Electronic Monitoring Devices: Necessary steps for their successful integration with current asthma care

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Abstract

Health monitoring devices are changing the way we treat, manage and understand chronic health conditions by continuously collecting data about medication use, symptoms, vital signs and a patient's surrounding environment.

Asthma is the most common chronic condition worldwide and has symptoms that include wheezing, coughing and shortness of breath - all typically treated with inhaled medication. By taking a daily 'preventer' inhaler a patient should be able to control their asthma and remain relatively symptom free. However, adherence to preventer medication is often poor, making patients prone to severe symptoms and asthma attacks. This leads to avoidable healthcare costs, mainly through preventable hospitalisations and wasted medication.

Electronic monitoring devices (EMDs) are the most accurate method currently available for recording inhaler use. Through rigorous testing they have been shown to be sufficiently accurate and reliable for use in clinical practise. Early signs also suggest that they may improve inhaler use when a ringtone is used to remind the patient when a new dose is due. However, no research to date has considered the attitudes of patients with asthma as well as healthcare providers towards these devices.

Human factors in healthcare is a now established area of research, with an international standard (ISO 62366) meaning that medical device developers are required to design for a usable and error-free experience. This creates clear scope for assessing the perceptions of patients and healthcare providers towards EMDs for use in the management of asthma. This was investigated in this thesis using three separate but related research studies. Two studies assessed the attitudes of patients and healthy volunteers, whilst the other analysed the opinions of healthcare providers and stakeholders in asthma care.

The first study assessed the attitudes of a sample of adolescents with asthma towards an exemplar EMD – the SmartTrack. Asthma is most prevalent in adolescents, adherence is notoriously poor, and they are often overlooked in medical device design - making assessing their views a priority. The participants used a SmartTrack device for one month and completed questionnaires and

interviews on their opinions towards important issues including being monitored and the device's appearance, social acceptability and practicality.

For the second study, a Delphi survey method was used to collect the opinions of stakeholders in asthma care including respiratory consultants, nurses and GPs towards EMDs. They were asked to state the key benefits they thought these devices could have, as well as the key potential costs and barriers for their introduction. Additional rounds of surveys were then used to assess which points they felt were most important and should be prioritised in the future development of these devices.

EMDs developed new capabilities over the course of this thesis, meaning that the third study was used to investigate attitudes towards location and activity data, as both were beginning to be integrated with data on inhaler use. Two workshops and a technology trial were conducted with a sample of healthy adolescents from a local sixth form. Participants had their location and activity tracked and then had this data presented back to them. They were asked for their opinions on the usefulness of this data, as well as any potential risks associated with recording it.

The findings from all three studies were then brought together to determine the requirements of EMDs going forward. A systems model of asthma care was developed to firstly consider the routes through which EMDs could be purchased, as well as the impacts EMDs could have on various points of the asthma care process, both for the patient and the healthcare provider. The requirements for EMDs were then also related back to this model, to help outline their importance and relevance to the asthma care pathway.

From the research it was determined that developers need to reduce the size of EMDs, as well as integrate the ability to monitor inhalation and technique. Commissioners need to work with clinical researchers to identify the types of patients who would benefit most from an EMD, in order to reduce risks of over-purchasing. Furthermore, researchers need to work with healthcare standards bodies to establish how the vast quantities of data produced by EMDs can be successfully integrated into the clinical care process.

This thesis has three key contributions. Firstly, it introduces human factors research methods to the domain of EMDs for asthma care. Secondly, it provides a set of requirements for EMDs to help ensure that these devices can be successfully introduced and used in clinical care. Lastly, it supplements the literature on human factors methods being applied to healthcare and provides a new example of where user-focused research has been used to elicit requirements for a medical device.

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Publications

Journal Papers

Howard, S., Lang, A., Sharples, S., & Shaw, D. (2017). See I told you I was taking it! – Attitudes of adolescents with asthma towards a device monitoring their inhaler use: Implications for future design. *Applied Ergonomics*, *58*, 224-237.

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Howard, S., Lang, A., Patel, M., Sharples, S., & Shaw, D. (2014). Electronic Monitoring of Adherence to Inhaled Medication in Asthma. *Current Respiratory Medicine Reviews*, 10(1), 50-63.

Conference Presentations

Howard, S., Lang, A., Youle, C., Vyas, H., Sharples, S., & Shaw, D. (2015). Exploring the attitudes of adolescents with asthma towards monitoring and sharing of data on their inhaler use. *European Respiratory Journal, 46(59) (Conference presentation at ERS 2015, Amsterdam, Netherlands)*

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Conference Posters

Howard, S., Lang A., Sharples, S., Shaw, D. (2015) A user evaluation of the 'SmartTrack' Smart Inhaler in a sample of adolescents with asthma. *International Symposium on Human Factors and Ergonomics in Healthcare: Improving the Outcomes. (Poster Presentation, Baltimore, USA)*

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Chapter 1 Introduction

1.1 Setting the scene and identifying a gap

"Once a year some individuals see a physician and get a checkup. At that time their blood pressure is measured, the heart is listened to, and laboratory tests are done to check things like liver and kidney function, fasting blood glucose and electrolytes. But in essence medicine in the current era is really like the fable of "The Blind Men and the Elephant." These are spot checks: a snapshot of the blood pressure and heart rhythm, a one-off measurement of blood glucose, or any other laboratory test…. we have such limited insight into the physiology of each and every individual - a non-representative, fleeting, pinhole view through an artificial environment prism."

Eric Topol, *The Creative Destruction of Medicine* (pg.60)

The above quote from Eric Topol - a cardiologist and digital health advocate, highlights how healthcare in the current age is limited to insights into an individual based on infrequent, reactive consultations. Internet-enabled devices such as smartphones are becoming increasingly more capable of recording data about our health, with connected accessories such as heart rate monitors, blood pressure monitors and pedometers allowing patients to record and observe many aspects of their health from their own home. Through capturing detailed information on a patient's vital signs, exercise levels and medication management it is possible to gain an in-depth understanding of a patient's health and the ways in which it fluctuates on a daily basis. This has tremendous potential for the healthcare industry as it could allow for warning signs of when a patient's health is at risk, earlier diagnoses for illnesses, and a greater understanding of how medication impacts on the health of different patients.

Whilst 'data-driven' healthcare would lead to greater insights into patients, illnesses and treatment, there are concerns for the capacity of the health service to sufficiently deal with this quantity of data. Jeremy Hunt, Health Secretary for the UK, made calls in 2013 for the National Health Service (NHS) to be entirely paperless by 2018 in order to save £4.8 billion a year. This was met with scepticism from those who remember the failings of a previous initiative - the National Programme for IT (NPfIT), which began in 2002 and was later dismantled in 2011 due to costs far exceeding the savings it promised.

With the health industry still struggling to fully adopt basic electronic health records, the addition of 'big data' from digital devices would have vast implications for both cost and IT infrastructure, as well as for staff training in interpreting and using the information effectively. Despite this, there could be huge benefits for harnessing and utilising this data, with this potential already recognized by the world's major technology companies.

Microsoft's 'HealthVault' was launched in the UK in 2010 as an online resource for patients to access their medical records and health information. This includes data recorded by health devices such as pedometers and blood pressure monitors, as well as information on the patient's medical history, lab results and prescription records. Similarly, in 2015 Apple launched 'ResearchKit' – a service allowing medical researchers to use iPhones as tools for studying conditions including diabetes, asthma, heart disease and Parkinson's. This demonstrates that regardless of the state of the NHS and its IT infrastructure - data is still being captured on patients and illnesses and this will have a major impact on the way in which we understand different health conditions and how they should be treated.

Asthma is a highly prevalent health condition with an emerging selection of digital devices that have the potential to provide benefit. Whilst the condition is highly treatable, there are currently major issues surrounding patients not using their inhalers as prescribed - leading to unnecessary costs, hospital admissions and even deaths. New electronic monitoring devices (EMDs) that are capable of recording the exact date and time whenever a patient uses their inhaler could have a major impact on this. By providing an objective measure of inhaler use there is potential for a patient to independently monitor their medication taking. Healthcare professionals could also utilise this data to determine if a patient's symptoms are due to ineffective medication or the patient not adhering to their treatment plan as prescribed. This could impact on care by allowing for earlier interventions to either change medication, dose, or target patients who are not adhering to treatment. As a result, this could potentially reduce costs through less wasted medication and a reduction in hospital admissions.

EMDs for asthma are rapidly developing, with research largely focused on extensive testing of the devices to ensure that they are sufficiently accurate and reliable to feasibly be used in clinical settings. Little research, however, has

considered the attitudes of both patients and healthcare providers towards these devices. A new international standard (ISO 62366) means that manufacturers of medical devices are now required to follow a usability engineering process to help ensure devices are designed to be usable and free from errors. This means there is clear scope to investigate the potential role of EMDs within the current healthcare system. Research of this nature would help establish user requirements for EMDs and would also contribute to the body of literature on the application of human factors methods to medical devices.

1.2 Methodology

For the research included in this thesis, a methodology was adopted that focused on using participatory methods in a 'systems' context. As EMDs would be interacted with by multiple stakeholders, including patients and healthcare providers, it was deemed important to take the entire asthma care system into account when assessing attitudes and requirements related to these devices. In all three studies included in the thesis, research methods were carefully selected to maximise the quality of user-related feedback that was received.

1.3 Horizon Centre for Doctoral Training (CDT)

This research is funded through the Horizon CDT at the University of Nottingham (RCUK Grant No. EP/G037574/1). The CDT is a multidisciplinary research centre bringing together students from a wide range of backgrounds including computer science, psychology, geography, law and business. The overall focus for researchers funded between the years 2009 and 2013 was ubiquitous computing for the digital society. For the research included in this thesis, the CDT's relationship with Nottingham University Hospitals (NUH) was utilised to secure clinical supervision from a respiratory consultant who provided expertise necessary to appropriately explore the medical and healthcare domain.

1.4 Outline of Thesis

This thesis follows a traditional structure which is visually represented in figure 1-1. Firstly, a literature review was conducted to identify the gap in the current research, followed by three studies to answer the research questions set out in section 1.5. Afterwards, the findings are brought together to consider the potential impacts of EMDs and requirements for research and development going forward. This is followed by an overall discussion of the research, with a reflection on how the work has answered the research questions, as well as an overall conclusion.

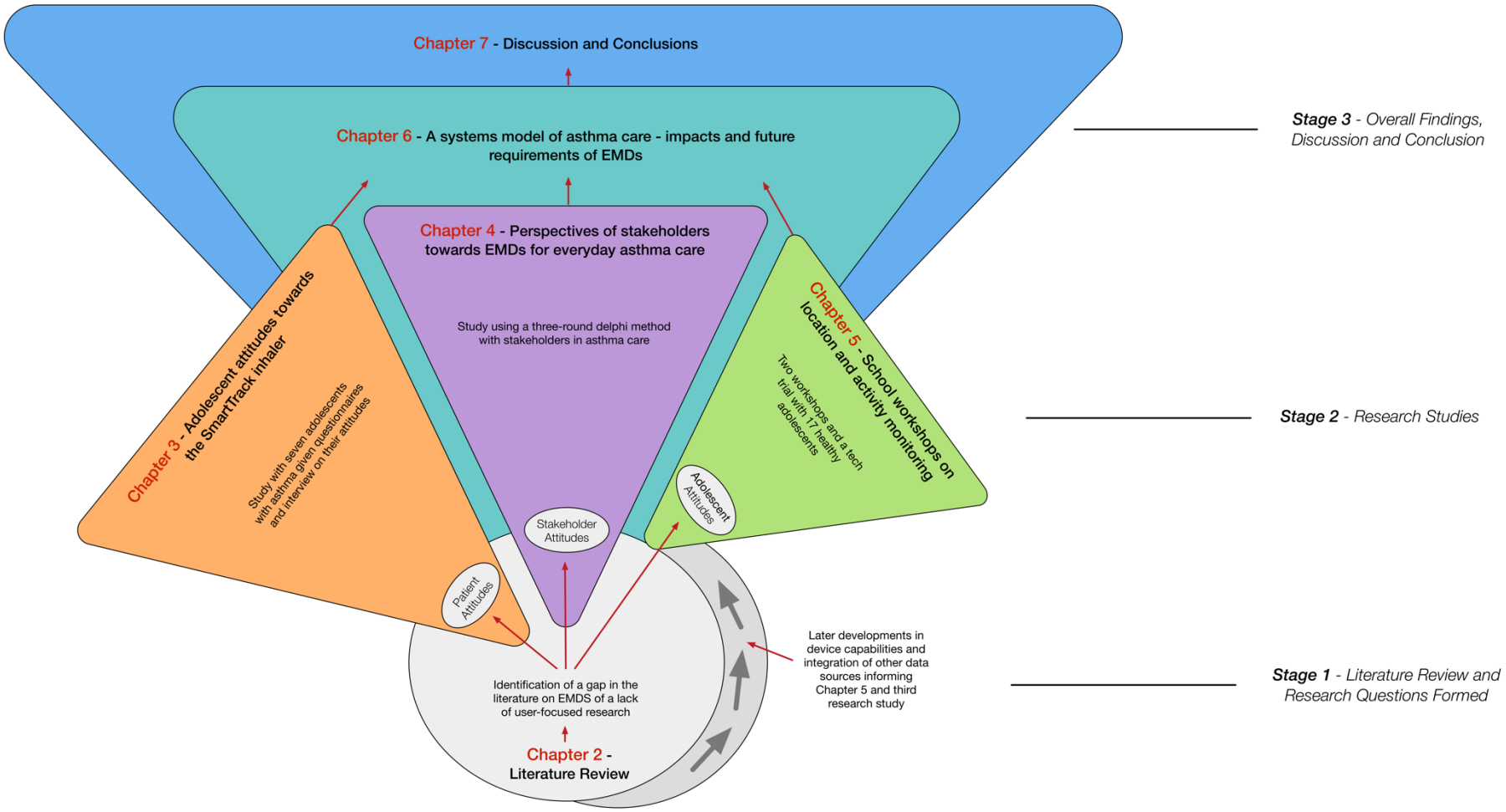

Figure 1-1 Outline of thesis chapters

1.4.1 Literature included in chapters

Whilst the literature review contains the main body of existing literature related to the topic of this thesis, the three study chapters afterwards contain additional literature that is more specific to each study. It was decided that this more specific literature would not be included in the initial literature review as it would be more intuitive to cover at the beginning of each of the study chapters and would help in painting a clear pathway throughout the thesis.

1.5 Research Questions

The three research questions upon which this PhD investigation is based will be discussed below, followed by an outline of how each will be answered by the three research study chapters of this thesis in table 1-1.

1. **What different perceptions are there towards technologies for monitoring health-related behaviours in asthma care?**

This research question will explore the views of different user groups including patients, non-patients (healthy adolescents) and healthcare providers towards digital devices capable of monitoring health-related behaviours, such as inhaler use. Through use of research methods including questionnaires, interviews, Delphi surveys and workshops, insight will be gained into the perceptions of people towards this type of technology.

2. **What are the requirements of patients and healthcare providers for data-centred health monitoring devices and technologies for asthma care?**

With health monitoring technologies for asthma having potential uses for both patients and healthcare providers, it is important to consider how these devices apply to both groups and to understand their individual requirements. Through assessing the views of both user groups in this research, this thesis will seek to establish where the priorities of both groups lie - to understand how their needs can be incorporated into the future design of these devices.

3. **What are the challenges and opportunities for health monitoring technologies going forward, as they become more widespread and develop new monitoring capabilities?**

In the latter stages of the thesis it will be noted that the capabilities of monitoring technologies for asthma are developing and expanding to include new sources of data to be integrated with information on medication use – such as where a patient is using their inhaler and their levels of daily activity. Different sources of data vary in levels of intrusiveness and potentially heighten concerns over privacy for a patient, as well as complicate the task of a healthcare provider. By building on the knowledge of user attitudes for current monitoring technologies, as well as through exploring perceptions towards other sources of monitoring, this research question will seek to establish the potential user-related issues that could affect monitoring technologies going forward.

Table 1-1 A table showing how each research chapter contributes in answering each of the three research questions

	Chapter 3 – Adolescent attitudes towards the SmartTrack inhaler	**Chapter 4** – Perspectives of stakeholders towards EMDs for everyday asthma care	**Chapter 5** – School workshops on location and activity monitoring
What different perceptions are there towards technologies for monitoring health-related behaviours in asthma care?	Attitudes of adolescents towards various aspects of the device including its appearance and ability to monitor their inhaler use	Investigating what stakeholders and healthcare providers believe the main benefits and barriers of monitoring inhaler use using technology are	Exploring perceptions of healthy adolescents towards technology that can monitor their location and activity levels
What are the requirements of patients and healthcare providers for data-centred health monitoring devices and technologies for asthma care?	Provides the perspective of a sample of adolescents with asthma – a chronic condition where monitoring could provide benefit	Provides the perspective of stakeholders and healthcare providers	Provides the perspective of healthy adolescents (non-patients), who may have differing opinions to adolescent patients with a chronic health condition
What are the challenges and opportunities for health monitoring technologies going forward, as they become more widespread and develop new monitoring capabilities?	Provides insight into current attitudes - which may help indicate how attitudes might form as technology develops	Advantages and disadvantages of monitoring technologies raised by stakeholders can be applied to new monitoring capabilities	Explores the benefits and concerns healthy adolescents believe having their location and activity levels monitored could potentially have

1.6 Contributions of this thesis

The three key contributions of this PhD research can be outlined as follows:

1.6.1 A first-step in understanding user-needs for EMDs in asthma

Through examining the needs of multiple user-groups including patients and healthcare providers, this thesis provides a key contribution in being the first known research to consider EMDs for asthma from a user perspective. Through providing a novel application of established human factors methods, it introduces this type of research to the domain of monitoring technologies for asthma. It is hoped this will trigger future user-research in this area and will

help in providing a guide for developers of EMDs to use when assessing the usability of their devices in accordance with ISO 62366.

1.6.2 Informing future design and development of EMDs

User requirements identified from the three studies conducted here will help inform the future design and development of EMDs going forward. By considering the attitudes of both patients and stakeholders, the major issues these devices need to address can be identified. Actionable recommendations are provided for how future iterations of the devices should be adjusted and improved to meet user-needs and help maximise their potential success.

1.6.3 Supplementing the growing research area where human factors methods have been applied to medical devices and the healthcare industry

Through a diverse publication list, this research contributes to both human factors as well as clinical literature. Furthermore, it contributes to the established body of literature where human factors methods have been applied to the healthcare industry by providing a new case-study where a human factors approach has been applied to a novel medical device. Whilst previous work in this area has often focused on safety and usability of non-digital medical devices, this research provides a key contribution through focusing on the data monitoring capabilities of EMDs. It provides an example case for how a digital device such as this should be assessed from a user-focused perspective, with the methods and findings potentially applicable to similar digital devices for other health conditions.

Chapter 2 Literature Review

2.1 Introduction

A narrative approach was used for the literature review as this was considered the most appropriate method for describing the context and ultimately identifying the gap that this thesis can fill. For identifying relevant and related research, Google Scholar was used as the primary database, with key searches also carried out on PubMed and Scopus. A summary of the primary and secondary literature topics covered in this chapter is shown in Fig 2-1.

The literature review firstly describes asthma and the methods for effectively treating it. It then provides evidence demonstrating that patients with asthma are notoriously poor at adhering to their medication. The main impacts associated with this non-adherence to treatment are then considered, before examining the main reasons why patients may not be taking their inhalers as prescribed.

Once non-adherence in asthma and the reasons for it have been established, the different ways we can measure and record inhaler use are discussed. Next, the different techniques that can be used to improve adherence in asthma treatment are examined.

After establishing that electronic monitoring devices (EMDs) can both record and potentially improve adherence in asthma, a review of their use in the clinical literature to date is provided, followed by a discussion of their potential limitations and issues going forward. A lack of consideration for user attitudes (both patient and healthcare provider) is stated as a key problem for these devices. This leads to the final section of the review where previous work that has involved users in the design of medical devices is provided.

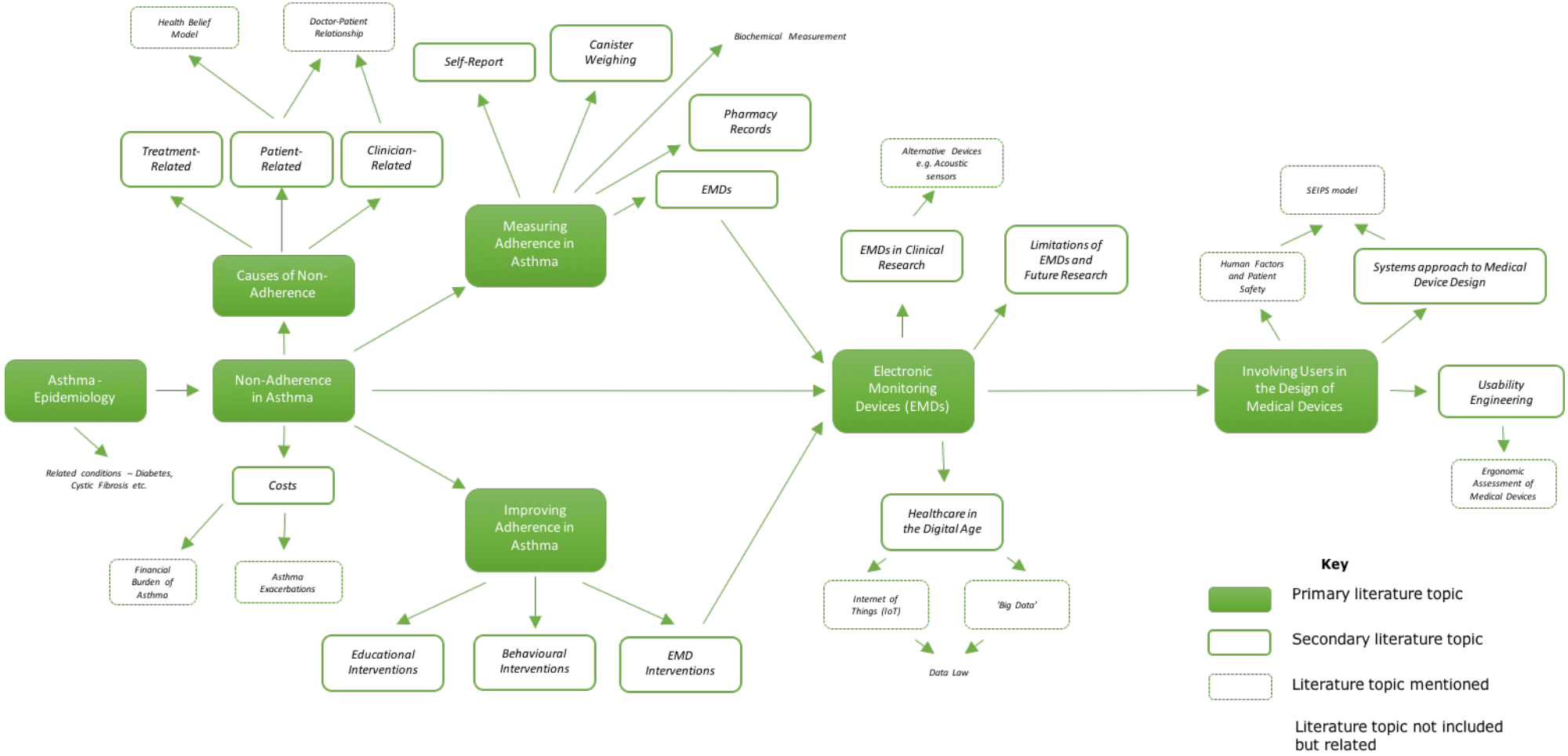

Figure 2-1 A diagram of the topics covered in the literature review

2.2 Asthma

Asthma is clinically diagnosed based on the presence of wheezing, shortness of breath and coughing, alongside evidence of airway inflammation and airflow obstruction (J. Rees, Kanabar, & Pattani, 2010; Tattersfield, Knox, Britton, & Hall, 2002).

