or a relationship of principal and agent.

This agreement (together with the Protocol) forms the entire agreement between us. Any variation to this agreement should be in writing and signed by our respective authorised signatories.

We should be grateful if you could arrange for both copies of this letter to be signed and dated below to show your agreement to these terms and return one for the University's records to Research and Innovation, East Atrium, Jubilee Conference Centre, Triumph Road, Nottingham, NG8 1DH . The other should be retained by you for your own records.

Yours faithfully

.....
For and on behalf of the University of Nottingham

Name:

Position:

Date:

Accepted by an authorised signatory for and on behalf of [GP SURGERY NAME]:

UNIVERSITY OF NOTTINGHAM HEALTH SERVICE

.....
For and on behalf of [GP SURGERY NAME] UNIVERSITY OF NOTTINGHAM HEALTH SERVICE

Name: DANIEL HAMMERSLEY
Position: CHIEF OPERATING OFFICER
Date: 25 JUN 2018

Appendix L: Copyright agreement and adapted clinical-vignettes.

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Title	The Development of an electronic Clinical Decision Support System for the identification, assessment and management of suicidal presentations in primary care
Expected presentation date	Sep 2019
Order reference number	001PHD
Requestor Location	University of Nottingham C Floor, the Institute of Mental Health,

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These vignettes are adapted from Chehil and Kutcher, 2012, and permission to use them has been obtained.

Case One:

Mrs J.S. is a 35 year older housewife with a 19 year history of depression. This is her third episode. In previous episodes she improved with antidepressant medication, usually within four to six weeks after beginning treatment. She has had no previous suicide attempts but her mother dies of suicide many years ago. She is currently in a major depressive episode of some two months duration, and feels hopeless and worthless. She does not see any future for her children or herself and thinks that she would be better off dead. She is divorced and lives alone with her two son, who are aged 8 and 6 years. She has been taking antidepressant medication for about two weeks and her mood is subjectively no better but she has more energy. Her major complaint (the reason why she came to see you) is painful headaches and she wants 'lots of strong painkillers'. At her last visit a week ago she told you she 'did not want to live with the black dog of depression anymore'. Today she admits to feeling that 'life often does not seem worth living' and tells you that she has thoughts about killing herself. When you directly question her about suicidal plans she is vague and evasive in her response. When you ask how her children are doing she tells you that she has sent them to visit her ex-husband.

Case two

Mr M.I. is a 48 year old unemployed male. About five weeks ago he had a heart attack from which he seems to have made a good recovery. He was discharged from the hospital about three weeks ago and has been at home since, mostly watching television and reading. He has come to see you complaining about back pain and constipation. At times during your interview he seems on the point of crying and he has told you that he is very unhappy with how things are turning out for him. He says that his friends tell him it is common to be depressed after a heart attack. He tells you that his biggest interest right now is the Church, in which he has been a member for over 20 years and talks about how his faith is very important to him and is sustaining him at this point in his life. He tells you that he is worried that he is losing his faith and talks about frequent anxiety attacks. ON direct questioning he admits to having frequent thoughts about killing himself by taking all his heart pills at once but is worried he will go to hell if he does. Yesterday he took all his tablets out of the drawer and sat looking at them for about 15 minutes trying to decide id he should take them all. He decided that his faith would not let him do it and that his wife would suffer if he killed himself so he put the pills away.

Case three

MR T. is a 46 year old unemployed male with a known history of alcohol abuse and depression. He had his last depressive episode about two years ago and he was lost to follow up after successful treatment with an antidepressant. He has not seen any health professional for a least one year and present today after being seen yesterday at the emergency room complaining of abdominal pain. A physical examination is unremarkable and an X-ray of the abdomen shows no pathological findings. He lives alone and denies using any alcohol or drugs in the last month. His main concerns are about his physical health and he presents a variety of vague complaints about his headaches and back pain after he is told there is nothing to find regarding his abdominal pain. He denies being depressed but becomes tearful when talking about going back to the street where he has been living. He asks for food and the emergency room nurse complains that he is abusing the system