Whilst family studies have shown that susceptibility to asthma is partially genetically determined (Ober et al., 1998; Wjst et al., 1999) a wide selection of environmental factors have also been shown to provoke the condition including: allergens, exercise, fumes, respiratory infections, and changes in temperature and humidity (Tattersfield et al., 2002). Whilst previously common in older adults, asthma is now most widespread in children and adolescents (NHS Information Centre, 2010), with roughly one in every 11 children and every 12 adults diagnosed with asthma in the UK today (NRAD, 2014). Recent estimates indicate that a total of 5.5 million people in the UK have asthma (NRAD, 2014).

Asthma has no known cure, but various treatment methods exist to control symptoms and help manage and prevent asthma attacks (Stern et al., 2006). Inhaled medication for asthma can be separated into two broad categories: short-term rescue medication often referred to as 'reliever' medication, and long-term control medication often referred to as 'controller' or 'preventer' (Stern et al., 2006).

Short-term reliever medication consists of β2 agonists taken by inhalation. These are fast acting, usually taking effect within 15 minutes and lasting for between four and six hours. They are used when a patient is experiencing severe asthma symptoms or an asthma attack, to relax and reduce inflammation of the airways to help make breathing easier. If a patient uses their reliever medication three or more times a week, or is woken from sleep due to their symptoms, these are strong signs that further treatment and condition management is required (J. Rees et al., 2010).

In long-term preventive medication, inhaled corticosteroids are considered the most effective treatment. Preventive medication needs to be taken regularly, usually twice a day, in order to be effective and to help control asthma and keep symptoms to a bare minimum (J. Rees et al., 2010).

Despite asthma being highly treatable and easily managed with effective medication, it still has a tremendous impact on the healthcare system. It is estimated that the economic burden of asthma on the NHS currently stands at roughly £1 billion annually (NHS Information Centre, 2010). A recent review of asthma deaths in the UK found that there were potentially preventable factors in over 60% of the deaths they investigated (NRAD, 2014). The review conducted by the Royal College of Physicians highlighted widespread excessive prescribing of short-term reliever inhalers as a major concern for asthma care in the UK today (NRAD, 2014).

2.3 Non-adherence in asthma

The World Health Organisation defines adherence as "the extent to which a person's behaviour – taking medication, following a diet, and/or, executing lifestyle changes, corresponds with agreed recommendations from a health care provider," (pg. 3) (Sabaté, 2003).

'Adherence' as a term is typically preferred to 'compliance' as this simply refers to how well a patient's behaviour matches a prescriber's recommendations (Horne, Weinman, Barber, & Elliott, 2005). This preference stems from a commonly held view that 'compliance' is too dictatorial and implies a lack of input and involvement from the patient (Horne et al., 2005; Morton, Everard, & Elphick, 2014). A third term - 'concordance', is also used in the UK and better emphasises the two-way agreement between prescriber and patient when establishing medication regimen (Horne et al., 2005; Morton et al., 2014). However, as the most widely accepted and used term, 'adherence' will be used here as opposed to other alternatives.

Patient adherence rates to treatment recommendations are measured by the percentage of prescribed doses taken (Osterberg & Blaschke, 2005). In asthma, adherence rates to preventer medication range from 30-70% (Rand & Wise, 1994), yet a rate of at least 80% is required for optimal asthma control (Lasmar et al., 2009). Poorly controlled asthma leads to overuse and reliance on bronchodilator medication to quickly relieve symptoms, but this in turn can lead to increased asthma symptoms, more frequent asthma attacks (Stern et al., 2006) as well as a higher likelihood of hospital and emergency room visits (Tan, Sarawate, Singer, & Elward, 2009).

Not only does poor adherence lead to health risks for asthma patients, but it is also regarded as one of the main causes for the high social and financial costs

associated with asthma care (Fink, 2001). Furthermore, of the preventable factors associated with asthma deaths, poor adherence has the strongest correlation (Department of Health, 2011).

The risks of overuse of reliever medication and the benefits of proper use of controller therapy are highlighted by two large long-term clinical trials looking at the relationships between preventer or reliever medication and asthma deaths.

The first study used a sample of 12,301 patients with asthma and studied them over a 7-year period from 1980 to 1987 (Suissa et al., 1994). 180 deaths occurred in this sample over this time, with 46 being asthma-related and the remaining 134 non-asthma related. Using this data alongside prescription refill data the researchers demonstrated a strong positive correlation between overuse of inhaled β2 agonists (reliever medication) and asthma mortality. The more inhaled β2 agonist therapy a patient used, the more likely they were to die from asthma related causes (Suissa et al., 1994).

The second study used a larger sample of 30,569 patients with asthma and 30 years' worth of medical data (Suissa, Ernst, Benayoun, Baltzan, & Cai, 2000). Using the records of 66 asthma deaths that occurred over this period and comparing to control patients, they calculated that the likelihood of death from asthma decreased by 21% for every additional canister of inhaled corticosteroid used the previous year. The researchers concluded that using low-dose inhaled corticosteroids is significantly correlated with a decreased risk of death from asthma, the exact opposite of their previous study where they examined use of β2 agonists (Suissa et al., 2000).

2.4 Costs of non-adherence in asthma

With robust evidence pointing to patients with asthma not taking their medication as prescribed (Milgrom et al., 1996; Rand & Wise, 1994) it is important to understand the impacts that non-adherent behaviour can have on the health of patients as well as the health care system.

Whilst poor adherence to asthma therapy does not guarantee negative health implications for a patient, in many cases it will aggravate symptoms and increase frequency of exacerbations (Bender, Milgrom, & Rand, 1997). In the UK it has been demonstrated that patients who experience an asthma attack on average costs the healthcare system 3.5 times more than patients who have no exacerbations (Hoskins et al., 2000).

There is also evidence of non-adherent patients costing the healthcare system more, with potential savings of £475 per patient per year if non-adherent behaviour is targeted and hospital admissions avoided (O'Neill, Gamble, Lindsay, & Heaney, 2011). Poor adherence has additionally been associated with a loss of workplace productivity in employees with asthma (Joshi et al., 2009).

Poor adherence can also have a detrimental effect on research studies, making the chance of drawing inaccurate conclusions increasingly likely, whether this be through patients failing to take medication, failing to perform other required tasks or failing to attend study visits (Bender et al., 1997).

2.5 Causes of non-adherence in asthma

Researchers have typically separated the reasons for non-adherence into two groups: intentional and unintentional. Intentional non-adherence involves the patient making an active and conscious decision to ignore prescribed therapy (Lehane & McCarthy, 2007). Whereas unintentional non-adherence can typically occur through forgetfulness, carelessness or a lack of critical knowledge regarding their health condition or treatment (Wroe, 2002). Research has shown that patients can often exhibit forms of both intentional and unintentional non-adherence (G. Rees, Leong, Crowston, & Lamoureux, 2010; Sewitch et al., 2003).

In asthma the reasons for non-adherence to treatment have tended to be divided into three different categories: treatment related, patient-related and clinician-related (Bender, 2002; Bender et al., 1997).

2.5.1 Factors related to treatment

Research has demonstrated that adherence to medication often decreases as the number of doses required per day increases (Bender et al., 1997). This was first shown in a study that found that adherence in adult patients was best for once-daily tablets, only slightly worse for twice-daily tablets and poorest for tablets needing to be taken three times a day (Pullar, Wiles, & Birtwell, 1988).

In asthma, one study of inhaler adherence in children with asthma found that twice-daily treatment was associated with 71% adherence, three times a day associated with 34% adherence and four times a day only 18% adherence (Coutts, Gibson, & Paton, 1992). This is a drastic change, all within the same

age group and condition. However, a later study with 29 children with asthma did not see this pattern and instead found great variation in all patients, regardless of whether they were on two, three or four times a day treatments (Gibson, Ferguson, Aitchison, & Paton, 1995).

Despite some inconsistencies in demonstrating how adherence decreases as daily dose increases, there is evidence that simplification of treatment leads to improvement. One study took medical records from 119 asthma patients all of whom had prescriptions for inhaled anti-inflammatory medication (taken three or more times day) and oral theophylline (taken once or twice a day). It was found that patients were significantly more compliant to the theophylline medication than the two inhaled anti-inflammatory medications, with no significant differences in adherence found relative to prescribed dosing frequency for either medication type (Kelloway, Wyatt, & Adlis, 1994). Simpler treatments for asthma have been repeatedly shown to improve adherence (Makela, Backer, Hedegaard, & Larsson, 2013), with inhaled therapy shown to result in worse adherence than oral medication (Fitzpatrick et al., 2009; Jones et al., 2003; McNally et al., 2009; Rand et al., 2007) and with injections (Broder, Chang, Ory, Kamath, & Sapra, 2009). However, inhaled medication is still regarded as the main treatment of asthma, with oral and injected medication used as 'add-on' therapy if asthma is not being sufficiently controlled by inhaler therapy alone (Asthma UK, 2016a).

A further treatment-related cause of non-adherence may be that for preventive medication the health benefits of adhering are delayed and can often go unnoticed by the patient (Bender, 2002). This is further complicated by the fact that patients can wrongly believe that when they have been taking controller medication correctly and symptoms subside, this means they no longer need to continue with treatment (Bender, 2002).

The inhaler device used has also been shown to affect adherence. A recent study found that dry powder inhalers (DPIs) such as the Accuhaler® have a negative effect on adherence in comparison to pressurised metered-dose inhalers (pMDIs), (Darba et al., 2016). Although DPIs are often prescribed by physicians due to patients having poor technique with their pMDI, the study found adherence was actually poorer in patients who use DPIs - but this may also have been affected by other confounding factors including age and asthma severity (Darba et al., 2016). In a study of 795 adult patients with Chronic Obstructive Pulmonary Disease (COPD) it was found that overuse of an inhaler was most

associated with devices where there was no dose counter, no feedback on correct inhaler technique, nor an ability to load a new dosage without actuation (Koehorst-ter Huurne, Movig, van der Valk, van der Palen, & Brusse-Keizer, 2016). Evidence also suggests that a patient's satisfaction with their inhaler can affect their adherence (Chrystyn et al., 2014). A 13-point survey given to 1443 adults with COPD asked for their satisfaction levels with their inhaler device. They found a significant association between adherence to treatment and inhaler satisfaction, and found that levels of satisfaction were mostly determined by the durability of the device (e.g. how well it is built to last), its design (e.g. easy to hold and carry) and its ease of use (e.g. simple, easy to follow instructions) (Chrystyn et al., 2014).

2.5.2 Factors related to the patient

It is hard to characterise all or even the majority of non-adherent patients under the same profile or trait - the non-adherent behaviour itself is the only common ground between them all (Bender et al., 1997).

However, some psychological traits have been shown to be significantly associated with non-adherent behaviour. Patients with clinically diagnosed depression are three times more likely to be non-adherent than patients without (DiMatteo, Lepper, & Croghan, 2000). In another study, it was found that age was the only significant predictor of adherence to inhaled steroids, with adherence increasing as age increased (Lacasse, Archibald, Ernst, & Boulet, 2005).

Knowledge and education can also have an influence. Particularly in the case of children, the level of understanding both they and their parents have about their condition and how to manage it can affect their adherence to medication and treatment (Gudas, Koocher, & Wypij, 1991; Modi & Quittner, 2006). This may be due to the purpose of controller medication being unclear to the patient, and it being hard to appreciate the delayed benefit they would receive from taking it properly over time (Bender, 2002). A similar case has also been found for adults with asthma, with degrees of asthma control found to be affected by knowledge and attitudes towards asthma management practises (Soriano, Rabe, & Vermeire, 2003).

The Health Belief Model (HBM) is a widely used framework for helping to explain and predict health behaviours and is useful when considering reasons why a

patient may not be taking their medication as prescribed (Besch, 1995; Rosenstock, 1966). Figure 2-2 depicts the model and its key components, with arrows indicating the pathway from moderating factors and beliefs through to health behaviours.

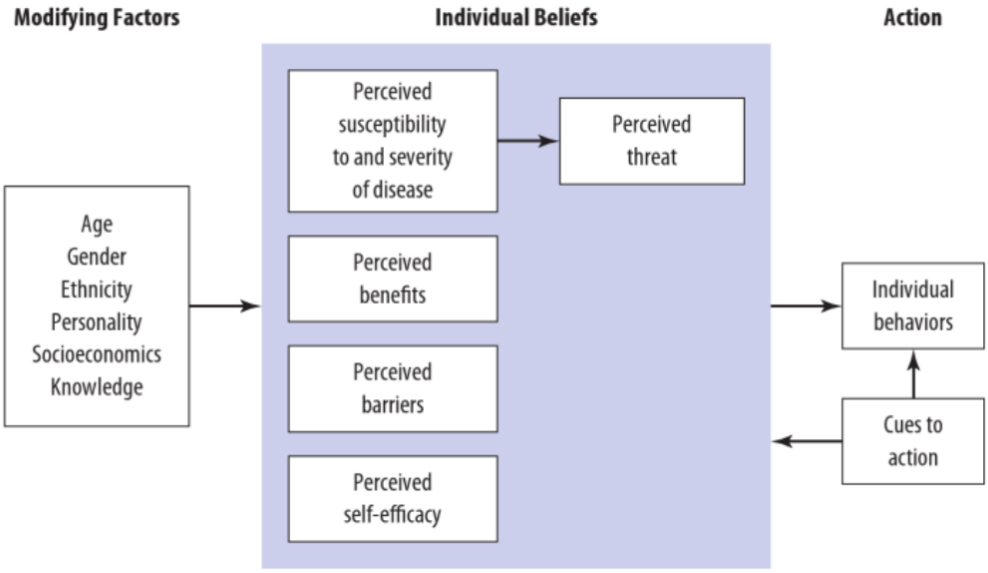

Figure 2-2 Components of the Health Belief Model (figure taken from Glanz et al. 2015)

Modifying factors such as age, gender and socioeconomic background can all have an influence on a person's health beliefs. For example, as most forms of cancer are more prevalent in older people, health beliefs may change as a person grows older, with cancer increasingly rated as a potential threat and influencing how likely an individual is to get screened for potential cancers (Glanz, Rimer, & Viswanath, 2015). The components of the health belief model depicted in figure 2-1 can be summarised as follows (Glanz et al., 2015):

1. **Perceived Susceptibility** – Patient's belief about their chances of getting a condition or experiencing symptoms of a condition
2. **Perceived Severity** – Patient's belief of how serious a condition and symptoms or effects would be
3. **Perceived Threat** – The combination of perceived susceptibility and severity, if either of the two is calculated as being zero, then the threat will be zero.

4. **Perceived Benefits** – Patient's belief about how effective advised action would be in reducing risk or effects
5. **Perceived Barriers** – Patient's beliefs about the potential costs of adhering to advised action
6. **Self-Efficacy –** Patient's beliefs about their own competency and ability to successfully perform a health related behaviour or action
7. **Cues to Action –** Either internal (e.g. pain or discomfort) or external (e.g. media campaign) cues that prompt health related behaviour

Two quantitative reviews of research that used the HBM looked at how well each component of the model could predict health behaviours (Harrison, Mullen, & Green, 1992; Janz & Becker, 1984). From both, it was found that perceived barriers were the most reliable predictor, with perceived susceptibility and perceived benefits next, followed by perceived severity (Harrison et al., 1992; Janz & Becker, 1984). However, it should be noted that whilst these components can be significant predictors of health behaviours, their effect sizes are often only small (Abraham & Sheeran, 2005).

2.5.3 Factors related to the clinician

When considering factors that are related to the clinician it is firstly important to acknowledge the large, established body of literature that exists for the doctor-patient relationship. Extensive research has investigated the impact that this relationship can have on health outcomes for the patient. For example, research investigating doctor-patient communication has found that patients can be left unhappy and dissatisfied even when a clinician believes their communication has been anywhere from adequate to excellent (Stewart, 1995), with surveys consistently showing that patients would like to receive better communication from their doctors (Duffy et al., 2004). Patient trust in their clinician has also been examined, with evidence pointing to levels of trust influencing both patient satisfaction and adherence to medical advice and treatment (Anderson & Dedrick, 1990; Mark A. Hall, 2006).

For asthma, the clinician and their clinical environment have also been shown to have an effect on patient adherence (Bender, 2002). If a patient's appointments with their clinician are too dispersed and/or their clinician appears uninterested and unwilling to spend time explaining or answering questions, this can influence how well a patient adheres to their prescribed therapy (Bender, 2002).

In an observational study of interactions between clinician and adult patients it was found that four physician characteristics promote adherence (DiMatteo et al., 1993). These were: having a busy practise, being willing to answer questions, ordering medical tests for the patient, and appearing to have a high level of job satisfaction (DiMatteo et al., 1993). Another study found that asthma outcomes and patient satisfaction can be improved by longer clinic visits, longer periods with the same clinician, a written asthma plan and providing patients with choices and responsibility for their care (Adams, Smith, & Ruffin, 2001). Similarly, it has been recommended that a clinician can help to improve their relationship with a patient and thus improve adherence to medical advice by adopting a warm and welcoming persona, providing the patient with a sense of control, and spending time getting to understand a patient's beliefs and perceptions about their condition and treatment (Bender et al., 1997).

Research has also indicated that asthma management and care can be influenced by whether the clinician and patient are from different ethnic backgrounds (Diette & Rand, 2007). One study found that physicians were more likely to underestimate the severity of asthma in black patients than white patients and that this underestimation was correlated with poorer adherence to inhaled corticosteroid therapy, poorer quality of care and a lower likelihood to have been instructed by their physician on how to deal with their asthma if they experienced an attack or severe symptoms (Okelo, Wu, Merriman, Krishnan, & Diette, 2007).

2.6 Measuring adherence in asthma

Multiple methods exist for assessing how adherent a patient is to their inhaled medication. Some measures have been omitted from this section such as biochemical measurement and clinical judgment, as these methods can be used for identifying non-adherent patients, but are not used for estimating the number of doses taken (Bender et al., 1997). Therefore, four key methods for estimating the number of inhaled doses will be discussed here.

2.6.1 Self-Report

In clinical and research settings the most commonly used measure for assessing a patient's health-related behaviour is self-report (Bender et al., 2007), with its widespread use largely due to its flexibility to suit and match the medical regimen in question (Rand, 2000). By directly asking the patient about their current treatment plan, this allows a clinician to collect rich in-depth feedback as

well as information on any side effects or concerns the patient may have (Rand, 2000).

Unlike other methods, the key advantage of self-reporting is that it not only captures information on the amount of medication used, but also provides insight into a patient's attitudes, beliefs and experience with their medical care (Rand, 2000). Despite this, a major disadvantage is that it relies on the memory and recall of the patient and this can easily be affected, particularly over long periods of time. Furthermore, factors such as age, illness, stress or other medical conditions can affect a patient's memory and make it harder for them to accurately recall how often they have been using their inhaler (Rand, 2000),

'Social desirability' bias (Fisher, 1993) may also affect self-reporting, the patient may feel compelled to please the clinician or researcher by reporting that they have been at a good level of medical adherence. This may be influenced by factors such as the environment in which the self-reporting occurs, as well as the patient's attitude and relationship with the clinician or researcher (Rand, 2000). Furthermore, if a patient fears that being honest may lead to negative consequences, such as not receiving payment for participating in research, then the patient may feel tentative towards admitting to problems or issues with their current treatment. Finally, if the method of self-report is interviews, the information gained may depend on the clinician's skill, available time, and their ability to encourage the patient to express information on their medical regime and their adherence to it (Rand, 2000).

A range of studies have demonstrated that when self-reporting is used alongside electronic monitoring to record actual adherence, patients have a tendency to overestimate their inhaler use (Coutts et al., 1992; Gibson et al., 1995). For example, one study found that through self-report measures, average adherence to inhaled steroids was reportedly over 80%. However, electronic data showed that actual adherence was significantly lower, at an average of 69% (Bender et al., 2000). A more recent study found 75% of a sample of 180 children had adherence of less than 80% when measured objectively, yet self-report measures wrongly indicated that only 6% had adherence of less than 80% (Krishnan et al., 2012).

2.6.2 Canister Weighing

Canister weighing is a method of measuring adherence where the exact weight of an inhaler canister at the point of prescription and the exact weight when it is returned by the patient are measured and an adherence score is calculated from the difference between the values (Bender et al., 1997).

Opinions on canister weighing are mixed. Some argue it is susceptible to inaccuracies under certain conditions, such as a child playing with their inhaler, a patient actuating test puffs, or a patient intentionally 'dose-dumping' to try and fool a clinician into believing they have been taking their medication as advised (Bender et al., 2000; Simmons, Nides, & Rand, 2000).

Further inaccuracies stem from the fact that inhalers can often be shared between different members of a household if there are multiple individuals with asthma on the same medication (Bender et al., 1997). This will clearly influence a measurement of canister weight, as it may show up as overuse if the patient and others are adherent, or may wrongly show up as adherent if more than one person is using the same inhaler and their collective use adds up to roughly the required amount for the actual patient. Furthermore, a major issue for canister weighing is that it gives no indication of the timing of a dose, meaning there is no way to know if a patient has taken doses in the morning and evening, or all at once (Bender et al., 1997).

2.6.3 Pharmacy Records

Pharmaceutical databases can be used as a source of information on a patient's medication. Data can be retrieved on the type of medication prescribed, the quantity of medication dispensed, as well as refills. In a similar way to canister weighing, this data can be used to roughly calculate the average number of doses a patient is taking daily over a period of time. However, it falls under similar limitations as canister weighing, as there is no way of knowing the exact times when the patient actually took the medication (Bender et al., 1997).

A study used pharmacy records and compared them to the ability of physicians to detect and identify non-adherent patients. They found that adherence for three different asthma medications ranged from 72% to 38%, whereas physicians only identified 49% of patients as non-adherent. The authors argued that checking prescription refills is both a practical and accurate method of

identifying non-adherent patients (Sherman, Hutson, Baumstein, & Hendeles, 2000).

This may be a sensible way of viewing pharmacy records. It can be viewed as a good way for identifying non-adherent individuals, but it must be recognised that its limitations mean that why or when these patients are being non-adherent is almost impossible to tell (Bender et al., 1997).

2.6.4 Electronic Monitoring Devices (EMDs)

A short overview of EMDs as a method of measuring adherence will be provided here, with a more thorough discussion of the literature surrounding them in section 2.8 after their utility for both measuring and improving adherence has been established in sections 2.6 and 2.7.

EMDs are considered the only accurate method available for recording the exact time and date when an inhaler has been used (Ingerski, Hente, Modi, & Hommel, 2011; Klok, Kaptein, & Brand, 2015). Although there is no gold standard, EMDs are regarded as the method by which other methods of measuring adherence should be compared against. The value of doing so is highlighted well by a study that compared EMDs to the other three methods covered here - self-report, canister weighing and pharmacy records (N. S. Jentzsch, Camargos, Colosimo, & Bousquet, 2009). Using a sample of 102 children with asthma, they found average adherence rates from self-report data stood at 97.9%, pharmacy records had an average of 70%, EMDs were 51.5% and canister weighing was 46.3% (N. S. Jentzsch et al., 2009). Comparison studies such as this highlight the inaccuracies of the other methods of measurement and support the need for EMDs to be the preferential tool for monitoring. Because of research such as this, there is now consensus that EMDs should be the method of choice for collection of objective, accurate and reliable results in clinical and research practise (Klok et al., 2015; Morton et al., 2014).

EMDs are capable of providing precise data on the timing of inhaler actuation and patterns of use (Foster et al., 2012) and can also detect ‘dose-dumping’ (Simmons et al., 1998) - one of the major limitations of canister weighing. Despite this, there have been concerns over issues such as faulty devices, patient misuse, computer hardware or software problems and the reliability of EMDs to accurately record every dose (Bender et al., 1997). However, with vast technological advancements in the past decade, EMDs are now available that

have been rigorously tested and deemed sufficiently reliable and accurate for use in clinical and research settings (Foster et al., 2012; Patel et al., 2012).

2.7 Improving adherence in asthma

With poor adherence in asthma a well-established issue, there have been varying approaches to improving inhaler use in patients and these will be summarised here.

2.7.1 Educational Interventions

As previously discussed in section 2.5.2. the knowledge and understanding a patient has for their condition and their prescribed treatment plan can often influence their adherence (Gudas et al., 1991; Modi & Quittner, 2006). A recent systematic review of educational interventions for children and adolescents with chronic health conditions found varying effects of education on medication taking behaviour (Dean, Walters, & Hall, 2010). Some found that educational strategies significantly improved adherence, such as a study where group discussions containing information and support were held with parents of preschool children with asthma (Hederos, Janson, & Hedlin, 2005). A significant improvement was also found in a study of inner-city children with asthma where trained asthma-educators visited their home and reviewed their inhaler technique, formulated an asthma action plan, and discussed beliefs and concerns regarding their condition (Otsuki et al., 2009). However, other studies have failed to show a significant difference for patients who have undergone an educational intervention (Holzheimer, 1998; Hughes, McLeod, Garner, & Goldbloom, 1991).

2.7.2 Behavioural Interventions

Interventions focused on encouraging behavioural change have also been shown to improve adherence. One study investigated the effects of encouraging teamwork and shared responsibility between a parent and child when managing a child's asthma (Duncan et al., 2013). This involved varying degrees of parental involvement as the child developed more responsibility, allowing them to gradually gain a greater level of independence for their asthma as time progressed. The researchers found that teamwork resulted in significantly higher levels of adherence than through an education-alone condition or a standard care group (Duncan et al., 2013). A similar improvement in adherence was observed in a study where participants were supervised at school every day and received guidance if they were not using their inhaler correctly (Gerald et al., 2010).

Text messaging has also recently been utilised as a method to adjust patients' health beliefs and attitudes to treatment (Petrie, Perry, Broadbent, & Weinman, 2012). Participants had texts sent between one and three times a day and the content of the texts was determined by their beliefs that were assessed pre-study. Texts were designed to change beliefs and included phrases such as "Your asthma symptoms may come and go but your asthma is always there". At the end of the trial, the researchers found that participants who had received texts had improved asthma management and treatment beliefs compared to the control group and also had significantly improved adherence (Petrie et al., 2012). However, adherence in this study was measured by self-report and this has been widely demonstrated to be unreliable as discussed in section 2.6.1. This is an issue with many interventional studies and is discussed in further detail in section 2.7.3.

2.7.3 EMD Interventions

Whilst section 2.6.4. established EMDs as the most accurate method available for objectively recording adherence to inhaled medication, research has also shown how EMDs can be used to improve adherence when data is used as feedback. A four-month clinical trial with 24 children with asthma presented adherence data from EMDs back to half of the participants and found a significant improvement in adherence over the study period (Burgess, Sly, & Devadason, 2010). A more recent study with five non-adherent patients had their inhaler use monitored with an EMD alongside feedback from medical staff and found an increase in adherence in three of the patients (Spaulding, Devine, Duncan, Wilson, & Hogan, 2012). Although both studies show promising signs for adherence improvement, both use small samples and large-scale clinical trials are required to fully demonstrate any effects (Morton et al., 2014).

As well as recording adherence, EMDs can also possess the functionality to remind a patient when their next dose is due. This has been shown to improve adherence in studies where a reminder condition and a control condition have been used (Chan, Stewart, et al., 2015; Charles et al., 2007). However, despite improving adherence, the study by Chan et al did not find any difference in health outcomes including Forced Expiratory Volume (FEV1) or emergency department visits (Chan, Stewart, et al., 2015).

EMDs have so far shown good potential for improving adherence but importantly they can also provide a critical role in objectively measuring adherence in studies looking at other interventions to improve inhaler use. Morton et al (2014) highlight that a major problem with the vast majority of studies that have previously looked at ways of improving medication taking is that they have used subjective measures of adherence, making the validity of any results questionable (Morton et al., 2014). Therefore, EMDs could play a vital role in all research investigating ways of improving adherence, regardless of whether the EMD itself is the intervention, or is being used alongside other educational or behavioural approaches.

2.8 Electronic Monitoring Devices (EMDs) for asthma

Evidence suggests that EMDs are the most accurate method available for monitoring inhaler use, allowing for the collection of accurate and objective adherence data for use in research and clinical care. Furthermore, there is initial evidence to suggest they can also improve adherence through feedback of data to patients and audio-visual reminders when new doses are due.

This section will cover research on EMDs to date by firstly discussing their relevance within the wider domain of 'data-driven healthcare', followed by presenting key studies carried out with the most widely used devices. The key focus will be on EMDs for standard metered dose inhaler (MDIs) as the majority of EMDs to date have been developed for this inhaler type. Afterwards, a discussion of the future issues for EMDs will be provided, including barriers to adoption and levels of stakeholder involvement.

2.8.1 Healthcare in the digital age

This section will provide a short overview of the trend towards 'data-driven' healthcare. It will firstly be noted that technology is increasingly being developed and integrated into the way we diagnose, treat and manage health conditions. This will be followed by a consideration of how EMDs for asthma could form an important part of this new system.

In a recent review of health promotion in the digital age, Lupton (2015) described the distinction between Web 1.0, 2.0 and 3.0 technologies. In the first wave of Web 1.0 the Internet became readily accessible to the public, allowing for people to access a wealth of information that would grow exponentially (Lupton, 2015). Then in 2004 the term Web 2.0 started to be used, this time

referring to a 'social web' with digital communication tools such as smartphones and tablets as well as social media platforms including Facebook and Twitter allowing the public to both consume and produce their own online content (Ritzer, Dean, & Jurgenson, 2012). Finally, we are now at the start of Web 3.0 – often referred to as the 'semantic web' or the 'internet of things' (Lupton, 2015). A fundamental part of Web 3.0 is the inter-connection of smart 'objects' or 'things' that are all internet enabled, have at least basic computing capabilities, and record data to be shared with other 'objects' (Miorandi, Sicari, De Pellegrini, & Chlamtac, 2012).

Devices falling under the umbrella term of 'Digital Health' have potential to provide medical information and advise, monitor and measure health vital signs, and let us share personal health records and experiences with others (Lupton, 2015; Topol, 2012). It has been argued that the major benefit that this could bring to healthcare is a shift from cure to prevention. Warning signs and symptoms could be spotted earlier and this would have huge implications for both the industry as well as public health (Walport, 2014). Monitoring a patient's vital signs, medication management and symptoms would create a wealth of data far greater than currently available through traditional clinical check-ups, allowing for a far greater understanding of a patient's health on a daily basis (Topol, 2012).

EMDs for asthma record data on a patient's inhaler use. The latest devices possess the ability to transfer this information to an online database to be viewed on a computer, smartphone or tablet (Howard, Lang, Patel, Sharples, & Shaw, 2014). This makes EMDs part of an emerging field of digital healthcare devices and highlights their important role in creating a far greater and more in-depth understanding of how individual asthma patients manage their condition.

2.8.2 EMDs in clinical research

The following section will cover the use of EMDs in clinical research, examining the main devices that have been developed, tested and used. An in-depth description of each device can be found in Howard et al, including features and limitations of all key EMDs that have been designed to date (Howard et al., 2014). This section will not provide the same level of detail, but will give an overview of the capabilities of the most widely used devices and highlight any relevant literature examining device reliability or impacts on adherence. A summary of the key features of each device can be found in table 2-1.

Table 2-1 Summary of EMD features

Device	Re-usable	FDA approved	Spacer Compatible	Records Date and Time of Actuation	Detects Inhalation	Detects Shaking of Inhaler	Record and Feedback Information on Inhalation Technique	Reminders for Patients	Device Screen to Display Information	Data Transferable to PC/Online Storage	Dedicated Smartphone Application
Nebulizer Chronolog		✓		✓						✓	
MDILog		✓	✓	✓	✓	✓		✓		✓	
Doser		✓	✓					Beeps for canister nearly empty	✓		
Smart Inhaler Tracker	✓	Info. not available	✓	✓				✓		✓	
SmartTrack	✓	✓	✓	✓				✓	✓	✓	✓

2.8.2.1 *Nebulizer Chronolog*

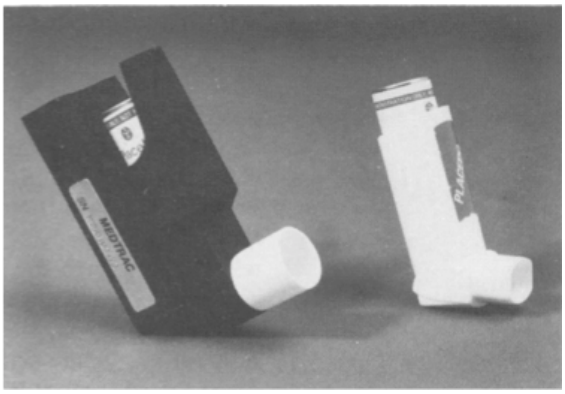

Figure 2-3 – A Nebulizer Chronolog (left) with an inhaler in its typical plastic casing (right).

The Nebulizer Chronolog (NC) is an EMD that requires the inhaler's usual plastic casing and mouthpiece to be removed, and the inhaler canister to be inserted into the NC's own custom-built case (Coutts et al., 1992). Actuations are recorded by the device through a micro-switch that detects whenever the canister is depressed, with 4000 actuations capable of being stored in the device's memory (Nides et al., 1993)

The NC has been used in clinical research, with its reliability in lab settings found to be 93% compared to manual recordings (Simmons et al., 1998). It has also been used in research investigating levels of adherence in children with asthma and showed how one patient actuated their inhaler 77 times in only thirteen minutes (Coutts et al., 1992). The NC was also used as part of a large 5-year clinical trial called the 'Lung Health Study' that investigated whether smoking cessation and inhaled medication could reduce the degradation of lung function in smokers with Chronic Obstructive Pulmonary Disease (COPD) (Nides et al., 1993). The Lung Health Study found that feedback on adherence collected by the NC improved inhaler use (Nides et al., 1993) and not informing patients of the NC's recording capabilities led to 'dose dumping' in 18% of participants in one study (Tashkin et al., 1991), and 30% in another (Simmons et al., 2000).

Whilst the NC can record date and time of actuations successfully, some of the limitations of this device include the fact it is not compatible with spacers, is only compatible with a metered dose inhaler (MDI), does not detected inhalation, technique, canister shaking and has no screen to display information on inhaler use (Howard et al., 2014).

2.8.2.2 *MDI Log*

Figure 2-4 – An MDILog device (white) attached to the back of an MDI

The MDILog is a white box that attaches to the back of an MDI and records actuations, shaking of the inhaler as well as inhalation through three separate mechanical mechanisms, with the date and time recorded for all three actions (Howard et al., 2014). The device also has a small LCD display that can show the patient feedback on their adherence and an auditory beep to remind the patient when their next dose is due or their inhaler canister is nearly empty (Howard et al., 2014; Weinstein, 2005).

The reliability of the MDILog has been tested in a variety of clinical studies. A study comparing the device to manual records found actuations for three MDILog devices to be 97%-100% accurate, inhalation recordings 82%-100% accurate and shaking 86%-95% accurate (Apter, Tor, & Feldman, 2001). The device has also been utilised in studies assessing inhaler adherence in children, where average adherence rates of 48% and 46% were found (Elizabeth L. McQuaid, Kopel, Klein, & Fritz, 2002; Walders, Kopel, Koinis-Mitchell, & McQuaid, 2005)

Whilst the MDILog is a more well-rounded device than the Nebulizer Chronolog and is capable of recording multiple aspects of inhaler use, it does still have limitations including an inability to be sterilized (Weinstein, 2005), a limited compatibility with MDIs only, as well as no feedback on technique (Howard et al., 2014).

2.8.2.3 *Doser*

Figure 2-5 - A Doser device attached to the top of an inhaler canister

The Doser records actuated doses through sufficient pressure being applied to the top of the device to depress the inhaler canister (Chan et al., 2013). The Doser will beep when an actuation has been recorded, as well as when the canister is nearly empty (Chan et al., 2013).

Clinical reliability testing for the Doser found it to have 94.3% accuracy for recording every dose, yet the inhaler empty alerts were sometimes premature (Julius, Sherman, & Hendeles, 2002). Other studies reported similar accuracy ratings (Burgess, Wilson, Cooper, Sly, & Devadason, 2006; Simmons et al., 1998), but one study found that some Doser devices suffered from mechanical faults including broken displays, battery failures and error messages (O'Connor et al., 2004). The Doser was also used to compare the accuracy of different methods of adherence measurement in a study previously referenced in section 2.5 (Bender et al., 2000). Here, they found self-reported adherence ratings averaged 80%, canister weighing averaged 69%, yet the recordings from Doser devices showed true adherence to be an average of 50% (Bender et al., 2000).

The Doser does have limitations, the most important of which is its inability to record the exact date and time of actuations, as it simply has a counter that resets at the end of each day (Julius et al., 2002). It also has no mechanisms for electronically transferring data to a computer, meaning recordings have to be transferred to paper manually (Julius et al., 2002). As well as this it cannot detect inhalation, canister shaking or technique and does not give feedback to patients (Howard et al., 2014).

2.8.2.4 *Smart Inhaler Tracker*

Figure 2-6 – A Smart Inhaler Tracker with a canister inserted into the device's plastic casing

The Smart Inhaler Tracker is the first generation of devices developed by Adherium from Auckland, New Zealand. Actuations are recorded by the device using an electronic switch that is activated when the canister is depressed, recording the date and time of dose (Chan et al., 2013; Patel, Pilcher, Travers, et al., 2013). Data is stored on the device and can be connected to a computer to be uploaded to an online database where it can be viewed by a patient, clinician or researcher dependent on whom has granted access (Patel, Pilcher, Travers, et al., 2013).

The reliability of the Smart Inhaler Tracker has been extensively tested, more so than any other EMD. One study tested ten devices for 30 days and found all were 100% accurate at recording every dose (Burgess et al., 2006). Another tested 22 devices for 24 weeks and found accuracy for recording every actuation to be 99.7% and accuracy of date and time to be 99.3% (Patel et al., 2012). Finally, a large-scale clinical trial found that out of 2498 devices, 94.5% successfully uploaded a full-data set to a computer (Patel, Pilcher, Travers, et al., 2013).

The Smart Inhaler Tracker has the capability of having an audio-visual reminder function (AVRF) added to it, to remind a patient when a new dose is due (Charles et al., 2007). Over a 12 week period with 110 participants, they found those who used the AVRF had an average adherence of 93% compared to 74% adherence in the control group (Charles et al., 2007). Another study used the Smart Inhaler Tracker to compare adherence recorded with an EMD to parental reports and questionnaires, finding that both significantly over-estimated adherence (Burgess, Sly, Morawska, & Devadason, 2008). Another study used the device in a sample of 93 children with asthma and found a median adherence rating of 93% over three months (Klok, Kaptein, Duiverman, &

Brand, 2012), the researchers believe this high adherence was due to education and follow-up with the patients (Klok et al., 2012).

The Smart Inhaler Tracker has been shown to be sufficiently reliable for use in research and clinical practise and has even been shown to improve adherence in some instances. However, there are limitations to the device including an inability to detect inhalation, shaking of the inhaler or technique (Howard et al., 2014). Furthermore, the AVRF doesn't show the patient when they last took a dose, it simply tells them when a new one is due (Howard et al., 2014).

2.8.2.5 *SmartTrack*

Figure 2-7 – A SmartTrack device clipped around an inhaler

The SmartTrack is the second generation of devices developed by Adherium, Auckland, New Zealand. Unlike the Smart Inhaler Tracker, the SmartTrack uses the MDIs standard casing and clips around it. The device consists of an LCD screen with four buttons and displays information on when the last dose was taken, as well as device settings like reminder times for when a new dose is due (Chan et al., 2013).

The SmartTrack records the date and time of every dose taken as well as MDI insertion/removal and setting changes such as turning reminders on or off (Foster et al., 2012). The device records actuation using an optical dose counter - a light transmitter and light receiver within the device have their connection broken when the canister is depressed and blocks the light and this is recorded as a dose (Howard et al., 2014). Like the Smart Inhaler Tracker, data can be transferred to a computer and uploaded to an online database. Data can also be viewed on the 'SmartInhalerLive' smartphone application where inhaler use can be viewed in a table or graph (Howard et al., 2014).

As a newer device, the main body of literature on the SmartTrack is still developing. The first known clinical study to use the device tested its reliability as well its acceptability in a small sample of patients (Foster et al., 2012). Using three separate tests of reliability where the device was tested for accuracy of actuation logs, reminder times, 'last puff taken' times and ringtones in both lab and real world settings, they found the device to be sufficiently reliable for use in clinical research (Foster et al., 2012). In the third reliability test where the SmartTrack was used by eight adults with asthma for seven days, the researchers asked for feedback on the device. All eight participants rated the device as easy to use, but commented on some negative aspects of the device e.g. "it was a bit bulky to take away for a weekend" (Foster et al., 2012).

A later study from the same researchers tested the impact of the SmartTrack's reminder function on adherence in 143 patients with moderate to severe asthma (Foster et al., 2014). Over six months, they found that patients who received reminders had an average adherence of 73%, compared to 46% in patients with no reminders. The authors recommended that reminders can offer a simple and feasible strategy for improving inhaler use in primary care (Foster et al., 2014). A similar study also investigated the impact of the SmartTrack's audio-visual reminder function in patients with asthma aged 6-15 (Chan, Stewart, et al., 2015). Over a six-month trial with 220 patients where half received reminders and half did not, average adherence in the intervention group was 84%, whereas it was only 30% in the control group. The authors concluded that use of an EMD with an audio-visual reminder function can significantly improve inhaler use in patients where poor asthma control is associated with poor adherence (Chan, Stewart, et al., 2015).

Like its predecessor, some key limitations of the SmartTrack are that it has no way of detecting inhalation, canister shaking or technique (Howard et al., 2014). Furthermore, the device adds a significant bulk to a standard MDI and this is supported by comments received from the patients in the study by Foster et al (2012

2.8.2.6 *Alternative Devices*

Whilst the majority of EMDs have been built for MDIs, a notable exception is the INCA (Inhaler Compliance Assessment) device which is compatible with a dry-powder Accuhaler™ (Holmes et al., 2013). Using a microphone to detect acoustic signals, this device can record both the date and time of doses taken, as well as inhalation technique (Holmes et al., 2013). Research is ongoing to establish whether use of the INCA device to record data on time and technique of inhaler use can both improve adherence and provide better clinical information (Sulaiman et al., 2016).