Case four

Miss C is a 23 year old single actress who has not been able to obtain steady work in her profession since she moved to this city some six months ago. She supports herself by waiting on tables in a local bar. She has cut her wrists with a kitchen knife after an argument with the bartender with whom she has been living for the past two weeks. This is the third episode of wrist-cutting she has experiences in the last three months. She also has cigarette burns on her upper arms and back and her face shows old bruises where she fell and hit her head while working. She does not have any history of depression or any other psychiatric disorder and before the above mentioned episodes no history of self-harm behaviours. She does not drink or use drugs and is uncomfortable at her apartment because her boyfriend 'drinks too much' and 'gets loud'. She complains about feeling sad but denies being hopeless. She says she did not want to kill herself but cut herself because she did not know what else she should do

Case five

Mr M is a 19 year old male who has taken a handful of aspirin tablets after an argument with his mother. This is his fifth episode of self-harm (always talking 'pills') in three years. He has never had any psychiatric diagnosis and in all previous cases he refused to see a psychiatrist or failed to show up at appointments after being seen in the emergency room. He has been in trouble with the law for selling drugs and for stealing from stores. His mother is a well-known political figure in the locality and she tells you that he is always trying to manipulate her into doing what he wants and always trying to 'get attention'. He denies any depressive symptoms but demands that you tell his mother to let him transfer to a new college because at his current college 'all the teachers are assholes'/ He threatens to take more pills when he gets home if he is denied his demand.

Case six

Mrs P is a 68 year old woman with a five year history of treated breast canc. She lives with her 70 year old husband, who is very supportive of her. Her eldest daughter, her son-in-law and her two grandchildren live next door. She is very close to them and visits daily. She has just been diagnosed with a recurrence of her cancer and broke down in her your office, crying and saying that she recently been thinking that she does not want to live anymore. She had a brief period of 'the blues' after her third child was born but never treated for any psychiatric problem. There is a strong history of depression in her biological family but not history of suicide. She denies having any suicidal plans and tells you that her thoughts about not wanting to live are gone. She denies feeling hopeless and wants to go home.

Case seven

Mr J is a 34 year old male who telephones the clinic and says (with slurred speech) that he is suicidal. He states that he has a rope and has decided to kill himself after he kills his wife and six month old child because 'they are possessed by the devil'. He wants a doctor to come to the house and make sure everyone is dead because that is the only way that he can think of to 'save their souls'.

Case eight

Mr RJ is a 67 year old bank executive and high profile community leader. He is active in a number of health charities and is the financial controller at his church. He is well known to the local hospital staff as he recently stepped down as chairman of the hospital board. This evening he presents to the emergency room with rapid onset of chest pain accompanied by respiratory distress, palpitations and thoughts the he will die. This episode came on suddenly as he and his wife were getting ready to go the cancer society fundraising dinner. It had largely resolved by the time he was assessed in the emergency room.

All investigations including EKG and cardiac enzymes are unremarkable. His wife, who had accompanied him to the hospital, has just left to 'go home and change clothes'. He asks to see you in private and confides that earlier that day he was informed by a physician in a confidential walk in clinic in a distant location of the city that he was HIV positive, the result of an eight month relationship with one of the teenage girls (a known sex worker and intravenous drug user) whom he had been 'counselling' through a church based programme for street youth. He has not told anyone what has happened and a counsellor at the walk in clinic has asked him to come to an appointment tomorrow to discuss what he needs to do.

Mr RJ has no personal or family history of mental illness and has never considered nor attempted suicide. He has had no significant medical illness and is taking no medications. However , since he received the news about his health status earlier today he has been having severe anxiety, numerous physical symptoms and is experiencing frequent suicidal thoughts that are intense but of short duration. He does not know what he should do. He is mortified at what his situation may do to his reputation and is convinced that he will be fired from his work. He feels guilty about his actions and does not know what he will tell his wife. He denies having a suicidal plan and does not want to keep his appointment at the HIV clinic tomorrow, but instead thinks that he should 'go for a holiday to try and sort this out'

Appendix M: System Usability Scale (Bangor et al.,2008)

Usability testing questionnaire: Suicidal Presentations-CDSS. Final version 1.0 19.07.2017

System Usability Scale and evaluation questionnaires

Modified SUS statements (Bangor et al 2008) – completed at first, and second rounds of usability testing