2.8.3 Future issues and limitations for EMDs

The research and development of EMDs has spanned over two decades, but substantial momentum is only beginning to occur now due to the rapidly growing trend for "data-driven" healthcare and the exponentially smaller and more powerful computer circuitry and hardware available in accordance with Moore's Law (Schaller, 1997). Developers can now build compact devices with capabilities that would previously have been impossible to incorporate into an EMD, such as wireless connectivity (e.g. Wi-Fi or Bluetooth®), global positioning system (GPS) location tracking and memories capable of storing large quantities of data.

With EMDs beginning to reach their potential and becoming increasingly capable and useful for everyday asthma care, it is important to consider the potential issues and limitations surrounding EMDs as they continue to develop in the near future. The following section will identify key potential issues and discuss how they should be approached for EMDs moving forward.

2.8.3.1 *Stakeholder Involvement*

With EMDs such as the SmartTrack capable of uploading data to an online database, this opens up the potential for a healthcare provider to monitor how well a patient is adhering to their prescribed treatment regime. As discussed in Howard et al (2014), this raises some interesting issues regarding a stakeholder's level of involvement and their responsibility to intervene. Using the data recorded by an EMD, a healthcare provider could gain a more in-depth and accurate understanding of a patient's medication taking behaviour compared to in a normal clinic visit. However, how would this sudden jump in quantities of data be handled?

An example of where this added level of detail on patient medication use can highlight potential dangers comes from a recent clinical trial of adults with asthma who regularly overused their reliever medication and underused their preventer (Patel, Pilcher, Pritchard, et al., 2013). Using EMDs to monitor inhaler use, the researchers observed 'extreme' cases of overuse of reliever medication in 40 of their 152 participants, with these patients actuating 32 or more puffs of beta-agonists in 24 hours (Patel, Pilcher, Pritchard, et al., 2013). With this level of overuse clearly creating cause for concern, this highlights a situation where it is likely that a healthcare provider would have a responsibility to intervene if the information were available to them.

A threshold needs to be established for exactly when a healthcare provider would need to intervene i.e. the number of puffs from which the patient's health is in danger (Howard et al., 2014). Then, the method of intervention also needs to be determined. In section 2.7 multiple methods for improving adherence were discussed such as educational and behavioural interventions, yet there is little agreement over which interventional technique is most effective and should therefore be recommended (Bender, Milgrom, & Apter, 2003).

A further issue for stakeholder involvement is how to account for the additional time and costs that would be spent on EMDs. If used in clinical practise, each device would need to be properly tested yet there is no clear guidance on how this could be realistically achieved in a real world clinical environment (Bender, 2013). It is also currently unclear how the costs of purchasing the devices, software and additional equipment for data download could be accounted for; with no evidence to suggest that patients, insurers or healthcare providers would be willing to take on the financial burden (Bender, 2013).

2.8.3.2 *Data Monitoring and protection*

EMDs have the ability to capture sensitive and personal information on a patient's health and adherence to a prescribed treatment regime. This data requires proper security and a suitable privacy framework, as leaked or hacked data could have major consequences for the patient, particularly if the information were to become available to employers, health insurers or other unauthorised individuals (Löhr, Sadeghi, & Winandy, 2010). Whilst leaked data would be of direct detriment to the patient, it could also lead to severe consequences for the healthcare providers or technology support staff involved, who could incur privacy violation charges as a result (Löhr et al., 2010).

As EMDs develop, adherence data is increasingly being stored in 'the cloud' (Chan et al., 2013; Howard et al., 2014; Kikidis, Konstantinos, Tzovaras, & Usmani, 2016), 'the cloud' refers to a new paradigm in computing where there is a shift from hardware and software based systems, to a networked system where data is accessible from any given location with internet access (Vaquero, Rodero-Merino, Caceres, & Lindner, 2009). This creates several potential issues including: the security of the datacentre the 'cloud' is run from and how well it is maintained, and the security of the end-user's computer and network (Löhr et al., 2010). Particularly for doctors running their own practise, it is likely they may lack the funding, knowledge, and time to effectively maintain and secure their computing infrastructure properly and this could put multiple patients at risk if many are using monitoring technologies like EMDs (Howard et al., 2014; Löhr et al., 2010).

2.8.3.3 *User Attitudes*

It has been established throughout this literature review that there is a growing body of research demonstrating that EMDs are the most accurate and reliable method available for measuring inhaler use in patients with asthma. Research to date has been clinically-focused, working to ensure that these devices are a viable technology to be utilised in research and clinical practise. However, little research so far has considered the attitudes of both patients and healthcare providers towards these devices.

The only notable examples where patient attitudes were considered is a study using the using the SmartTrack and another using the Smart Inhaler Tracker (Foster et al., 2012; Turton, Glasgow, & Brannan, 2011). Even here, feedback from patients was a secondary objective and consisted of a small set of questions asked in a short interview or questionnaire format. Whilst capable of offering a small amount of insight, the level of research currently available is not sufficient enough to help ensure that EMDs will be widely accepted and used by patients.

To ensure the ultimate success of EMDs it is important that user needs are considered. As the devices will be used by both patients and caregivers, the views of both are important to take into account as key user categories. Taking user requirements into account can have multiple benefits for medical devices, including: improved usability and efficiency, a reduction in device recalls, and

improved patient outcomes and satisfaction (Martin, Murphy, Crowe, & Norris, 2006).

The lack of user-focused research for EMDs in asthma indicates a clear gap in the literature for these devices and provides suitable justification for the research presented in this thesis. With research methods available for involving users in medical device design and capturing user requirements in a medical context, there is clear scope for introducing this type of focus to the domain of EMDs for asthma. The remainder of this literature review will discuss previous research that has adopted this user-focused approach in other aspects of healthcare with other medical devices.

2.9 Involving users in the design of medical devices

With a lack of user-focused research identified as a gap in the literature on EMDs for asthma, it is important to review the existing literature on involving users in medical device design in the healthcare domain. This section will seek to establish why designing to meet user needs is a crucial process for successful medical devices. Then, previous work that has employed user-focused research methods in this context will be described, followed by a discussion on using a 'systems approach' to medical device design.

Usability can be defined as the *"The extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use"* (ISO 9241-11). Sharples et al (2012) describe how in the context of medical devices 'effectiveness' refers to how successfully the user can achieve their goals, 'efficiency' refers to the resources required to successfully achieve these goals and 'satisfaction' relates to a positive attitudes towards the device along with a sense of satisfaction and an absence of any feelings of discomfort (Sharples et al., 2012). The discipline of Human Factors (HF) has demonstrated that well designed devices will have positive implications for these three elements of usability (Sharples et al., 2012).

Although HF as a discipline has strong traditional ties with complex domains such as rail and aviation. The methods and values promoted by the discipline are increasingly being applied to the equally complex domain of healthcare. For medical devices, the vast number of potential users such as patients, doctors, nurses, and family members makes understanding user needs and designing to

meet them wherever possible an essential process (Grocott, Weir, & Ram, 2007).

The publication of ISO 62366 'Medical Devices: Application of usability engineering to medical devices' (ISO, 2008) has meant that medical device developers are now required to undertake a nine-stage 'Usability Engineering Process' in order to help ensure devices are designed to be usable and error-free. This usability engineering process involves the development of a usability specification and validation testing with either experts or end-users to ensure user-goals are met. In order to comply with the standard, developers are required to document the process in a Usability Engineering File (ISO, 2008).

There has now been significant progress both in the UK and USA for HF specialists working closely with patients and healthcare providers (Waterson & Catchpole, 2015). The development of the NHS Concordat on Human Factors in Healthcare has further strengthened the relationship between HF and healthcare and emphasises the benefit HF brings in improving the design of devices, equipment, and procedures as well as improving the quality of teams and services (NHS England, 2014).

However, whilst these regulations are important steps in ensuring the development of safe, usable medical devices, they do little to assess whether the devices are useful and appealing for patients. Whilst safety should always be a primary concern, more work is needed to ensure medical devices enhance and improve the lives of patients, as well as keep them safe.

2.9.1 Previous work involving users in medical device design

An early example of where a medical device was redesigned based on user-feedback is the defibrillator. Used in emergency situations when an individual is experiencing a cardiac arrest, a defibrillator is a device designed to 'shock' a heart back into a steady beating rhythm using targeted electrical impulses (Kroll, Kroll, & Gilman, 1991). Through interviewing physicians and observing the most common mistakes and shortcomings made by end-users, the defibrillator was successfully redesigned as an automated external defibrillator (AED), capable of being used error-free by an individual with no medical training (Kroll et al., 1991). More recently, usability testing and focus groups were utilised to help inform the redesign of infusion pumps. Here, involving users helped to reduce the number of errors and handling issues associated with these

devices (Garmer, Liljegren, Osvalder, & Dahlman, 2002; Liljegren, Osvalder, & Dahlman, 2000).

Furniss et al (2014) recently noted that whilst glucometers are regarded as an important medical device that is essential in the management of diabetes, there has been a lack of case studies assessing their usability (Furniss, Masci, Curzon, Mayer, & Blandford, 2014). Earlier research claimed that whilst glucometers are supposed to be simple and easy to use, there are actually 50 steps necessary to successfully take a glucose reading (Rogers, Mykityshyn, Campbell, & Fisk, 2001). Furniss et al performed a situated ergonomic assessment of the glucometer, carrying out over 150 hours of observations and interviews with users. Through doing so, they identified 19 usability issues that they subsequently grouped into seven broad themes for medical device evaluation. These included: usability of the device, gaps in user knowledge, and impact of policy. The authors recommend that the seven usability themes they identified could be applied in the evaluation of other medical devices and could be built upon with other themes that may emerge (Furniss et al., 2014).

Elsewhere, in mental health, a recent study looked at designing a new personal monitoring system for patients with bipolar disorder (Bardram, Frost, Faurholt-Jepsen, Vinberg, & Kessing, 2013). For bi-polar disorder, monitoring technologies are useful for recording mood patterns and symptoms, allowing for an 'early-warning' system, and for recording medication use. The researchers here gave 12 patients with bi-polar disorder a new monitoring system – 'MONARCA', to use for a 14-week period. Using three questionnaires focusing on the usability and usefulness of the system, they gained feedback from the patients on their experiences with the monitoring technology. Through using these methods, they discovered that participants found the application easy to use and also found it useful for their condition, with features such as the self-assessment tool and the alarms rated as the most useful (Bardram et al., 2013).

Finally, a study by Martin et al adopted a user-centred approach to elicit the requirements for a new blood vessel imaging device (Martin, Clark, Morgan, Crowe, & Murphy, 2012). They aimed to highlight how user research should be a core process throughout device development - even for smaller companies where knowledge and expertise may be lacking. Their approach firstly consisted of a brainstorming session with the device development team where they were asked to identify all potential users of the device. Next, semi-structured

interviews were conducted with potential users in order to elicit device requirements such as design, types of data required and problems users currently encounter. This approach was particularly successful as the clinical need for the device identified from the interviews was markedly different to the perceived clinical need originally stated by the developers. This led to the developers changing their approach and highlights how involving users in the early stages of development can have a positive impact on future design (Martin et al., 2012).

2.9.2 A systems approach to medical device design

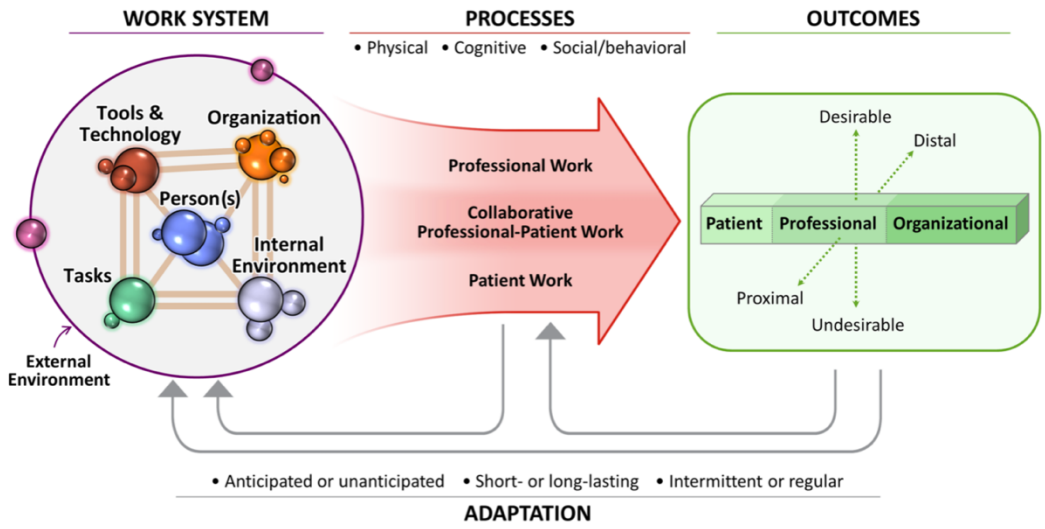

Figure 2-8 The SEIPS 2.0 (Systems Engineering for Patient Safety) model - taken from Holden et al (2013)

For a highly complex domain like healthcare, it is crucial that human factors interventions consider the entire work system in order to ensure successful, positive change (Carayon et al., 2014). This means that when introducing a new medical device, equipment, procedure or tool it is important to investigate the impact that it could have on organisational processes, tasks, work environment and people, and think about the effect this could have on both patient and organisational outcomes (Carayon, Hundt, & Karsh, 2006). The challenge for human factors and ergonomics research is that in healthcare, the focus is typically on either the care receiver (patient) or the caregiver (clinician), often without considering the interaction between the two (Hignett, Carayon, Buckle, & Catchpole, 2013).

The SEIPS model 2.0 (Systems Engineering Initiative for Patient Safety) is a work system and patient safety model that can be utilised in guiding research

that is aimed at improving patient safety and quality of care (Holden, Carayon, Gurses, Hoonakker, & Schoofs Hundt, 2013) (see Fig 2-8). It takes a work system which includes artefacts such as tools, tasks, as well as patients and healthcare providers and shows how these create work process, which ultimately lead to patient, professional and organisational outcomes (Holden et al., 2013). The model can be used by healthcare organisations to assess patient safety events and anticipate consequences of sociotechnological changes such as new medical devices (Carayon et al., 2014). SEIPS has been a significant step in promoting and introducing human factors to healthcare researchers and healthcare providers and its 'systems' approach is a useful concept to adopt in medical device design.

Sharples et al propose that medical device design should be approached from a 'systems' perspective (Sharples et al., 2012). They emphasise that for device design to effectively meet the three factors of usability – effectiveness, efficiency and satisfaction, it is important to consider the wider context and system surrounding the device. To help ensure that a device is not only usable in isolation, but is usable within the complex environment it is intended to be used within, they argue that it is important to consider the organisational and social context as well as the views of multiple user groups and stakeholders (Sharples et al., 2012). Improving the design of medical devices is important, but if we fail to understand the organisational context in which they will be used, devices may not be used safely and may be 'usable' but not 'useful' (Carayon et al., 2014).

A systems approach would be highly applicable in the case of EMDs for asthma as the potential users of this device and the data it records are wide-ranging. The paper from Sharples et al brings attention to the fact that it is not only the views of the patient that should be taken into account, but also the views of other key stakeholders including physicians, nurses and GPs for where EMDs could affect their workflow, the information that informs their clinical care, as well as the discussions they hold with patients.

2.10 Summary

This literature review has established the problem of non-adherence in asthma and the viable solution EMDs could provide in both accurately measuring and either directly or indirectly improving inhaler use in patients. The importance of involving users in medical device design has also been discussed and the current gap in the literature on EMDs for investigating user attitudes towards the devices

has been identified. There is clear scope for research examining the views of both patients and healthcare providers towards EMDs. Carrying out research of this nature should be considered essential in helping to ensure that these devices improve inhaler use and asthma control, as well as provide clinicians with a more accurate and in-depth source of information about their patients.

2.10.1 Take away messages

- Poor adherence to inhaled medication in asthma is an avoidable issue that is currently associated with increased healthcare costs, wasted medication, a rise in hospitalisations and even mortalities.
- EMDs are the most accurate and reliable method available for recording a patient's inhaler use
- EMDs have also been shown to improve adherence in certain cases, when they play reminders or data on inhaler use is fed back to the patient
- Little research has considered the attitudes of users towards these devices, yet this could be crucial information to know in order for them to have successful uptake from both patients and the healthcare system

Chapter 3 Adolescent attitudes towards the SmartTrack inhaler

3.1 Introduction

This chapter describes a study that assessed the attitudes of a sample of adolescents with asthma towards an exemplar electronic monitoring device (EMD) – the SmartTrack. This device records the date and time whenever a patient uses their inhaler and can also play auditory tones to remind them when a new dose is due.

Chapter 2 highlighted a lack of user-focused research as a key challenge facing EMD's going forward. The study described in this chapter gathered the views of a small sample of patients, to help understand what their perceptions are towards having their medication use monitored, who they might be willing to share this information with, as well as their feelings towards the device's appearance, practicality and social acceptability.

Firstly, the chapter covers literature on the stages of adolescence and health behaviours associated with this age - such as poor adherence and reduced supervision from parents. It then covers literature relating to adolescents with asthma - including reasons for poor adherence and costs associated with this. The design of the study is then described in detail, before the results are presented with an in-depth look at both questionnaire and interview data. In the discussion, it is considered how the questionnaire and interview data relate to each other, how the emerging themes from the interview analysis support other existing themes in the domain, as well as study limitations and future research opportunities.

3.2 Literature

3.2.1 Adolescence

Adolescence is a highly complex phase of development characterised by a separation from parents and caregivers and a drive towards becoming an autonomously functioning adult (Barrett, 1996). Traditionally defined as a time of "storm and stress" (GS Hall, 1904), research has demonstrated that whilst it can be a problematic and stressful decade for some, it is more universally characterised by a challenging period of change and transition (Petersen, Leffert, & Graham, 1995).

3.2.1.1 *The three stages of adolescence*

Although the details and exact ages of transition can vary, there is common consensus that adolescence is split into three developmental stages:

Early Adolescence – Key pubertal stage between the ages of 11-14 where the transition from childhood to adolescence is actually made (Leffert & Petersen, 1996). In this stage, adolescence is associated with a period of 'belonging' where there is a focus on conformity to peers and personal identity is strongly tied to the identities of best friends (Barrett, 1996). Children at this age have such a desire to 'belong' that they can often act against their better judgment to avoid the social anxieties associated with not fitting in with a group of friends (Barrett, 1996).

Middle Adolescence – At an age of roughly 15-17 years the focus of adolescence changes to a stage of independence (Dashiff, 2001). Children look to unearth their abilities and interests and form 'cliques' with like-minded peers whom they share attitudes or behaviour with (Barrett, 1996).

Late Adolescence – Aged 18-20 years, this final stage of adolescence completes the child's transition into adulthood as they begin to take on the responsibilities associated with being 'grown-up' (Crockett & Petersen, 1993). By this time, the child's focus shifts to feelings of 'worthiness' as they search for personal meaning in life, and often feel nostalgic for the dependency of childhood (Barrett, 1996).

3.2.1.2 *Adolescent health behaviours*

Investing in the health and well-being of adolescents is beneficial for their health at present, their health as they develop into adulthood, and the health of their future children (Patton et al., 2016). Historically, adolescence has attracted little attention and investment from health services as it is period of time where mortality is at it's lowest and many of the characteristics of a healthy mind and body are at their peak. However, targeting adolescence is crucial, as the health behaviours and habits experienced at this stage of life tend to set a trajectory for adulthood and later life (Patton et al., 2016; Viner & Macfarlane, 2005).

As a child transitions through the three stages of adolescence their attitudes to managing their health change. In early adolescence there is a tendency for a child to only have interest in their present state and be unable to comprehend any negative effects of their behaviour long-term (Michaud, Suris, & Viner, 2007; Patton et al., 2016). In middle adolescence a child is likely to want greater freedom and control over their own health as they seek independence - making them less likely to respond well to advice from healthcare workers. Finally, in late adolescence there is a period of acceptance for any health conditions that the child may possess, as they begin to take better control over their health management (Michaud et al., 2007; Patton et al., 2016).

With adolescents in the earlier stages of development often only thinking about the present, they become prone to risk-taking behaviours (Irwin, 2003) and this can manifest itself in low levels of adherence to medical advice and treatment. Generally speaking, it has been reported that only half of adolescents with chronic health conditions adhere to their medical treatment regime (Kyngäs, 2000).

This makes poor adherence an important behaviour to target in this age group, in order to improve health long-term and ensure good habits are developed as the child progresses into autonomous adult life.

3.2.2 Adolescents with asthma

3.2.2.1 *Prevalence*

Worldwide, asthma is the most common chronic disease in children and adolescents (Asher & Pearce, 2014). Although it can be difficult to assess the prevalence of chronic conditions in adolescents due to a lack of quality data (Michaud et al., 2007), the International Study of Asthma and Allergies in Childhood (ISAAC) found that the prevalence of asthma in the UK for children aged 13-14 was 20.7% in 1997 and 25.1% in 2002-2003 (Lai et al., 2009).

3.2.2.2 *Costs of poor adherence*

As already stated, adolescents are notoriously poor at adhering to medical treatment and asthma provides a prime example of this. For asthma patients aged 18 years and below, the adherence rates to inhaled corticosteroids (two doses, twice daily) obtained from clinical studies typically range from 30% to 70% (Klok et al., 2015). This is problematic as research indicates that adherence needs to be at least 75-80% for inhaled corticosteroids to sufficiently control asthma symptoms (Lasmar et al., 2009; Morton et al., 2014).

Children with poor adherence to asthma therapy are more likely to have poorly controlled asthma (Nulma S. Jentzsch, Camargos, Sarinho, & Bousquet, 2012), worse lung function (Krishnan et al., 2012), and are more likely to require courses of oral steroids (Milgrom et al., 1996). Because of this, children with poor adherence to asthma medication have higher use of healthcare facilities and higher healthcare costs (McGrady & Hommel, 2013).

3.2.2.3 *Reasons for poor adherence*

The causes of poor adherence were covered in chapter 2, but there are additional reasons specific to children. In a study where parents and their child were asked about the main reasons for not using their inhaler as prescribed, the most commonly given reasons included forgetting, being busy, struggling to incorporate inhaler use into their daily routine and being asleep before the evening dose was required (Burgess et al., 2008). Research has also shown that a child may have poor adherence if their parents have a negative attitude towards inhaled steroids and have concerns about the possible side effects of using them (Klok et al., 2012; E. L. McQuaid et al., 2012).

As mentioned, adolescence is a period of time when a child seeks independence and relies less on their parents. This type of shift has been observed in children with asthma, with the responsibility for taking an inhaler changing from the parents' duty when the child is young, to the child taking over as they grow into adolescence (Orrell-Valente, Jarlsberg, Hill, & Cabana, 2008). Research has shown that adherence to inhaled medication is better in young children and gradually gets worse as they grow older and gain more responsibility (E. S. Koster, Raaijmakers, Vijverberg, & Maitland-van der Zee, 2011). This reinforces the potential benefit that EMDs could have for this age group. With adherence often poor and adolescents seeking independence, EMDs offer a way to encourage inhaler use and facilitate better asthma management.

3.2.3 Involving adolescents in the design of medical devices

Historically, adolescents have been overlooked in many research disciplines, including medicine (Irwin, 2003; Patton et al., 2016). Medical devices in particular, have typically been designed for adults, occasionally for children, but very rarely have the needs of adolescents been taken into consideration in their development (Geljins, Killelea, & Vitale, 2005).

As already established, adolescents are an important age group to target in health research (Patton et al., 2016; Viner & Macfarlane, 2005), yet researchers can be hesitant to focus on this age due to the potential complications it can create during ethical review, such as high sensitivity to breaches of confidentiality (Hester, 2004; Patton et al., 2016). However, with strong evidence for adolescents being consistently poor at adhering to medical treatment regimes, there is concern that failing to meet their needs in device design may be contributing to this (Fielding & Duff, 1999; Suris, Michaud, & Viner, 2004).

In recent years there have been notable examples of researchers involving adolescents in medical device design. One study interviewed twenty teenagers with cystic fibrosis and assessed their views towards the acapella® device for clearance of airways (Lang, Martin, Sharples, & Crowe, 2014). The researchers found that the adolescents wanted a device that would encourage independence, be usable in a variety of settings and environments, fit in to daily routines and increase motivation (Lang et al., 2014). Another study interviewed adolescents with diabetes in order to help in the design of an mHealth smartphone application for blood glucose monitoring (Cafazzo, Casselman, Hamming,

Katzman, & Palmert, 2012). Whilst a further study (although not directly related to a medical device) utilised a sample of hospitalised teenagers to help in the design of privacy settings for a new social network for young hospital patients (van der Velden & Culén, 2013)

3.2.4 Adolescent attitudes towards EMDs

The literature review in chapter 2 identified the scope for examining the views of patients towards EMDs. The literature in chapter 3 has then shown how adolescence is associated with high asthma, poor adherence and a tendency to be overlooked in medical device design. Together, this led to the development of a study to investigate the views of adolescents with asthma towards EMDs.

3.3 Method

A sample of seven adolescents with asthma used a SmartTrack EMD with their usual preventer inhaler for a period of one month. During this time, they met with the researcher at their asthma clinic and completed a series of questionnaires and interviews on their attitudes.

3.3.1 The SmartTrack device

Figure 3-1 – A SmartTrack device (black) clipped around an inhaler (purple)

The capabilities and associated literature for the SmartTrack device were described in section 3.8 of chapter 2. The device can record the exact date and time whenever the inhaler is actuated and can also play an audible tone to remind a patient when their next dose is due. A small sample of SmartTracks were acquired after successful negotiations with the developers of the device (Adherium, New Zealand). Whilst Adherium provided the devices, they played no part in the design or running of the study.

3.3.2 Patient Public Involvement (PPI) and Young Persons Advisory (YPA) group

To assist in securing NHS ethical approval for the study, PPI work was carried out to help ensure the research study would be appropriate for the targeted population (adolescents with asthma). A workshop was carried out with a YPA group at the Medicine for Children Research Network (MCRN) at Queens Medical Centre (QMC) hospital, Nottingham, UK. This session included 11 children (male and female) aged 9-17 and was mostly used to ensure that the participant information sheet for the study was clear and easy to understand for the appropriate age range.

At the workshop, the children were given a brief outline of the study by the researcher, before they all individually read through the participant information sheet and highlighted anything they did not understand. The young people all agreed that the participant information sheet was clear, easy to understand and of a good length. The younger children stated that they would like more colour and for the details of the stages of the study to be split up into a table format. All of the young people agreed that the research was important research to carry out and would all have liked to do the study if given the opportunity.

3.3.3 NHS Ethics

Full NHS ethical approval was required for the study and this was successfully obtained from the Nottingham Research Ethics Committee 1 (REC ref: 14/EM/0003). In order to obtain approval, a detailed study protocol was written, an online application was completed on IRAS (Integrated Research Approval System -https://www.myresearchproject.org.uk) and all study documents were fully written and formalized. The study plan was then fully assessed by a panel of medical professionals at the REC and the researcher was required to meet before the panel and answer any questions. Ethical approval took six months to obtain, but was a valuable process for refining and formalizing the study procedure to ensure that it ran successfully.

3.3.4 Participant recruitment and sample

Participants were recruited from the Children's Respiratory Service at QMC hospital. The study was advertised through two main routes. Firstly, posters were placed on the children's ward, asking for children with asthma to help test out a new 'Smart Inhaler' for a month (see Appendix 1). Secondly, the main asthma nurse at the respiratory clinic approached eligible patients, providing

them with information on the study (see Appendix 2) and asking if they would be interested in taking part. The respiratory clinic in question dealt with secondary care patients (i.e. children with asthma requiring long-term follow up).

The inclusion criteria for the study were that the participant had to be aged between 11 and 16, have a diagnosis of asthma, be a patient at the Children's Respiratory Service, and use a seretide preventer inhaler (compatible with the SmartTrack device). The exclusion criteria were if they were unable to give informed consent and/or unable to attend the three clinic visits required for the study.

16 participants were approached by the nurse in total, with nine deciding not to take part. Three patients declined due to the distance and frequency of visits that would be required. One declined due to upcoming exams, two failed to respond to phone calls and the remaining three patients simply did not want to participate (one felt he was too old). None of the participants were recruited through the posters that were put up on the wards.

The study sample therefore consisted of seven adolescents with asthma. Their ages ranged from 11-16 years (mean of 13.4). Five of the participants were male and two were female. A parent for each of the participants also took part in the study, filling in a questionnaire for each of the three clinic visits. For all seven participants it was their mother who took part in this role.

3.3.5 Study Procedure

After being provided with the relevant study information (see Appendix 2), the adolescents were firstly given at least 24 hours to decide whether to consent to taking part. Participants over 16 provided their own consent, whereas participants under 16 had consent provided by a parent or guardian - accompanied by the participant's own assent. Upon agreement to take part, an initial clinic visit was arranged so they could be assigned a SmartTrack device and provide their initial thoughts and feedback on it.

The study consisted of three separate clinic visits. These occurred in the participants' usual clinic room with their parent sat outside to reduce any influence they may have over their child's answers. A nurse was always present but sat away from the participant and was there in case of any medical questions the researcher was unqualified to answer.

During the first clinic visit, participants were shown the SmartTrack device and had its capabilities explained. The device was then set up to present reminders at times consistent with the participant's current treatment plan and play a ringtone whenever their next dose was due. The researcher initially set up the ringtone reminders, but to show they understood how the reminder time and tone could be changed, participants were then asked to navigate to these settings on their own under the researcher's supervision.

Both the adolescents and their parent were made fully aware of the purpose of the SmartTrack device through the initial information sheet and the subsequent demonstration carried out by the researcher. This meant that they were fully aware of its monitoring capabilities in particular, and understood that their data would remain anonymous and would not affect their future care.

On all three occasions the participant was required to fill out a questionnaire and complete a semi-structured interview on their attitudes towards the SmartTrack device. The details of the questionnaires and interviews are described below.

3.3.5.1 *Questionnaires*

Each questionnaire contained 35 statements (see Appendix 3 for a full list of questionnaire statements). Participants were required to select one option for each statement, either 'strongly agree', 'agree', 'disagree' or 'strongly disagree'. A neutral option was not provided to prevent participants from 'sitting on the fence' about issues directly relevant and important to their own condition.

The questionnaire design was initially based on the Adolescent Medical Devices Assessment Toolkit (AMDAT) which contains a range of statements that can be included in an evaluation of medical devices for this age group (Lang, 2012). Statements that were relevant to the SmartTrack device were taken from the AMDAT. These statements fell under the themes; 'Ease of Use', 'Social Acceptance', 'Portability and Practicality' and 'Aesthetics'. The themes 'Maintenance' and 'Adherence to regular and correct use' were not included as the SmartTrack does not record or influence inhaler technique, nor requires maintenance and cleaning.

Due to the key issues surrounding monitoring and sharing of data, three new themes were added to the questionnaire design, these were; 'Data Monitoring', 'Data Sharing' and 'Communication and Feedback'. Questions were formed for these themes based on the authors own knowledge of the SmartTrack device as

well as their knowledge of the associated literature and followed the format of the statements taken from the AMDAT.

Seven themes were used in the three questionnaire, with 5 statements used per theme, per questionnaire. An example of a statement for each theme can be viewed in Table 3-1.

Table 3-1 The seven themes used in the questionnaire with an example statement for each

Theme	Example Statement
Ease of Use	*The information on the device's screen is easy to read*
Social Acceptance	*I would take the device to a friend's house*
Portability and Practicality	*The device would stay intact and not break if it was dropped on the floor*
Aesthetics	*I like the shape of the device*
Data Monitoring	*I feel happy with the device recording my inhaler use*
Data Sharing	*I would feel happy sharing information on my inhaler use collected by this device with my parents/guardians*
Communication and Feedback	*I would like it if I could receive feedback on my inhaler use on a weekly basis.*

A parent for each participant was also required to fill out a questionnaire at each of the three clinic visits. This was the same questionnaire, but the statements were framed to investigate what parents thought their child's attitudes would be, for example; "The information on the devices screen is easy to read" was adjusted to "***I think my child would think*** the information on the devices screen is easy to read". These questionnaires were given to parents in order to create comparison between participant attitudes and what the parents believed their child's attitudes would be.

3.3.5.2 *Interviews*

Interviews ranged from 5 to 31 minutes in length (mean average of 15:05 minutes) and an overall total of 5 hours and 24 minutes of interviews were recorded. Although there was insufficient clinic time available to interview the parents, they were encouraged to write comments at the end of their questionnaires. The interviews were guided by a schedule containing a set of open-ended questions (see Appendix 4), with some being followed up with prompts for more specific information if the participant was providing short answers.

At the first and third clinic visit, participants were questioned on their experiences with the SmartTrack. However, for the second clinic visit the interview focused specifically on alternative methods for monitoring their inhaler use. These alternative methods were firstly explained to participants using a set of vignettes. Five vignettes were used, with each covering a different method of monitoring, namely: patient self-report; dose counting; canister weighing; pharmacy records; and electronic monitoring devices (EMDs) such as the SmartTrack. The five vignettes used are shown in Figure 3-2. For each method, the researcher used the visual aid of the vignettes to briefly describe how each method of monitoring worked. Each method was framed for participants in terms of what they would need to do and what they would get in return.

Dose-counting was included as a method of monitoring here because the nurse at the clinic recommended that this was something the participants were familiar with for checking up on inhaler use. Although this isn't typically recognised as a method in the literature, it was included because of the participants' knowledge and familiarity with it.

To aid discussion, participants were asked to rank the five methods of monitoring in terms of their personal preference and then explain why they had chosen that order. Firstly, they made their ranking judgment purely on the basis of what they need to do, then they ranked based purely on what they get in return, and lastly they ranked them overall.

The rankings were used as a mechanism for getting the participants to think critically about what would be best in their own asthma care, thinking in particular about the effort on their own part, as well as the potential benefits they could gain from some methods in terms of more detailed data, better feedback and ultimately better asthma management.

After completing the ranking exercise, an interview schedule was used to help encourage the participants to provide their thoughts and feedback. For all three ranking exercises (what you need to do, what you get in return and overall) the following questions were asked, as well as on-the-fly questions based on participant responses:

- Can you explain the order you've put them in for what you have to do?
- Why would your first choice be best in your asthma treatment?
- Why would your fifth choice be the worst for your asthma treatment?

- What do you think your parents would think is the best?
- What do you think your doctor would think is the best?

Figure 3-2 The five vignettes used to explain the methods of monitoring adherence to the participants

3.3.6 SmartTrack data upload

At the second and third clinic visits, the participants had their SmartTrack device connected to the researcher's laptop so that data could be uploaded to the Smart Inhaler online database. Participants were given a username and password so that they could logon to the website and view their adherence data if they wished.

Adherence was not a primary research aim of the study, so this data was only checked by the researcher to ensure that participants were not taking a potentially dangerous amount of medication. This would be judged through dialogue with the researcher's clinical supervisor who could then take necessary steps to alert the patient's GP – a situation that did not occur.

3.4 Results

The results of the questionnaire data for both the adolescents and their parents are presented here first, followed by the results of the interview data - where a thematic analysis was carried out to uncover emergent themes.

1.1.1 Questionnaire Results

To analyse the questionnaire results, the responses were totalled for the seven themes to assess the number that fell under each of the four levels of agreement (strongly agree, agree, disagree, strongly disagree). Bonferroni corrected Chi-square tests were then used to investigate the distribution of responses and Bonferroni corrected Mann-Whitney U tests were used to identify differences between the responses of the adolescents and their parents.

Figure 3-3 shows a graph of the responses from the seven participants. The equivalent responses from their parents are also shown. As can be seen, for all seven themes in both adolescent participants and their parents, there were noticeably more positive responses compared to negative. For example, in the theme of 'monitoring' 100 participant responses to the range of statements about the SmartTrack were positive (either agree or strongly agree) whereas only 5 were negative (either disagree or strongly disagree). In comparison, the parents' responses for statements under this theme yielded 102 positive responses and only 3 negative ones, none of which were 'strongly disagree'.

The most noticeable differences between the adolescent and parent responses shown in figure 3-3 occur for the theme 'Communication and Feedback' where there were 19 disagrees for the adolescents compared to just 6 from the parents. The theme 'Ease of Use' is similar, with 24 negative responses (either strongly disagree or disagree) from the adolescents, compared to just 9 negative responses from the parents.

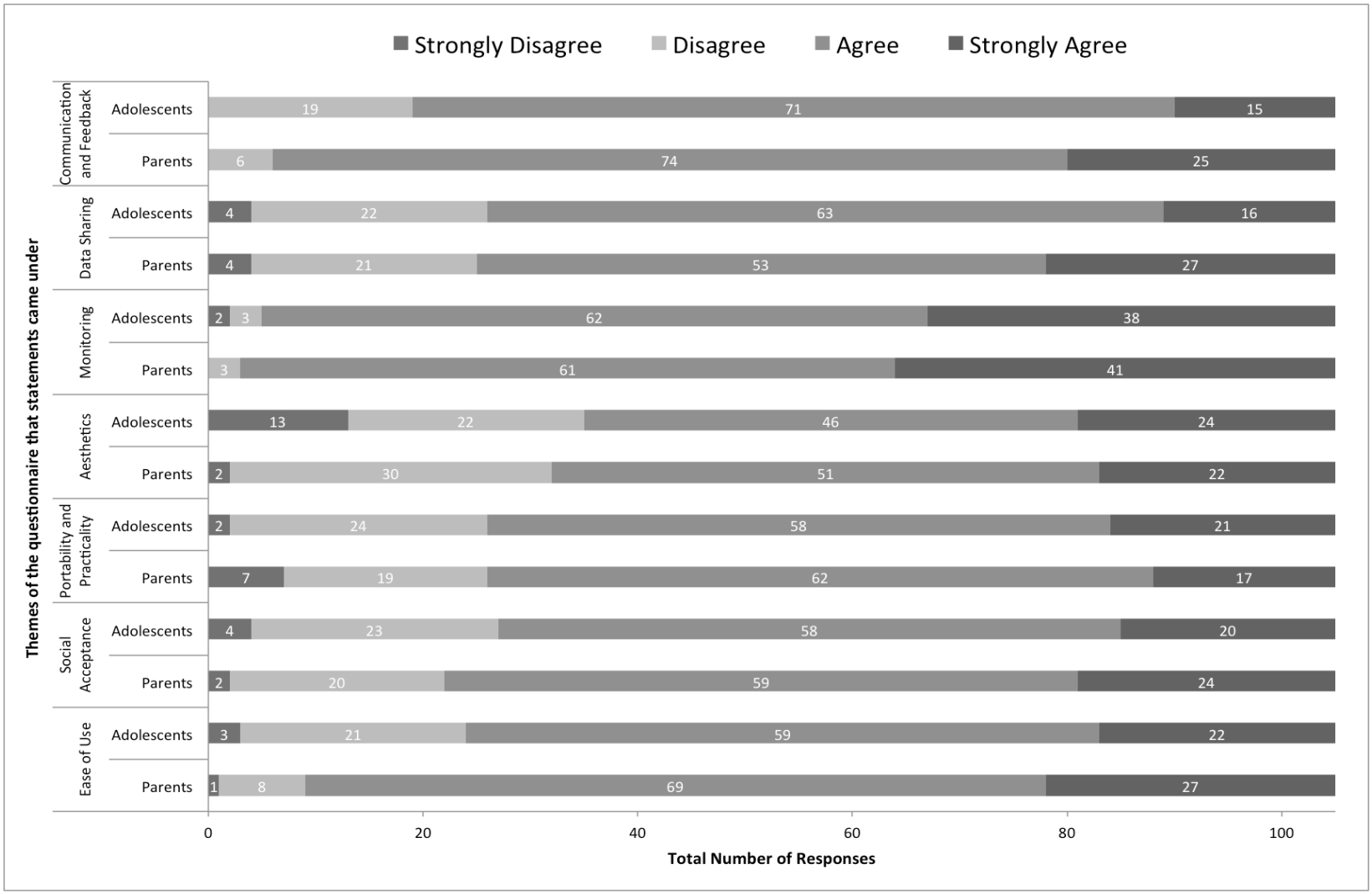

Figure 3-3 A graph showing the total responses from both the adolescent participants and their parents for the seven themes of the questionnaire

To investigate the distribution of responses for the seven themes, Bonferroni corrected Chi-square tests were carried out on each theme for both participant and parent data. For the purpose of this analysis, the data was adjusted, with the strongly disagrees and disagrees merged into a single disagreement category and the strongly agrees and agrees merged into a single agreement category. For all seven themes, the adolescent and parent data showed a significant preference in agreement with the statements ($p<0.003$). The questionnaire results therefore suggest clear positivity from both the adolescents and their parents towards the SmartTrack device across the range of themes.

To identify any differences between adolescent and parental responses, nonparametric Bonferroni corrected Mann-Whitney U tests were carried out on the two most noticeably varied themes; 'Communication and Feedback' and 'Ease of Use'. It was found that there was a significant difference between adolescent and parent responses for the theme 'Communication and Feedback' ($U=4497.5$, $n1 = n2 = 105$, $p<0.025$, two-tailed) and from the graph in figure 3-3 it can be seen that adolescents had more 'disagree' responses (19 – 6) whilst the parents had more 'strongly agree' responses (25-15), showing that the parents were in greater agreement with statements related to this theme compared to their children.

Tests showed there was no significant difference between adolescents and parents for 'Ease of Use' ($p>0.025$). However, there was a tendency for the adolescents to be more critical for this theme, with 3 'strongly disagree' responses and 21 'disagree' responses compared to only 1 'strongly disagree' and 8 'disagree' for the parents (see figure 3-3). This suggests that this may be an important factor to take into consideration when designing for adolescents.

Also of note in the data, is the larger amount of 'strongly disagree' responses from the adolescents (13) for the theme 'Aesthetics' compared to the parents (2) (see figure 3-3). This again indicates that this may be an important factor to take into consideration when designing devices for this demographic. A further exploration of the questionnaire data including an inspection of specific questions is covered in the discussion.

1.1.2 Interview Results

A six stage systematic approach was used to carry out a thematic analysis on the interview data (Braun & Clarke, 2006). This firstly involved a prolonged period of familiarisation with the data, followed by an initial process of coding the data for basic issues and factors. Codes were then grouped into an initial set of themes that were reviewed to check that they appropriately reflected the data. Once the researcher was satisfied with the themes produced, their names and descriptions were determined and a report of the outcomes of the thematic analysis was produced (Braun & Clarke, 2006; Thomson, Martin, & Sharples, 2013).

Four major themes were identified from the analysis of the interview data, these were: 'Taking control of condition', 'Social compatibility', 'Sharing and feedback of adherence data', and 'Practical improvements for more effective use'. For each of the major themes, three sub-themes were identified. These themes will be discussed, with supporting quotes from participants to demonstrate key points.

Participants will be referred to throughout this section using 'Ad' for adolescent and a number from one to seven, e.g. Ad1 - this is to demonstrate that comments came from all participants, rather than a select few.