Statement	Strongly Agree				Strongly disagree
I think that I would like to use this product frequently	1	2	3	4	5
I found the product unnecessarily complex	1	2	3	4	5
I thought the product was easy to use	1	2	3	4	5
I think that I would need the support of a technical person to be able to use this product	1	2	3	4	5
I found that the various functions in this product were well integrated	1	2	3	4	5
I thought that there was too much inconsistency in this product	1	2	3	4	5
I would imagine that most people would learn to use this product very Quickly	1	2	3	4	5
I found the product very awkward to use	1	2	3	4	5
I felt very confident using the product	1	2	3	4	5
I needed to learn a lot of things before I could get going with this product	1	2	3	4	5

Appendix N: Non-validated questionnaire, (adapted from Gray, 2014)

Usability testing questionnaire: Suicidal Presentations-CDSS. Final version 1.0 19.07.2017

Additional Evaluation Questions

First Round Usability Testing Questionnaire:

To be completed by primary-care practitioners, after simulated data entry in response to clinical vignettes.

1) On average how long does it take to complete a suicide consultation using the new CDSS / processes

2) How could the order of the CDSS sections be improved?

3) Could you find all the sections and information you needed within the CDSS?

Yes (go to q.6) ☐ No ☐

4) How could this be improved?

5) How relevant were the questions and prompts within the tool

Not at all 0 1 2 3 4 5 6 7 8 9 10 **completely**

6) How could they be improved? or What was missing?

7) How well did the questions asked in the CDSS support your decision making process

Poorly 0 1 2 3 4 5 6 7 8 9 10 **satisfied**

8) Did the CDSS prompt discussion of the important factors relevant to this appointment?

Not at all 0 1 2 3 4 5 6 7 8 9 10 **completely**

9) What was missing? Or how could it be improved?

Usability testing questionnaire: Suicidal Presentations-CDSS. Final version 1.0 19.07.2017

10) Did the CDSS lead to any new information or useful clinical actions that the existing approaches would have missed?

Yes ☐ No (please go to Q.13 ☐

11) Please mark any new information elicited by use of the CDSS?

Medication review		Psychiatric or substance use referral (e.g. CRHT, CMHT)	
Mental state assessment		Other mental health referral (e.g. counselling, CBT)	
Mental health screening		Referral to support agency (e.g. CAB, debt advice)	
Relationship factors		Safety planning / safety advice	
Substance use		Other: Please specify	
Debt or occupational factors			
Risky behaviour			

12) If you were going to suggest a new management plan, or refer to another service, how well does the information produced by the CDSS meet your requirements now?

Dissatisfied 0 1 2 3 4 5 6 7 8 9 10 **satisfied**

13b) what is missing? How could it be improved?

13) Overall How easy to use if the CDSS?

Dissatisfied 0 1 2 3 4 5 6 7 8 9 10 **satisfied**

Usability testing questionnaire: Suicidal Presentations-CDSS. Final version 1.0 19.07.2017

Thinking aloud exercise

This questionnaire features questions that will be asked by the investigator as you are processing the information contained in the vignette. The second stage features questions for you to complete after you have completed this simulated patient consultation.

Thinking questions	
What key words or key information have you heard that you want to explore?	*free text response*
what does not seem to fit within the clinical vignette?	*free text response*
What rules of thumb or heuristics might be being triggered for you?	*free text response*
How are the questions within the tool leading your line of thinking?	*free text response*
How are the questions within the tool changing your line of thinking?	*free text response*
How well is the CDSS supporting your clinical reasoning processes?	**poor** 0 1 2 3 4 5 6 7 8 9 10 **acceptable**
Ease of use navigability questions	
As you are exploring this line of thinking what do you want to consider next in the CDSS? (decision chain analysis)	*free text response*
How easy is it to check, or to review your developing line of reasoning? (analytical checkpoints)	**poor** 0 1 2 3 4 5 6 7 8 9 10 **acceptable**
If you need to swap between different sections of the CDSS how easy is it?	**poor** 0 1 2 3 4 5 6 7 8 9 10 **acceptable**
If you need to cross reference with other parts of the patient's electronic record, how easy is it?	**poor** 0 1 2 3 4 5 6 7 8 9 10 **acceptable**
How easy is it to use the CDSS	**poor** 0 1 2 3 4 5 6 7 8 9 10 **acceptable**