3.4.1.1 *Taking Control of Condition*

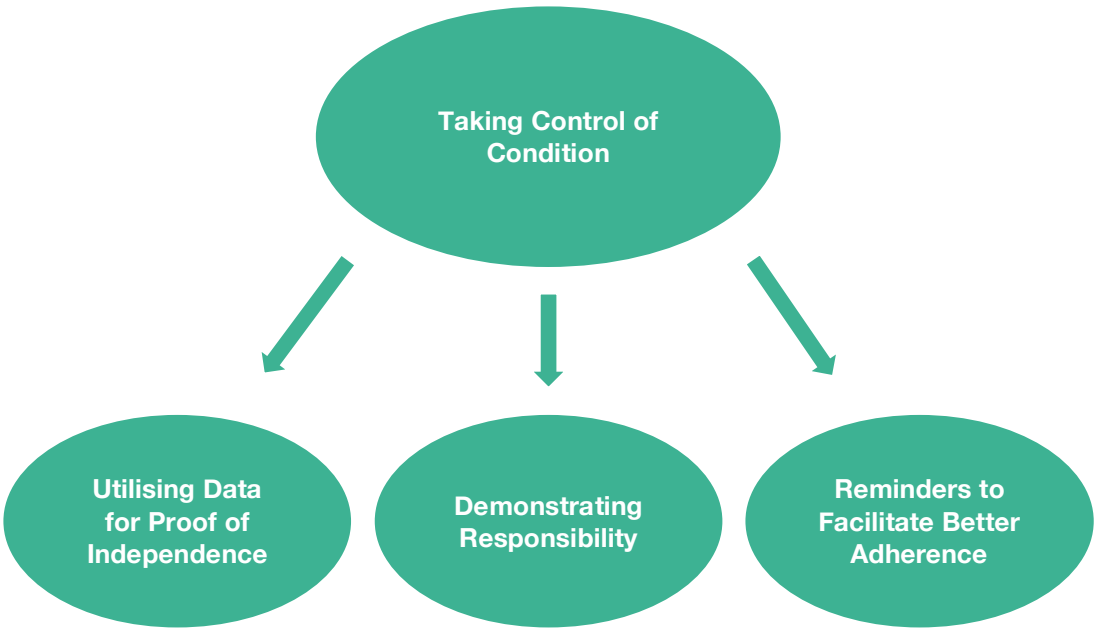

Figure 3-4 Main theme 'Taking Control of Condition' with three subthemes

The adolescents expressed enthusiasm for utilising the SmartTrack device to help them take control of their asthma, remember to take their inhaler independently, and demonstrate to their parents and caregivers that they can be responsible and look after their own health. The subthemes here were: utilising data for proof of independence, demonstrating responsibility, and reminders to facilitate better adherence.

3.4.1.1.1 Utilising data for proof of independence

All seven of the participants spoke about how they could use the data collected by the SmartTrack to show their parents and healthcare providers that they have been taking their inhaler as prescribed. A selection of supporting quotes from the participants are provided below:

"My mum nags me quite a bit about taking my inhaler, so does my Dad. So I think they might stop nagging as much if they know I'm taking it properly."
(Ad7)

"Recording the information so that the doctor can actually see that I've been taking it, and if my asthma is not improving then there's proof there that it's the inhaler (at fault) and not me not taking it"
(Ad4)

"Because it records when I've had it, I could show them so they actually believe me"
(Ad6)

The quotes suggest that the adolescents could see the positive side of having data recorded on their inhaler use. The comments indicate that the participants are used to being questioned on their inhaler use by their parents and caregivers and can see the potential for the 'SmartTrack' to help reduce this 'nagging' for them.

3.4.1.1.2 Demonstrating Responsibility

Throughout the three interviews of the study, participants also consistently demonstrated that they took responsibility for the management of their asthma. This was often through talking about why it is important that they take their inhaler, as well as recognizing the negative impact that dishonesty about their

inhaler use could have on their health. Some of the supporting quotes from participants were:

"I don't want to be having asthma for the rest of my life really, and it could help me get rid of it in a way, and grow out of it"

(Ad2)

"I'll be able to look at it and see when I've done it. See where its common I've forgotten, like what day, and try to improve taking it that day."

(Ad7)

"They assume that you've used it up, so you might not have used it you might have just gone in at the right time…I might not be using it, and they wouldn't be able to tell and they'd assume I'm using it so they wouldn't do anything, they'd just give me a new one"

(Ad4)

The quotes suggest that these adolescents understood why taking their inhaler is important and recognised the benefit that correct inhaler use could have for improving their health and building a trusting relationship with their healthcare providers. This links well with the previous theme related to independence, as through showing their healthcare providers that they can be responsible in managing their asthma, this should help foster a trusting relationship - allowing the adolescent to gain greater independence and manage their asthma with less interruption or intervention.

3.4.1.1.3 Reminders to facilitate better adherence

Although the primary function of the SmartTrack device is to record inhaler use, participants expressed enthusiasm for the secondary function of the device – playing ringtones to remind them when their next dose was due. Participants spoke about how this feature helped them to remember to take their medication on time, with example quotes including:

"If you didn't have that to remind you, you'd just wake up and wouldn't think about it, and then you'd go to sleep and you wouldn't think about it and you'd end up forgetting to take it"

(Ad4)

"Teenagers because they are starting to live their life, and when they get home will probably forget to take their inhaler, so it would be nice to have a reminder"

(Ad6)

"Sometimes I miss it, so it helps that I've got the reminders on, it'll help me remember to take it"

(Ad3)

This theme is related to the two themes prior to it, as the reminders can act as a useful function to support the adolescent in independently managing their asthma. Instead of relying on their parents to remind them, this provides them with their own tool to do so.

An interesting part of the shared enthusiasm for the reminders was that despite appreciating their helpfulness, participants also spoke about how annoying they could be, whilst still recognising their overall benefit in helping them to remember to take their inhaler on time.

"The ringtone got on my nerves...It's helped... it's like you have to do this, if you want to do that, kind of. Like you have to live with the constant annoyance if you want to be healthy!"

(Ad5)

"The one thing that's worked bad about it, when I'm so tired and I'm trying to get up, the alarm on the smart inhaler is so annoying because I'm just so tired and it just rings until I take it. It's really annoying…. It's a good thing, if it just rang and didn't ring again I'd forget about it."

(Ad6)

3.4.1.2 *Social Compatibility*

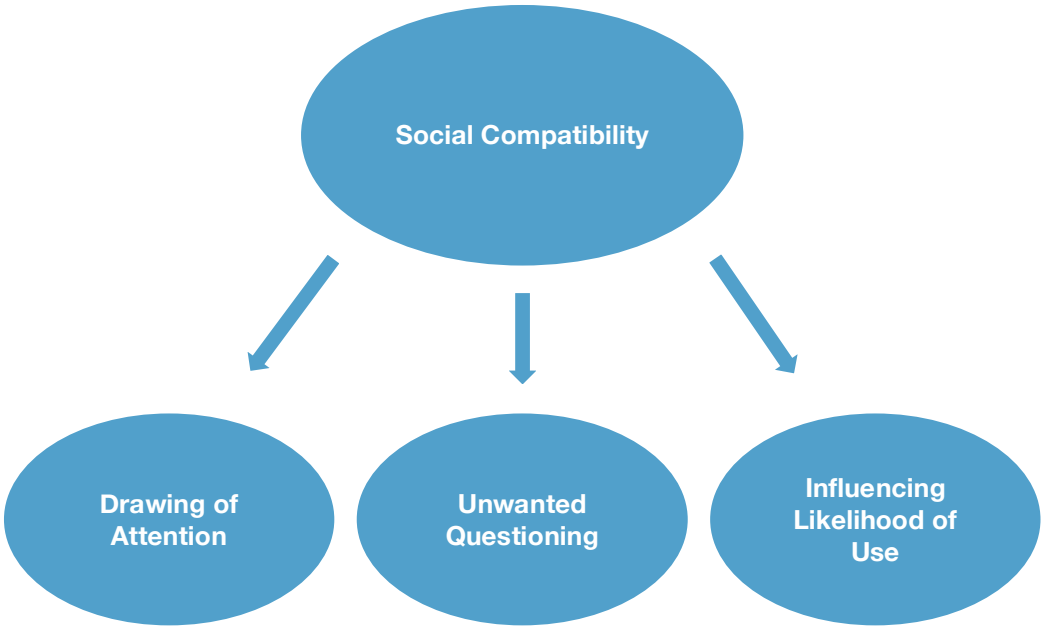

Figure 3-5 - Main theme 'Social Compatibility' with three subthemes

As opposed to the positivity participants showed for the functionality of the device and its ability to record and remind them about their inhaler use, there was general concern for the social acceptability of the device in terms of its appearance and the attention and questioning it could draw. Subthemes here were: drawing of attention, unwanted questioning and influencing likelihood of use.

3.4.1.2.1 Drawing of attention

Four participants directly commented on what their friends or peers would think if they saw them with the device:

"They'll probably take the mick. They'll think I have really bad disabilities, they'll think I've just got problems…If people had a problem with me, maybe the thing they'd get me with is that. But my friends wouldn't take the mick, they'd probably think it's cool"

(Ad5)

"At primary school when I had the spacer for my inhaler, everyone used to stare at me. So it would probably be the same thing."

(Ad6)

"If there's loads of people it would feel a bit weird, just pulling out this thing…It's just different, when you're walking around you don't usually see people with them, people might think you're a bit strange"

(Ad4)

"People might find the ringtone a bit silly and not like it. Or just think it looks really weird…People you don't really like, they might start teasing you about it, because they don't have it and it's not normal…a lot of people have asthma, they might think this is a new special type of inhaler that only one person has got, and it's different"

(Ad7)

The comments demonstrate how these participants clearly felt that the device's appearance was sufficiently different from a 'normal' inhaler for it to draw attention and potentially make them a target for bullying or teasing. Terms such as 'weird', 'strange' and 'different' were often used, and participant Ad6 related it to previous experience they had with using a spacer with their inhaler at primary school when other students would stare.

3.4.1.2.2 Unwanted Questioning

Two participants went a step further than simply having concerns about attention alone and additionally felt that the device could be the cause of unwanted questioning from friends, peers and even their teachers.

"*I just wouldn't take it around with them (friends)...they'd ask loads of questions... You can tell it's different - not meant to be on there. Everyone would be like, 'What's that? What's that?'"*

(Ad3)

"In assembly at school when there's lots of people there. I'm taking it out, and most people have normal inhalers and I'm pulling this massive thing out. Even the teachers would be looking at me like 'what's that?' There'd be a lot of questions, especially the teachers, because they would want to know what it is and everything"

(Ad5)

Although this is highly related and overlaps with the previous theme of drawing of attention, these comments are subtly different because participants felt they would have to actively explain to people what the device was, rather than simply

put up with people staring at them. The added need to answer questions about the device may create added effort for the adolescent, as they would have to explain the SmartTrack's purpose, rather than just put up with people staring at it.

3.4.1.2.3 Influencing likelihood of use

When contemplating the drawing of attention and unwanted questioning that the device may create, two participants commented that this might directly influence whether they would use the SmartTrack at all - despite the positive belief they had for it in helping them to manage their condition.

"I think it might. If you become unpopular with your friends and they start laughing at you for having something weird clipped around your inhaler"
(Ad7)

"I wouldn't really be very comfortable with it, some other people who just have asthma like me just have a normal inhaler, and then I've just got this technical one, which seems a bit awkward"
(Ad6)

However, one participant had a more relaxed opinion and did not seem as bothered by what his peers might think. This participant appeared to believe that it is simply something he has to do, so it is better to just get on with it.

"They wouldn't think any different, it's what I've got to do. If I've got to take it, I've got to take it. It's just like a normal inhaler, but with something on the end of it."
(Ad4)

3.4.1.3 *Sharing and feedback of adherence data*

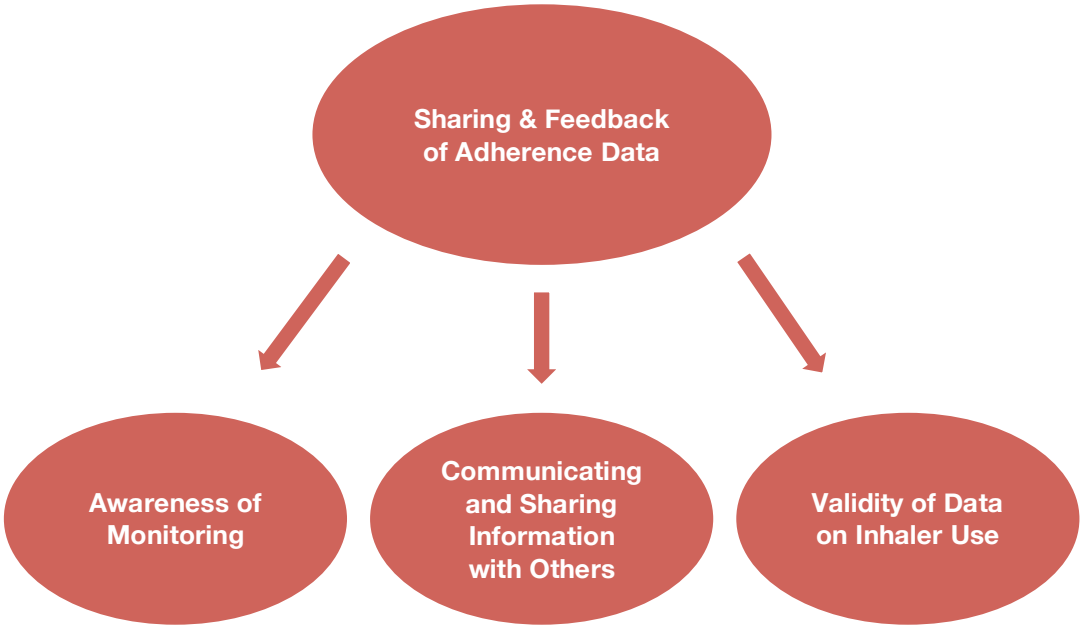

Figure 3-6 - Main theme 'Sharing and Feedback of Adherence Data' with three subthemes

When discussing the SmartTrack's ability to record information on their inhaler use, participants spoke of the effects that sharing this information could have as well as the way they would like to receive feedback on their adherence. Subthemes here were: Awareness of monitoring; communicating and sharing with others; and validity of data on inhaler use.

3.4.1.3.1 Awareness of monitoring

Some of the comments made by the participants indicated that the idea of having their inhaler use monitored would influence their medication taking behaviour, potentially making them more likely to use their inhaler as they knew it would be checked up on properly. This aligns well with the earlier theme of 'utilising data for proof of independence' as it suggests that the participants recognised that if their inhaler use was being checked up on and they were not adherent – they may lose that sense of independence and require a greater level of supervision from their healthcare providers.

"I've felt aware, but I suppose that's a reason for you to take it as well, because if you haven't taken it your doctor will see and then he'll moan at you, so you've got to take it so you don't get moaned at. So that's kind of like another reminder"

(Ad4)

"I'm always taking it more, because I know that it's being monitored so I know I need to take it more"

(Ad1)

Participants appeared to view this monitoring as a positive thing, recognising that inhaler use is an important thing to monitor, that the data will help them to demonstrate that they are taking their inhaler as recommended, and the people viewing that information will treat it appropriately.

"It's not just like anyone is seeing it, it's professionals so it's alright"

(Ad1)

"I don't really mind, because it tells people that I actually use it, so they won't think any less of me"

(Ad6)

3.4.1.3.2 Communicating and sharing information with others

Participants spoke about who they would share information on their inhaler use with and why sharing this data might be a good thing. Two of the participants spoke specifically about the benefits of sharing information through patient self-report, for example:

"Because you're talking to your doctor about information then, and you can talk about how you're feeling as well"

(Ad2)

One participant gave real consideration to who they would like to be able to see SmartTrack data on their inhaler use, demonstrating that they had reflected on the dangers or negative implications that being too open with their information could have:

"I'd share it with my doctors and nurses, parents and guardians, maybe cousins and maybe if they got used to it, some really close friends who I know won't laugh at it...I've got a couple of friends who I often fall out with, so I probably wouldn't like to share it with them. And strangers, because stranger danger. People who'd laugh at it."

(Ad7)

Another participant spoke about the way in which they would ideally like to communicate and share adherence data with their doctor. They suggested that a smartphone application would be an effective way to view and send data on their inhaler use and could allow them to be in control of who sees information, by sending it themselves.

"It would be good to have a smartphone app. Because then it's always there, you can do it on the go, you don't have to be at home or on your laptop or computer, or at the doctors. Also, if on the app there was a way of sharing, like sort of messaging, that you could do on it, to send info on your inhaler (use)"
(Ad4)

3.4.1.3.3 Validity of data on inhaler use

In the second interviews participants mainly discussed alternative methods of measuring adherence and the comments received suggested that participants understood how the validity of the data collected by these different methods varied. When discussing patient self-report, one participant talked about the benefit of speaking to your doctor or nurse, but acknowledged that relying on the patient to recall inhaler use may not be the most accurate method. The same participant then additionally commented on the improved accuracy of the dose count an EMD records compared to typical dose counting on a standard MDI.

"*It does help you talk to your doctors and nurses about what you've been doing, like more confidently. But if they're getting it from me, they're not getting all the information because even though I can keep track, sometimes I'll probably forget"*
(Ad5)

"Yeah, the inhaler already has a count of how many puffs you took, but that keeps a better track, a digital track"
(Ad5)

3.4.1.4 *Practical improvements for more effective use*

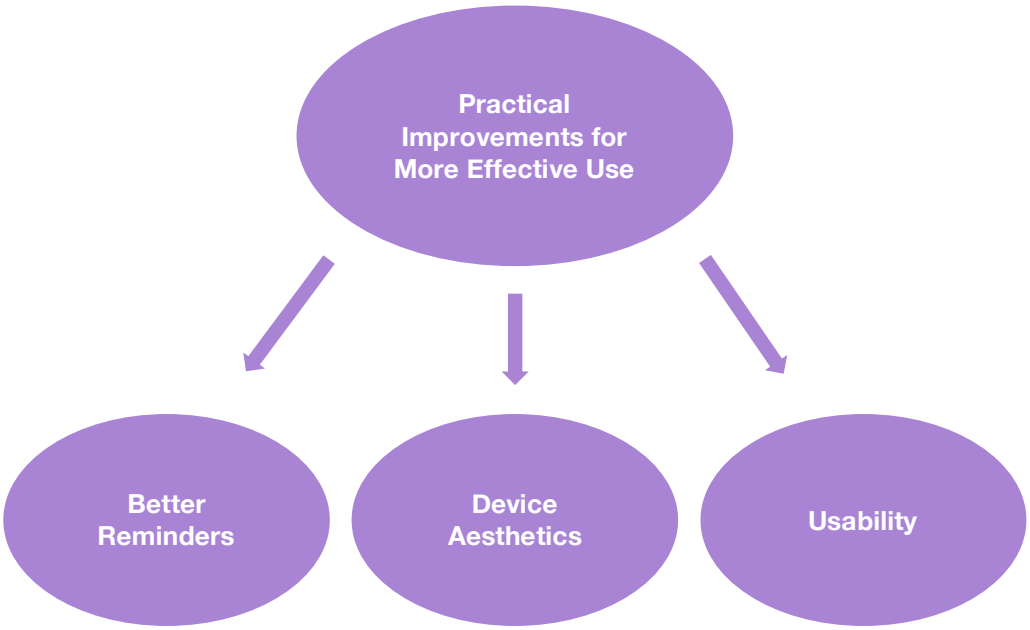

Figure 3-7 Main theme 'Practical Improvements for More Effective Use' with three subthemes

Participants provided helpful suggestions and recommendations for how the SmartTrack device could be improved to more effectively meet their needs. Subthemes here were; better reminders, device aesthetics and usability.

3.4.1.4.1 Better Reminders

Although participants spoke of the usefulness of the reminders for helping them take their inhaler more often, many believed the ringtones could be improved by including the ability to use your own music or tones.

"It would be better if you could plug it into the computer and have your own tune, rather than just the default tune."
(Ad4)

However, not all participants felt they would like the ability to put their own ringtones on the device. One participant felt this might be too complicated and would prefer a pre-loaded list to be able to select from. They also felt that the tones should be loud and of sufficient duration for you to locate the device if you have misplaced it somewhere in the house.

"I think it would be too complicated to put my own on. So I'd like the list, but good ones. It doesn't have to be a good theme tune but something that's loud

enough so you can hear it...I want it to be quite long so you can hear it and hear where it is. When it goes off you spend like half an hour trying to find it"

(Ad5)

3.4.1.4.2 Device Aesthetics

When discussing what their friends and peers might think of the device, participants expressed opinions on the SmartTrack's appearance and how it could be improved. This largely focused on reducing the size of the device, with some participants additionally suggesting that introducing a range of colours would make the device more appealing.

"It's quite small, but it looks a bit too bulky, it could be a bit thinner. But the colours alright...It would just look better if it was thinner and not as fat"

(Ad4)

"*Make it a bit smaller and change the colour...bright colours"*

(Ad3)

"I think the colour of the device is fine, I don't know anyone who dislikes the colour black, but I think it's a good idea to have a range of colours"

(Ad5)

3.4.1.4.3 Usability

Participants also offered suggestions for how the device could be easier to use. This often involved the buttons of the device, or the screen where information is displayed. Participants felt that the buttons needed to be clearer and more distinct, as all four looked the same. They also felt that the screen was too small and that the text displayed on it could be difficult for people with poor eyesight to read.

"If someone has bad eye-sight you could make the screen bigger…it's a tiny bit small. They could make it bigger and touchscreen"

(Ad5)

"*The buttons. They're just like four normal buttons, they all look the same. They should look a bit different to remind you."*

(Ad6)

Participants also spoke about how the size of the device could affect their use of it, with one participant commenting on the concerns they would have for getting

their inhaler out of their bag rather than their pocket if they were having an asthma attack.

"I usually have my blue inhaler in the side pocket of my blazer, and I don't think with this around it...I think after it would be bigger because my blue inhaler is actually quite big...I could put it in my bag, but if I'm having an asthma attack, it'll take me a while to get it out my bag"

(Ad5)

There was also an interesting case where the current design of the device was influencing the way in which the participant used their inhaler. The participant was utilising the 'time since last use' feature on the screen of the device to count the 5 seconds between their two puffs (see Fig 3-8). This isn't a recommended way to take an inhaler, so future design of the device should look to afford an upright and typical method of inhalation.

"I kind of take it on its side so I can see the timer there so I can see how long it's been, to make sure I'm taking it properly. Because I have to breathe in and out five times after I've puffed it, and I make sure I do that for 5 seconds, so I've been looking at that...Yeah I kind of hold it on its side now, so I can see the screen and count 1, 2, 3, 4, 5 so I know I'm doing it properly."

(Ad7)

Figure 3-8 Correct inhaler orientation (left) and incorrect orientation used by Ad7 (right)

3.4.1.5 *Vignette ranking results*

Although the ranking exercise of alternative ways of monitoring was primarily used as a way to get participants thinking critically about these methods to aid discussion; the results of the rankings still offer some indication of participant preferences.

Table 3-2 Methods of monitoring ranked according to their mode average

Average Mode Rank	What you need to do	What you get in return	Overall
1	EMD	EMD	EMD
2	Patient self-report	Patient self-report	Patient self-report
3	Dose counting	Dose counting	Dose counting
4	Canister weighing	Pharmacy Records	Canister weighing
5	Pharmacy Records	Canister weighing	Pharmacy Records

Participant ranked each method from 1 to 5, and these rankings were accumulated and the average mode rank for each method was calculated for 'what you need to do', 'what you get in return' and 'overall'.

As can be seen from Table 3-2, EMD was consistently ranked first across the three different ranking exercises. In fact, EMD was ranked first by all participants across all three ranking exercises, apart from on one occasion. One of the participants ranked EMD last for 'What you need to do' and commented that the patient actually has more to do for EMD's compared to the other methods. However, they ranked EMD top for 'What you get in return' and 'Overall', indicating that the benefits of EMDs outweighed the efforts on their part, in terms of carrying the device around with them, charging it and uploading data. This may be because this participant understood the purpose of the task better than the others and recognised that when thinking purely about what they need to do (as the researcher asked them to do) they understood that EMD would require more effort on their part than the other methods.

3.4.1.6 *Parental Feedback*

Although parents were not interviewed, they were encouraged to write comments on the back of their questionnaires if they had any feedback on the SmartTrack device and it's use in their child's asthma. Only four of the parents provided comments (see Table 3-3), but all focused on the utility of the device in helping their child to take their inhaler and keeping an accurate record of adherence.

Table 3-3 Comments from four of the parents for the adolescent participants

Parent	Quote
Parent for Ad1	*"Since using the Smart Inhaler *name*'s asthma has improved a great deal. He was using his blue inhaler too much before he started to use his Smart Inhaler, now he is down to taking it 2-3 times a week. A massive improvement."*
Parent for Ad2	*"Excellent innovation and useful re 'reminder' option"* *"Since using the Smart Inhaler my child's asthma has noticeably improved and he has not needed his Ventolin as much, if ever. To me this indicates he has taken his preventive inhaler regularly as the alarm on the Smart Inhaler has reminded him. I have not needed to remind him"*
Parent for Ad4	*"This device would be very useful with the blue salbutamol inhaler to see when and how much children are using their inhaler"*
Parent for Ad7	*"Every time the smart inhaler's ringtone goes off, *Ad7* is enthusiastic about going and taking his inhaler."*

3.5 Discussion

The user trial with the SmartTrack device has shown positive results for the use of this type of monitoring technology in the treatment of asthma for adolescents. The questionnaire results highlighted a significant preference in agreement with statements for all seven themes. The interview data largely supported these findings, with participants expressing enthusiasm for using this device as a way to prove they can independently manage their condition responsibly.

This discussion will firstly examine and compare the questionnaire and interview results, looking at how they support each other and the benefit using both methods brings in terms of added insight and feedback. Next, the themes that emerged from the interview analysis will be discussed in relation to existing themes in this domain from similar studies. There will then be consideration of the support this research provides for a holistic approach to user research in medical device design. Finally, the limitations and challenges surrounding the study, as well recommendations for the future of EMDs will be highlighted.

3.5.1 Comparison of questionnaire and interview results

3.5.1.1 *'Communication and Feedback'*

The questionnaire results showed a significant difference between adolescents and parents for the theme 'Communication and Feedback'. The majority of negative responses from the adolescents came for the statements 'I would like it if I could receive feedback on my inhaler use by e-mail' (four disagreed) and 'I would like it if I could receive feedback on my inhaler use by phone call' (five disagreed). In comparison, all parents either agreed or strongly agreed that they thought their child would like to receive feedback through e-mail. This therefore highlights where the adolescents' preferences for communication methods differ to their parents' expectations.

For the adolescents, three strongly agreed and four agreed that they would like to receive feedback through a dedicated smartphone app. This helps demonstrate that they would like to receive feedback - but certain methods would be preferred over others. This could mean that the negative responses may be due to preferences over mode of communication, rather than the concept of sharing data and receiving feedback. The preference for a smartphone app is supported in the interview data by a quote from Ad4 who stated "*It would be good to have a smartphone app. Because then it's always there, you can do it on the go, you don't have to be at home or on your laptop or computer, or at the doctors. Also, if on the app there was a way of sharing, like sort of messaging, that you could do on it, to send info on your inhaler (use)".* This preference for a smartphone app is supported by a recent, similar study that examined adolescent preferences in asthma management and found that this was the most commonly suggested and popular solution for improving inhaler use (Ellen S. Koster, Philbert, de Vries, van Dijk, & Bouvy, 2015).

3.5.1.2 *Other statements that received negative responses*

Although there was largely very positive response to nearly all questionnaire statements, there were statements that received more negative response. These were inspected further, to identify why this may have occurred and explore how the interview data may support it.

For the theme 'Portability and Practicality' the statement "It would be an improvement if the device could fit in a jacket or trouser pocket" collected five agrees and one strongly agree from the participants (these were subsequently reversed to five disagrees and one strongly disagree during data analysis due to the negative framing of this statement, as 'agreement' with it would be a negative for the device). This is supported by the interview data. For example, Ad2 stated *"Definitely make it smaller. Just so it could fit in your pocket better, so there isn't a massive bulge in your pocket".* Simply by looking at the SmartTrack device in Fig 3-1, it is clear that it adds considerable bulk to the inhaler which would make it difficult to fit into a pocket, which explains the negative responses to this statement.

A further example comes from a statement for the theme Aesthetics - "The device would benefit from customizable decoration" which received six agrees and one strongly agree (these were again reversed to be disagrees for statistical analysis). This can also be supported by the interview data, for example, Ad5 stated *"It could have accessories, like you know on a phone it has a corner and you can hang a little keychain off it or something"* whilst many of the other participants commented on how they would like a range of colours to be available. A similar response was received in previous research with a device for cystic fibrosis, where it was found that the younger participants (below 18 years) liked the idea of being able to personalise their device to make it less boring and to add some colour and variety (Lang et al., 2014).

3.5.1.3 *Differences between participants*

One participant in particular stood out as having lower scores for statements related to 'Aesthetics' (average mode response of 1, 'strongly disagree') and 'Social Acceptance' (average mode response of 2, 'disagree') compared to the others. This was again supported by the interview data, as this participant consistently commented on the concerns they would have about how their friends would respond to the devices appearance. For example, they stated *"I don't think they'd care about the asthma side, they'd just care about how it*

looks" as well as *"Well some of my friends would be like 'oh it's so cool' and then others would be like, it's a really weird shape and is really weird."*
Throughout all three interviews, this participant expressed their concern about the appearance of the device, particularly if they were to use it in front of their friends or peers. The fact that the questionnaire data was very well in-line with the opinions brought out in the interview data highlights the consistency between these two data sources.

The fact some participants felt more strongly about the appearance of the device than others reinforces previous research with medical devices for adolescents, where some were in preference of 'customisation' of the device both in appearance and auditory reminders, whereas others were more of the opinion that it is just a medical device and the appearance should not really matter (Lang, Martin, Sharples, & Crowe, 2014). Enabling personalization of medical devices for adolescents may be a way of engaging a wide range of teenage users, as it allows those who care about the devices appearance to tailor it more to their individual preferences, without disengaging those who are happy with a more typical medical device with no customisation

3.5.1.4 *Overlap between questionnaire and interview themes*

It is important to consider where the seven themes of the questionnaire and the emerging themes from the interview data overlap. The largest overlap appears with the practical aspects of the device such as its appearance and usability. The interview data formed themes such as 'device appearance' 'drawing of attention' and 'unwanted questioning' and these are highly related to the themes 'aesthetics' and 'social acceptance' in the questionnaire. Furthermore, the interview subtheme 'Usability' is highly related to the questionnaire theme 'Ease of Use'. This should be considered positive, as it suggests that the AMDAT is successful at capturing the views of adolescents towards medical devices.

3.5.2 Support for existing themes in the domain of user research for medical device design

The emergent themes from the interview data both support and further the research already carried out in this area. Similarities can be drawn with the themes uncovered by Lang et al in their research with adolescents with cystic fibrosis where the theme 'respecting independence and capabilities' is discussed, highlighting the adolescents' desire to be in control (Lang et al., 2014). This

rings true with the findings here, where a main emergent theme was 'taking control of condition'.

Whilst other research in this field has uncovered themes largely related to use of medical devices in social situations (O'Kane, Rogers, & Blandford, 2014, 2015) or their usability in particular settings (Furniss et al., 2014), this research has focused more on issues surrounding data - particularly in terms of monitoring and sharing.

3.5.3 A systems approach to user research for medical device design

The results from the study reinforce the need for a systems approach when evaluating medical devices. Whilst the data monitoring, sharing and reminder function of the SmartTrack were viewed positively by participants, the device's appearance as well as the choice of ringtones available received largely negative feedback. This highlights the importance of taking all aspects of design into account, including functionality, usability and aesthetics.

Sharples et al discuss the difficulties in linking medical device design with consequent user behaviour due to the complex nature of the context in which these devices are used (Sharples et al., 2012). It is important we consider all aspects of design, both for the device itself, its multiple user groups as well as the context it is used in, as just one negative aspect can disrupt the entire system (Sharples et al., 2012). For EMDs, there appears to be good potential for the reminders to help encourage inhaler use and for the data recorded by the devices to help adolescents in becoming more independent and responsible for their condition. However, the current aesthetics of the device as well as the choice of ringtones may reduce or even remove this potential benefit.

3.5.4 Study limitations and challenges

The ethical approval for the study required all researcher-participant interactions to occur in a clinical environment. This could be considered a limitation for the research, as the clinical setting imposed time restrictions on interviews as the room was needed for other patient appointments. Furthermore, the formal nature of the environment may have influenced how relaxed participants were and how freely they felt they could express their opinions.

One effect that should be considered was having a nurse present in the room. Although the nurse was always busy with other tasks and was placed sufficiently away from the participant and researcher to attempt to minimize any effects,

there is still a possibility that their presence altered how freely participants spoke. The 'power' dynamic of the researcher- participant relationship must also be considered, as the young age of the participants may have affected how openly they felt they could talk with the researcher (Davies, 2008). However, as the researcher who conducted the interviews was a young PhD student, this may have helped to limit this effect in comparison to if a more senior researcher had been the interviewer.

There were also recruitment challenges for the study. Many patients that could have been eligible to be approached were not because they did not use an inhaler that would be compatible with the SmartTrack device (seretide or flixotide are the only two compatible types). Many patients used a 'turbohaler' instead of a standard metered dose inhaler. This is a finding in itself and creates an added challenge for developers of EMDs for asthma inhalers, as a variety of inhaler types exist and accommodating for all variations is necessary to maximize the potential impact EMDs could have.

The small sample size should also be considered a limitation, as seven participants from a similar area with similar social, educational and economic backgrounds may not be representative of all adolescents with asthma.

The addition of the themes 'data monitoring', 'data sharing' and 'communication and feedback' to the questionnaire could also be considered a potential limitation as they have not been validated elsewhere and were formed based on the researcher's knowledge of the SmartTrack device's capabilities and the structure of existing AMDAT statements.

3.5.5 Recommendations for the future of EMDs

3.5.5.1 *Future Research*

The positive attitudes expressed by adolescents and their parents for the reminder function of the device supports the findings of a recent clinical trial where it was found that use of the SmartTrack and its audiovisual reminder function significantly improved adherence in school children with poorly controlled asthma (Chan et al., 2015). Now with evidence for the clinical effectiveness of these reminders as well as the positive attitude patients appear to have towards them, future research is needed to further investigate the impact that these reminders could have on asthma care. The adolescents in this study commented on how they would like to be able to customize the ringtones

and use their own music. A future clinical study could investigate the impact that this alteration could have on adherence.

The questionnaire results provide support for previous research that used the AMDAT where it was found that the category 'Aesthetics' received some of the most unfavorable responses (Lang, 2012). For the SmartTrack there was a noticeable amount of 'strongly disagree' responses to statements related to aesthetics and although this was not significant, this may be due to device aesthetics reportedly only being important to some adolescents rather than all (Lang et al., 2012). Future research should look to replicate the AMDAT method with other medical devices to investigate whether similar responses are received for aesthetics, as well as for the more positive categories that were found here, such as data monitoring.

This research has provided a first step for user-involvement in the design of EMDs for asthma. With asthma affecting all ages and with multiple EMD designs available, there is still a great need for continued inclusion of patients in the development of these devices to ensure they have maximum clinical effectiveness. Further research is also required to understand the attitudes of healthcare providers and stakeholders in asthma care towards these devices, as they will have important views that will be critical to take into consideration when determining the provision of these devices, as well as issues including data governance and handling.

3.5.5.2 *Design and development*

The participants in this study expressed concern about the size of the device and felt that it may attract unwanted attention to them. Future developmental efforts should focus on designing a smaller and less conspicuous device which does not add significant bulk or change the appearance of the inhaler. Participants also felt that there should be a better choice of ringtones as well as an ability to add your own. Their feedback also indicated that the device should be designed to be more usable, by making the purpose of the different buttons clearer or by introducing a touch-screen interface.

3.5.5.3 *Implementation*

There were recruitment challenges in this research caused by other adolescent patients with asthma using types of inhaled medication that were incompatible

with the SmartTrack device. This needs to be a consideration for EMDs, as the device may need to be compatible across a wide-range of inhaler types.

3.5.5.4 *Commissioning and purchasing*

Seretide is currently the costliest drug for the NHS, with an annual financial burden of £170 million (NHS Information Centre, 2011). The participants in this study all used Seretide medication and all expressed a positive attitude towards using the SmartTrack device to better manage their asthma medication and take their inhaler as prescribed. Evidence such as this should be used alongside evidence from clinical trials where EMDs have improved inhaler use (e.g. Chan et al, 2015) to demonstrate how providing patients with severe asthma with these types of devices could help cut costs associated with unused inhalers, whilst also reducing the costs related to hospital admissions caused by asthma exacerbations.

3.6 Conclusions

This study has provided new valuable insight into the views of adolescents with asthma towards a device for monitoring their inhaler use. The results have shown positive signs for these participants being open to having their medication taking behaviour monitored. They appeared to view the prospect of sharing data with their parents and healthcare providers as an opportunity to demonstrate the responsibility they have for their condition, allowing them to experience a greater sense of independence.

The reminders that the device can provide were particularly favored by participants and they spoke enthusiastically about the everyday benefit they could have for their condition in helping them to remember to take their medication at times when they otherwise would have forgotten.
The concerns participants had for the appearance of the device and the implications it could have in social situations highlights the importance of involving these types of users in future design and development of devices like the SmartTrack. By using an iterative design process with regular user feedback on issues that are important to them, these devices can be developed to fit seamlessly into the everyday lives of patients.

3.6.1 Implications for thesis

- This study has assessed the attitudes of a sample of adolescents with asthma towards an exemplar EMD – the SmartTrack
- This provides valuable insight into patient attitudes towards these devices
- Using a systems approach to EMDs for asthma, it is also important to consider the opinions of stakeholders in asthma care. The data produced by EMDs could help inform patient consultations and increase a clinician's knowledge of a patient's asthma. This makes it important to also understand their attitudes towards these devices.

Chapter 4 Perspectives of stakeholders towards EMDs for everyday asthma care

4.1 Introduction

Chapter 3 examined the attitudes of a sample of adolescents with asthma towards the SmartTrack device. The purpose of the study described here was to assess the perspectives of stakeholders and decision-makers in asthma care towards EMDs. Although these devices would primarily be for patients, they would also be used by healthcare providers to view patient inhaler use. This means that they also have attitudes and requirements that are important to take into account.

This chapter firstly covers literature that helps define who stakeholders are, who makes key decisions such as procurement in the National Health Service (NHS), and methods for engaging with stakeholders and collecting their opinions. It then describes the design of the study in detail and provides information about the occupations of the participants that were successfully recruited. The results are then presented to show what these stakeholders believe the key benefits and costs are for the introduction of EMDs into everyday asthma care. These results are then discussed to examine their implications for the developers of EMDs going forward, as well as lessons that were learned from the recruitment challenges experienced, potential limitations of the study, and future research.

4.2 Stakeholders Literature

The literature review in Chapter 2 highlighted 'stakeholder involvement' as a key issue for EMD's going forward. Whilst these devices would primarily be used by patients, there would be implications if their data was made available to healthcare providers.

4.2.1 Defining Stakeholders

In the healthcare industry, stakeholders have been defined as individuals with expert knowledge who have a direct interest in the outcomes of a project and/or will play a critical role in its implementation (Burton & Adams, 2008). Deverka et al (2013) provide a description of different categories of stakeholder, shown in table 4-1.

Table 4-1 Stakeholder categories taken from (Deverka, Lavallee, Desai, Esmail, & Scott, 2013)

Type of Stakeholder	Description
Patients and Consumers	Individuals or organisations who represent the perspective of patients. This could be people with particular health conditions, carers, or patient advocates.
Clinicians	Physicians, nurses, pharmacists, general practitioners (GPs)
Healthcare Providers	Healthcare institutions and organisations, such as hospitals and nursing homes
Payers and Purchasers	Funding bodies for healthcare goods and services
Policymakers and Regulators	Government, medical and professional organisations who form and regulate policies related to healthcare.
Life Sciences Industry	Companies and organisations involved in the development and marketing of new technologies, devices, pharmaceuticals, and diagnostics.
Researchers	Clinical, health and scientific researchers
Research Funders	Organisations providing monetary support for health and clinical research

The categories provided by Deverka et al (2013) give a good starting point for determining who would be most important to ask about EMDs. Whilst the attitudes of 'patients and consumers' have been addressed in Chapter 3, several of the other categories listed in table 4-1 could be targeted in this research. Of particular interest would be the opinions of clinicians, who treat asthma patients on a daily basis and will have first-hand insight into how EMDs could fit into current care. Furthermore, payers and purchasers will have experience in how services are funded and the issues that need to be addressed before a product becomes financially viable.

4.2.2 Structure of the NHS – Who makes the decisions?

To properly identify who stakeholders in asthma care may be, it is important to understand the way in which the NHS is structured, including how money flows from the treasury all the way down to the commissioned health services on the ground.

The organisation of the NHS changed dramatically in 2012 due to the Health and Social Care Act (BMJ and NHS England, 2014). This saw a major drive towards 'clinically led commissioning' with a push for health care providers to play a major role in decision making and allocation of funding. England's 152 primary care trusts (PCTs) were subsequently disbanded and replaced by 211 clinical commissioning groups (CCGs). By law, each CCG contains a chair and a deputy chair, a registered nurse, a secondary care specialist, as well as two 'lay' members of the public. The members of each CCG are recruited from the local area, to help ensure they have good knowledge of the health services available to the local community and are well placed for commissioning services that they know will be of benefit. CCGs now control the majority of the NHS budget, whilst NHS England is responsible for the national commissioning, which includes primary care and highly specialised services (BMJ and NHS England, 2014). Figure 4-1 provides a visual summary of the way in which funding is distributed from the treasury, through the department of health to both NHS England and the CCGs.

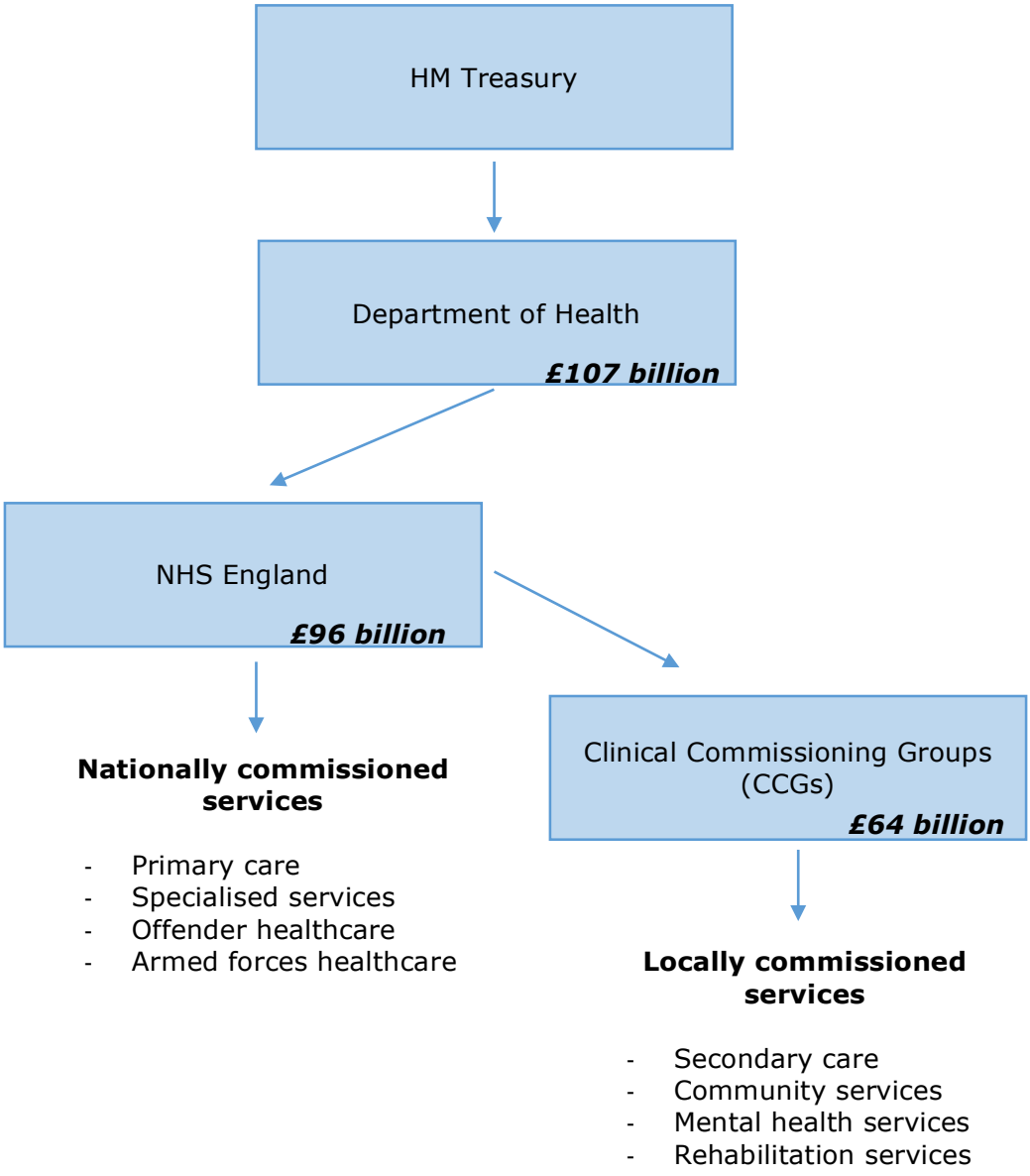

Figure 4-1 - Flow of funding and commissioning through the NHS (BMJ and NHS England, 2014)

By understanding the basic structure of the NHS it becomes clear that CCG members are an important group to target in stakeholder research for EMDs. With responsibilities in commissioning local services for secondary care, CCGs could make key decisions on whether funding should be allocated to providing EMDs for patients with severe asthma. Furthermore, as these groups are made up of clinically-focused individuals including GPs, nurses and secondary care specialists, many will have direct experience and insight into the potential

benefits and costs that EMDs could have for asthma patients, as well as their care providers.