THIS SECTION TO BE COMPLETED AFTER USING THE e-CDSS Comparison to previous approach.		
Please compare and score the CDSS and your previous approach, 0-10 for the following items (Where 0 = poor, and 10 = acceptable.)		
(Clinical appropriateness)	Addresses patient needs	CDSS __/10 Previous approach __/10
	Addresses your needs to provide clinically appropriate care in this consultation	CDSS __/10 Previous approach __/10
	Provides a detailed decision making process taking account of relevant information and factors	CDSS __/10 Previous approach __/10
(Contextual appropriateness)	Provides a time efficient process suitable for time constraints in primary-care	CDSS __/10 Previous approach __/10

Usability testing questionnaire: Suicidal Presentations-CDSS. Final version 1.0 19.07.2017

	Integrates with workflow tasks	CDSS __/10 Previous approach __/10
	Integrates with existing IT systems	CDSS __/10 Previous approach __/10
(Actionable Decision Support)	Adds confidence to your clinical reasoning process	CDSS __/10 Previous approach __/10
	Appropriately guiding your decision making	CDSS __/10 Previous approach __/10
	Adds value to the consultation	CDSS __/10 Previous approach __/10
Practitioner satisfaction questions		
Has well has the CDSS prompted analysis of the important factors relevant to this appointment?	**poor** 0 1 2 3 4 5 6 7 8 9 10 **acceptable**	
How satisfied are you with the questions and prompts within the tool	**Not at all** 0 1 2 3 4 5 6 7 8 9 10 **completely**	
What could be improved?	*free text response*	
How well has the CDSS performed in supporting your decision-making process?	**poor** 0 1 2 3 4 5 6 7 8 9 10 **acceptable**	
Please note anything else that would improve your experience of using the CDSS	*free text response*	

Appendix O: Information sheet – Usability testing

The University of Nottingham
UNITED KINGDOM · CHINA · MALAYSIA

Participant Information Sheet: Usability Testing (Service Users)
(Final version 1.2 / 04.10.09.2017)

IRAS Project ID: 226469

Title of Study:
The development of an electronic clinical decision support system to assist GPs with their identification, assessment and management of suicidal presentations in primary care

Name of Researcher: Mr M Horrocks (PhD Student)

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through this information sheet with you and answer any questions you have. Talk to others about the study if you wish. Ask us if there is anything that is not clear.

What is the purpose of the study?

The study is being conducted as part of a degree. at the University of Nottingham. The aim of the study is to develop and evaluate an online computer programme (known as an electronic clinical decision support system or e-CDSS) to support GPs to ask patients about suicidal thoughts, feelings or behaviours. Helping GPs to think and ask about people's possible suicide risk is important because up to 45% of people who die by suicide have a GP appointment in the month before their death.

In order to develop and test the online computer programme which will help GPs ask patients about their suicidal thoughts and feelings it is being used in some appointments in the practice today.

Why have I been invited?

You are being invited to take part because you are attending the practice for an appointment with your GP on one of the days that we are asking the GPs to use online computer programme.

Do I have to take part.

No you do not have to take part.
It is up to you to decide whether or not to take part.

If you decide to take part you are still free to withdraw at any time and without giving a reason. This would not affect your legal rights or your NHS treatment.

What will happen to me if I take part?

If you agree to take part – we will ask you to sign a consent form. Then we would like you to take this information sheet and your copy of the consent form into your GP appointment and please also tell your GP that you have agreed to take part in this research study.

If you agree to take part;

- Depending on the nature of your appointment with your GP and other information contained within your medical records, your GP may decide to use the online tool in your appointment.
- The GP will not use the online tool in the appointment of everyone taking part.

Clinical decision support for potential suicide risk in primary care
Information sheet – Usability Testing (Service Users) final version 1.2 04.10.2017

- Regardless of whether or not the online tool is used in your appointment, your confidentiality will be protected as none of your medical records or clinical data will be available to the researcher or seen by anyone else outside of the GP practice.
- If your GP decides to use the tool in your appointment you will be asked questions about possible risk factors for suicide, such as suicidal thoughts or feelings.

Expenses and payments

You will not be paid an inconvenience allowance to participate in the study.

What are the possible disadvantages and risks of taking part?

We do not anticipate any risks from taking part in this study. Being asked questions about mental health and suicide risk is a potentially sensitive issue. Although talking about suicide risk could be upsetting, there is no evidence that GPs asking people about suicide risk leads to higher risk or harm. In fact studies show that service users may find talking about suicide risk helpful. However you retain the right to leave the study at any point before or during your GP appointment.

What are the possible benefits of taking part?

We cannot promise the study will help you, but the information we get from this study may help GPs to explore suicide risk with other service-users. People sometime find that they enjoy taking part in research which might help the NHS to deliver better care in the future.

What happens when the research study stops?

When the study ends, you will continue to receive your usual care from your GP.

At this early stage in its development we cannot say how the online computer programme will be eventually used, and at the end of the study there is no guarantee that the online computer programme will be available for use in local GP practices in the future.

We will send you a summary of the research findings, unless you ask us not to.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. The researchers contact details are given at the end of this information sheet. If you remain unhappy and wish to complain formally, you can do this by contacting the Patient Advice and Liaison services within either the Nottingham city or county Clinical Commissioning group areas. For GP surgeries based in the City of Nottingham please contact 0800 1830456 or email PALS@nottinghamcity.nhs.uk; for GP surgeries based in Nottinghamshire please contact 0800 0283693 or email PALS@nottspct.nhs.uk

Will my taking part in the study be kept confidential?

We will follow ethical and legal practice and all information about you will be handled in confidence.

If you join the study, the data collected for the study will be looked at by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

All information which is collected about you during the course of the research will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database. Any information

about you which leaves the NHS will have your name and address removed (anonymised) and a unique code will be used so that you cannot be recognised from it.

Your personal data (address, telephone number) will be kept for less than 3 months after the end of the study so that we are able to contact you about the findings of the study a*nd possible follow-up studies* unless you advise us that you do not wish to be contacted. All other data (research data) will be kept securely for 7 years. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team will have access to your personal data.

At the end of the study we will send you a summary of the research findings unless you advise us that you do not wish to be contacted.

What will happen if I don't want to carry on with the study?

Your participation is voluntary and you are free to withdraw from the study at any time during your GP appointment, without giving any reason, and without your legal rights being affected. If you withdraw then the information collected so far cannot be erased and this information may still be used in the project analysis.

What will happen to the results of the research study?

The study results will be published in scientific journals, and presented at scientific conferences and service-user meetings. Lay summaries of the findings will be written and sent out to interested stakeholders. We will also seek to present information about the study to interested parties/stakeholder groups, including people who design and pay for local health and social care provision. Additionally the study will also be written up for an educational qualification (PhD) with University of Nottingham. Your identity will be protected in any publications so that no one will know you took part in the study.

Who is organising and funding the research?

This research is being organised as a PhD project at the University of Nottingham and is being funded by the National Institute for Health Research's Collaboration for Leadership in Applied Health Research and Care – East Midlands.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the Nottingham 1 Research Ethics Committee.

Further information and contact details

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Clinical decision support for potential suicide risk in primary care
Information sheet – Usability Testing (Service Users) final version 1.2 04.10.2017

Appendix P: Debrief sheet

Usability Testing: patient support sheet suicidal presentations-CDSS. Final version 1.0 19.07.2017

The University of Nottingham
UNITED KINGDOM · CHINA · MALAYSIA

The development of an electronic clinical decision support system to assist GPs with their identification, assessment and management of suicidal presentations in primary care

Sponsor Reference: 17053, IRAS Project ID: 226469

Patient Support Sheet

Please read this sheet carefully.

Thank you for agreeing to participate in our research study today – as you know in today's GP appointments we have been evaluating the online tool we are developing, which is intended to help GPs ask patients about suicidal thoughts, feelings or behaviour and suggest possible sources of support which might be of use to people who need help. As we explained to you before your GP appointment, this work is being done as part of a research study at the University of Nottingham

We understand that you have just been in an appointment with your GP, where you have been asked about suicidal thoughts, feelings or behaviours. It may be that this is a particularly difficult time for you, and we wish to make sure you are aware of what was happening in your GP appointment.

During your appointment, you may have noticed your GP entering data into their computer system.

GPs are expected to keep their own clinical record of your appointment today. GPs normally use electronic medical records to make notes about their patient's health and support needs. Data contained in your GPs clinical records are separate to this study and none of your personal details or records of exactly what you talked about with your GP are being passed to us at the University of Nottingham.

In addition, some of your GPs computer data entry will have been in relation to using the tool and evaluating how useful they found the online tool.

To evaluate how useful GPs find the online tool we are asking your GP to provide feedback on how useful they felt the inline tool was in relation to your appointment. None of your personal information is being provided to us at the University of Nottingham. Therefore, your identity is protected in this process.

We hope that our online tool can support GPs and their patients to talking about suicidal thoughts, feelings or behaviours.

This is really important because many people have thoughts about suicide, or feel like life is hopeless at times, but these thoughts and feelings are usually temporary. Many people who have thought about or felt like ending their own live, or even tried to end their own life, look back with relief that they were not successful in acting on their intention. How we think, feel and how we behave can and does change.

However, if you are feeling suicidal we would urge you to get some help and support, by either speaking to someone you trust or contacting one of the services listed on the other side of this sheet

Usability Testing: patient support sheet suicidal presentations-CDSS. Final version 1.0 19.07.2017

Don't be afraid to ask for help, with support things can get better. If you reach crisis point, and feel unable to keep yourself safe from suicide please seek help straight away, and ask for someone to keep you company until the feelings pass.

IF YOU NEED URGENT HELP, PLEASE:

- **Phone 999 for emergency support.**
- **Go back to your GP or doctor.**
- **Attend your local A&E.**

OTHER USEFUL NUMBERS & CONTACTS (**non urgent help**)

The Tomorrow Project	Text: 07594 008 356	Email: tomorrow@harmless.org.uk
HopeLine (people up to 35 years old)	0800 068 41 41 Weekdays: 10am-5pm, 7pm-10pm Weekends: 2pm-5pm	Email: pat@papyrus-uk.org
CALM (men of all ages)	0800 58 58 58 (5pm to midnight)	Webchat: https://www.thecalmzone.net/help/webchat/
SANEline	0845 767 8000 (6-11pm)	
Samaritans	116 123 (24 hours)	Email: jo@samaritans.org
ChildLine (people upto 19 years old)	0800 1111 (24 hours)	
NHS 111 (non-emergency advice)	111	

If you would like to discuss the research study further, please contact:

Matthew Horrocks,
PhD Student, University of Nottingham
Tel: (to be confirmed)
Email: matthew.horrocks@nottingham.ac.uk

Appendix Q: Live usability testing – outcomes chart

Usability – Live testing_ Suicidal presentations e-CDSS final version 1.0 19.7.17

Guidance to GPs: Please use this form after each use of the GPS[3] protocol with an individual patient, to record how often you have used protocol during today's surgery, and how it has effected the consultation.

Please fill in the form for each use of the protocol with different patients, ticking the relevant boxes, recording whether or not you have decided to follow the recommendations within the protocol and whether or not it has prompted your review or discussion of the following areas:

		Record of use of the e-CDSS with patients in today's clinic									
		1	2	3	4	5	6	7	8	9	10
Patient Sex	M/F										
Patient Age bracket	14-16										
	16-24										
	24-29										
	30-44										
	45-59										
	60-74										
	75 and over										
Have you complied with the care planning recommendations	Yes										
	No										
Diagnosis	Screening for mental health problem										
	Review of existing mental health diagnosis										
	New mental health diagnosis										
Medication	New prescription										
	Medication review										
Exploration of risk factors	Discussion of patients relationships										
	Discussion of alcohol / substance misuse										
	Discussion of financial stressors										
Mental state	Mental state assessment										
	Mental capacity assessment										
Referral	Psychiatric / CRHT										
	Substance use										
	Talking therapy										
	Self-harm / suicide support										
	Other support agency / service										
Other action taken	Created a safety plan										
	Maintaining in primary care										
	Bring back for further appointment										
Date of use:	Dr's Signature:					Designation:					

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