4.2.3 Methods for engaging with stakeholders

According to Deverka et al (2013), stakeholder engagement can be defined as "*an iterative process of actively soliciting the knowledge, experience, judgment and values of individuals selected to represent a broad range of direct interests in a particular issue, for the dual purpose of:*

- *Creating a shared understanding*
- *Making relevant, transparent and effective decisions*" (pg. 5)

In order to solicit the views of stakeholders in asthma care, a range of research methods are available for collecting both quantitative and qualitative feedback (Deverka et al., 2013). Table 4-2 lists the main methods recommended for engaging with stakeholders. The nominal group technique and the Delphi method in particular, are often used as successful methods of engagement to reach consensus on a given issue (Ryan et al., 2001). Whilst questionnaires and online surveys can be useful techniques for gathering information and feedback, they are often supplemented by face-to-face techniques such as interviews or workshops in order to provide richer, qualitative information which may not have been picked up by a survey alone (Fearon, 1998). For this reason, when determining the most effective methods for engaging with stakeholders, the Delphi method and the nominal group technique were initially selected as the most appropriate research tools and were inspected further to determine which would be the most appropriate for engaging with stakeholders in asthma care.

Table 4-2 Methods for engaging with stakeholders, taken from Deverka et al (2013)

Quantitative	Qualitative
• Questionnaires • Delphi method • Multi-criteria mapping • Value of information modelling	• Nominal group technique • Facilitated workshops • Stakeholder decision analysis

4.2.3.1 *The nominal group technique*

The nominal group technique requires a selection of experts to gather in the same room for a session similar to a focus group. Experts are given a brief introduction and are asked the "nominal group question" for which they will then be given roughly fifteen minutes to write down comments. An example nominal group question could be "what things are important in making people satisfied with diabetic care?" (Gallagher, Hares, Spencer, Bradshaw, & Webb, 1993). Each expert is then asked to provide one comment to be written on a board for everyone to view. After an item from each member is written out, there is a group discussion to talk about each item in turn; offering an opportunity for new items to be generated or others to be dismissed. The next stage of the process is for each person to select their top ten most important issues from the list, with these ratings then gathered to generate a 'top ten' based on the ratings from all of the experts. This is then followed by another discussion about the ranked list, where experts can put cases forward for items to be ranked higher or lower. For the final stage, each person is given the opportunity to re-rank or adjust their top ten list if they wish (Gallagher et al., 1993).

Whilst the nominal group technique would be an ideal method for generating the key issues surrounding the introduction of EMDs into asthma care, it has a major drawback in requiring experts to be co-located in the same room at the same time for an hour or more. This makes the nominal group technique an inappropriate method for engaging with stakeholders in asthma care, particularly for members of CCGs, who will be located in different areas of the country and are likely to be unwilling or unable to commit time to travelling to and attending a group meeting.

4.2.3.2 *The Delphi method*

Unlike the nominal group technique, the Delphi method gathers attitudes and feedback from experts on a particular topic without requiring them to attend a meeting or be physically co-located (Ryan et al., 2001). A survey is posted out to each individual expert and asks for their opinion using open-ended questions. These surveys are then returned and the responses are combined and compiled into a second survey where experts can view the anonymous opinions of other experts. Each individual is asked to provide their level of agreement with the statements made and the responses are then collected again to determine the level of consensus in the sample. Multiple rounds can be used where experts can

see agreement ratings given by other respondents, with the ultimate goal being to reach a sufficient level of consensus on the original issue (Ryan et al., 2001).

The Delphi method and the nominal group technique are similar techniques for gathering the opinions of experts and asking them to produce issues related to a certain topic and rate their levels of importance. The benefit of using the Delphi method is that it removes the necessity for experts to attend a meeting together and means they can provide their opinions remotely without being constrained to certain time pressures (Czinkota & Ronkainen, 1997). This makes the Delphi method more preferable for engaging with stakeholders in asthma care, as it means individuals from multiple different CCGs, hospitals and healthcare facilities can be approached and they can provide their opinions in their own time. However, a potential disadvantage that must be acknowledged and accepted is that response rates in Delphi studies are often low, and there is often a large drop-out as the rounds progress (Williams & Webb, 1994)

4.2.4 The Delphi method in health research

For health research, the Delphi method is regarded as well suited as there are typically a small selection of experts for a given topic (Meyrick, 2003). A classic Delphi method is characterised by four key features (Rowe & Wright, 1999):

1. **Anonymity** – responses given by participants have no name or identifiable information attached, reducing any pressures to conform and allowing participants to speak freely.
2. **Iteration** – participants can adjust and refine their opinions over multiple rounds of surveys.
3. **Controlled Feedback** – from the second round onwards, participants can see the responses of others and adjust their own views accordingly.
4. **Statistical Aggregation of Group Responses** – collecting and combining responses from the entire group allows for quantitative analysis to uncover insight into the groups opinions.

The Delphi method has been used extensively in health research (Meyrick, 2003). One study used a Delphi technique to gather the opinions of paediatric intensive care nurses towards the needs of critically ill children (Endacott, Clifford, & Tripp, 1999), another used the method to determine research priorities in occupational health (Harrington, 1994). A Delphi was also widely distributed on a national level to ask surgeons and anaesthetists for their

opinions on the maximum potential for day surgery (Gabbay & Francis, 1988), whilst a Delphi method has also previously been utilised to select the optimal content of electronic records for patients with asthma (van Steenkiste, Jacobs, Verheijen, Levelink, & Bottema, 2002).

4.2.5 Summary

From the existing literature and the care pathway it has been possible to define stakeholders and determine the most appropriate stakeholders to target in asthma care, with CCG members being identified as key decision makers. From assessing the methods available for stakeholder engagement, the Delphi method has been selected as the most appropriate, with significant benefits coming from the ability for individuals to provide their opinions remotely, yet still view and interact with the responses of others.

4.3 Method

4.3.1 Defining Stakeholders

In order to access stakeholders with a direct interest in the introduction of EMDs into everyday asthma care it was important to identify and define who these stakeholders would be. Using the stakeholder categories laid out by Deverka et al (2013) as an initial guide and supplementing this with knowledge of the structure of the NHS (BMJ and NHS England, 2014), the following stakeholders groups were identified as appropriate to target:

- **Healthcare providers** – GPs, Nurses, Consultants and Physicians
- **Payers and Purchasers** – NHS Clinicial Commissioning Groups (CCGs)
- **Advisory Boards** – British Thoracic Society (BTS) Asthma Specialist Advisory Group

4.3.2 Ethics

Ethical approval for the study was granted by the University of Nottingham, Faculty of Engineering ethics committee. It was agreed that study response data, information about participant occupations, and addresses for posting paper surveys would all be stored in a password protected folder on the researcher's University computer. Paper survey responses were also stored in a locked cabinet in the researcher's University office. Online survey responses were stored on Qualtrics – the host of the survey. Qualtrics uses high-end firewall systems as well as Transport Layer Security (TLS) encryption for transmission of

all data. Surveys are additionally protected by passwords and all data is stored on third-party data centers that meet SSAE-16 SOC II standards.

4.3.3 Recruitment

As the targeted population was anticipated to be difficult to recruit from, several routes were used for contacting potential participants, with £3 donations to Asthma Research UK used as an incentive for every survey response received.

Paper Survey

Initially, it was determined that the most effective method for recruitment would be through paper surveys either posted or handed directly to stakeholders (see Appendix 5). These were distributed in the following ways:

- Handed out to the respiratory teams at Queens Medical Centre (QMC) and City Hospital in Nottingham, UK.
- Posted to members of local Clinical Commissioning Groups (CCGs) where they had listed their interests or specialties as 'asthma', 'respiratory', or 'paediatrics'.
- Sent to members of the British Thoracic Society (BTS) asthma specialist advisory group.
- Handed out to delegates at the East Midlands Asthma Day (2015) at the University of Nottingham, UK.

Online Survey

Unfortunately, the paper surveys did not yield a response rate as high as was hoped. An online version of the survey was created in order to access more stakeholders and was distributed in the following ways:

- E-mailed to doctors and nurses in Leicestershire, UK
- E-mailed to members of the Respiratory Effectiveness Group (REG) - an investigator-led, not-for-profit research initiative (http://www.effectivenessevaluation.org)
- Shared on Twitter by the REG (@RespirEffect)
- Article and link to survey posted on the Respiratory Futures website (respiratoryfutures.org.uk)

4.3.4 Materials

As described in the previous section, two versions of the survey were created based on the route of recruitment. The content for each was kept the same, with a participant information sheet, consent form and survey always included (see Appendix 5). The content of the surveys was reviewed by a respiratory consultant to help ensure the information was clear and concise for the intended audience. The materials used for the paper and online versions are described here.

Paper Survey

Paper surveys were distributed in envelopes containing an additional envelope inside with pre-paid postage and a return address already written to make posting completed surveys back as easy as possible.

Some paper surveys were posted, whilst others were handed out. Surveys that were posted contained an opening letter providing a short explanation of who the researcher was, what the research was about as well as details of how they could easily complete the survey and post it back free of charge. Surveys that were handed out had no letter, but were accompanied by a post-it note with a hand written message from the researcher, personally explaining how appreciative they would be of their input. This was used as a recruitment technique as previous research has found that personalised Post-it notes yield significantly higher return rates for surveys, compared to surveys with a blank post-it note, or no post-it note at all (Garner, 2004).

For the large-scale distribution of the survey at the East Midlands Asthma Day (2015), no post-it notes were included as the researcher had face-to-face contact with the delegates. Respondents to the survey in this instance were asked to provide their occupation, as well as an address to send the next round of the survey to.

Online Survey

The online version of the survey was run using Qualtrics (www.qualtrics.com). The content including the information sheet, consent form and questions were kept the same as in the paper version, but as participants were accessing the

survey from multiple different routes, they were asked to provide details of their occupation as well as an e-mail address so that later rounds of the survey could be sent to them.

4.3.5 Rounds of the Delphi survey

The Delphi method used here was initially based on suggestions laid out by Okoli et al. who provide a guide and some design considerations for using the Delphi as a research tool. They recommend using an initial questionnaire to ask experts to list 6 or more important factors related to the given topic (Okoli & Pawlowski, 2004). Next, participants review the points raised and rank each one using a likert scale from 1-10 (Scott, 2000). The third and final round was adjusted during the study, this change is described and justified in section 4.3.5.3.

4.3.5.1 *Round One*

In the first round of the Delphi (see Appendix 5), participants were initially given a short explanation of EMDs for asthma in case they were unaware of their purpose. This was carefully worded to avoid biases for or against the devices and focused on explaining the practical aspects of the device. This included:

- The key function of all EMDs is to precisely record the date and time whenever the inhaler is actuated
- Data can be uploaded to a dedicated website where a patient or anyone with granted access can view detailed information on exactly when the individual has been using their inhaler
- Some EMDs possess additional features including audible tones to remind a patient when a new dose is due, and location tracking to identify the exact location where the inhaler was used

Suggestions were also provided to participants about things they may wish to consider when thinking about their answers:

- Who could use the data collected by the EMDs?
- What could the data collected by the EMDs be used for?
- How would this wealth of data affect asthma treatment in its current form?
- Could EMDs have a negative impact on asthma care? If so, how?

After reading the information, participants moved onto the first stage of the Delphi, where they were asked to provide at least six benefits that they felt EMDs could have for asthma. They were told these benefits could be for treatment of asthma as a whole, or benefits they could see EMDs having in their own personal work, if they have direct contact with asthma patients. Participants were asked to provide a short explanation for each point they provided, in order to help justify and clarify the factors that they raised.

After providing six or more benefits, participants were asked to do the same for costs/barriers – give six or more costs/barriers that there could be for the introduction of EMDs in asthma. They were told this could again draw on their own personal experience, or asthma care as a whole.

4.3.5.2 *Round Two*

Round two of the Delphi was formed based on the responses received in round one. This meant that the benefits and costs/barriers that were collected in round one were aggregated and similar responses where two or more participants had raised the same point were merged. This process was similar to a thematic analysis (Braun & Clarke, 2006) but was simpler as the points tended to be short and could easily be grouped. Grouping points together was carried out by the researcher and lead to a set of 29 unique benefits and 32 unique costs/barriers. This process is shown using two examples in Table 4-3.

Table 4-3 An example of how points raised by the participants were grouped during analysis in preparation for round two

Example points raised by participants	Grouped benefit/cost
Reminder for patient Potential to help patient remember dosing Audible tone to remind patient to improve compliance Audible bleep. This is a good way to remind patients Alarm – excellent for people who forget Reminder to take meds Patients would be reminded to use their preventer	Reminding the patient to use their inhaler
Cost!! Cost. Would need to understand full cost vs benefit	Cost of Devices

analysis Who pays? Who funds the device? How expensive is the device? Cost of unit Actual cost of device More expensive for practise Cost – depends on how much An expensive high-tech solution Likely to be more expensive	

For round two, the grouped benefits and costs/barriers were presented back to the participants in randomised lists. They were then asked to rate each point from 1-10 with 1 being "least important" and 10 being "most important". They could use any point on the scale as many times as they liked.

4.3.5.3 *Round Three*

Like in round two, the third and final round of the Delphi was based on the responses gathered from the previous survey (see section 4.4.3. for these results). The ratings of importance participants gave in round two were collated and analysed to form a ranked list of the most important benefits and costs/barriers associated with EMDs, according to the sample.

Originally it was planned that participants would be asked to rate their levels of agreement with the ranked lists - to indicate whether they felt certain points should be regarded as more important and others as less. This was due to Delphi research typically aiming to reach consensus between stakeholders. However, it was decided that the purpose of this research was actually more exploratory and about gathering a wide range of perspectives on EMDs - rather than encouraging agreement and a like-minded attitude. The traditional Delphi method has previously been adjusted in a similar way - the 'Policy Delphi' was developed as a way to gather the widest range of possible solutions for a given problem, rather than to reach to consensus (Turoff, 1970). Whilst the Delphi used here would not be considered a Policy Delphi, it adjusts it in a similar way and does still maintain the four key characteristics of a Delphi; anonymity, iteration, controlled feedback, and statistical aggregation (Rowe & Wright, 1999).

Therefore, in round three the top five (most important) and bottom five (least important) benefits and costs/barriers were presented to the participants and they were asked for final qualitative feedback on these lists, as well as the research more generally. Questions asked were:

Top Five Benefits:

1. After viewing the top 5 benefits above, do you believe any should not be considered this important? If so, why not?
2. Are there any other benefits that you feel should be in this top 5 list that currently are not? If so, what are they and why?

Bottom Five Benefits:

1. After viewing the bottom 5 benefits above, do you believe any should be considered more important than this? If so, why?
2. Are there any other benefits that you feel should be in this bottom 5 list that currently are not? If so, what are they and why?

The same questions were then used for the top and bottom five costs/barriers. Afterwards, a final question was asked: "As a final question of this study, I would like to know if your opinion on EMDs has been changed at all through taking part in this research. Are your views different now to when you started? If so, how?"

4.4 Delphi results by round

4.4.1 Study Population

It was not possible to accurately estimate the number of potential participants compared to the number who responded because of multiple different routes for recruiting participants. Furthermore, due to the survey being shared on Twitter, the Respiratory Futures website, as well as by the REG, eight responses were received from overseas participants. These responses have been omitted from the main results, but are outlined in the 'Impact of Overseas Participants' section 4.4.5.

Participants recruited into the study all took part in round one of the Delphi, with drop-out meaning a reduced number responded to round two and a further

reduced number completed round three. Details of the UK-based sample at each stage are provided in table 4-4.

Table 4-4 Sample size across the three rounds of the Delphi survey with occupation demographics included (N/A = no occupation provided)

Delphi Round	Total	Consultants	GPs	Nurses	Pharmacists	N/A	CCG/Advisory Board members (from the existing sample)
Round One	31	8	6	9	1	7	5
Round Two	18	8	3	6	1	0	4
Round Three	10	3	1	6	0	0	1

4.4.2 Round one results

After collecting the responses for round one, the 154 benefits and 159 costs/barriers of EMDs provided by the respondents were analysed to find occasions where different participants had raised the same point. Responses were then grouped and given names to accurately report every unique point raised by the participants (see Appendix 6 and 7). This process was described in section 4.3.5.2.

A total of 29 benefits and 32 costs/barriers were found from the data in survey one and are displayed in table 4-5 and table 4-6 respectively. The number of times each point was raised independently is shown in the tables and provides an indication of the factors that were brought up most frequently. As can be seen, for benefits the participants spoke most often about EMDs providing an accurate record of adherence and reminding patients. For costs/barriers the points raised the most included concerns about the costs of the devices, as well as their bulkiness and appearance potentially being off-putting to patients.

Table 4-5 The 29 benefits participants gave for electronically monitoring inhaler use, with the number of times each point was raised

Benefits	Sum
1. An accurate record of adherence for clinicians/nurses/GPs to use in auditing and review	24
2. Reminding the patient to use their inhaler	17
3. For identifying patterns of inhaler use e.g. days, times, school, holidays etc.	12
4. Aiding discussions between the clinician and patient e.g. visual evidence	11
5. Improve compliance	8
6. Reducing costs through less wasted medication and less time in hospital	8
7. Relating an accurate record of a patients inhaler use to their health outcomes and asthma control	7
8. Data for research	6
9. Patient can see their inhaler use from home and know if they are underusing/overusing	6
10. Patient has proof of their adherence to share with their clinician - increasing trust	6
11. Increase patient involvement and motivation for treating their condition	5
12. More informed decision making for clinicians	5
13. Better asthma control and improved quality of life	4
14. Adding the ability to alert when the inhaler is about to run out would be beneficial	3
15. Adding the ability to monitor inhaler technique would be beneficial	3
16. Can be used to identify inhaler types that are less likely to be used - to ultimately find the most widely accepted and used inhaler types	3
17. Increasing patient independence, accountability and self-management for their asthma	3
18. Parents can check on their child's inhaler use	3

19. The patient's awareness of monitoring by their clinician may improve their compliance	3
20. 'Cool' technology may appeal to patients	2
21. Could reduce exacerbations	2
22. GPS would be beneficial in identifying triggers for a patients asthma e.g. pollen, pollution	2
23. Could be used with other monitoring techniques e.g. peak flow	1
24. Helpful for identifying dose dumping	1
25. Increasing patient confidence in their care	1
26. Long term - could be used to develop bio feedback	1
27. Promote competition	1
28. Useful data for emergency situations	1
29. Useful to monitor adherence of different groups of patients on different treatments	1

Table 4-6 The 32 cons participants gave for electronically monitoring inhaler use, with the number of times each point was raised

Costs/Barriers	**Sum**
1. Cost of devices	32
2. Bulkiness and appearance may put patients off	14
3. Patient may not like being 'watched'	12
4. Accuracy and reliability of the device, as well as potential technical issues	9
5. Concerns over the time and workload this would add to the consultation process	9
6. Concerns if this is only compatible with MDIs	7
7. Records actuation but not inhalation, technique, nor identifies if canister is empty or inhaler is shared	7
8. Whose responsibility is downloading, processing and interpreting the data and discussing with patients?	7

9. How is data stored and who has access?	6
10. An EMD may be required for more than one inhaler per patient	5
11. Evidence of the effectiveness of EMDs is required	4
12. Cleaning and maintenance of the device	3
13. Concerns about the role of pharma companies	3
14. Could interfere with inhalation technique or not be compatible with spacer	3
15. Data overload	3
16. Ease of use - Another thing patients have to learn	3
17. Elderly patients may struggle with the technology or have a negative attitude towards it	3
18. May make no difference to already unengaged patients	3
19. May put patients off coming to clinic particularly if they have failed	3
20. Paternalistic approach	3
21. Added cost/time/workload of training clinicians and staff on how to use device, how to teach patients and how to interpret results	2
22. Are there better alternatives e.g. Tele-health or Medication Possession Ratio (MPR)?	2
23. Over-reliance on data - also need to determine reasons for non-adherence	2
24. Patient may forget to bring device with them to clinic	2
25. Patient resistance or refusal to use the device	2
26. Patients may find the reminders a nuisance	2
27. Bad for the environment - plastic and batteries	1
28. Could create potential conflicts between the patient and their clinician or parents	1
29. Many who get this device may do so as there are adherence concerns and therefore will show (inevitably) that adherence is poor	1
30. More benefits for researchers than patients, meaning patients may fail to see worth	1
31. Non-adopters leads to selection biases	1
32. This will not address intentional non-adherence	1

4.4.3 Round two results

Participants in round two rated each point for its relative importance on a scale where 10 was most important and 1 was least important. To analyse these data, the number of 10s, 9s and 8s were counted, as well as the number of 1s, 2s and 3s. The most important issues were then selected using the following criteria:

1. Total number of 10s and 9s
2. If still equal between two or more issues – the total number of 10s, 9s and 8s.

The same was then done for selecting the least important issues, with the total number of 1s and 2s used as the first criteria, and then the total number of 1s, 2s and 3s used if two or more issues were still level. These calculations were done for the full sample of participants (N=18) as well as for the two largest sub-groups – consultants (n=8) and nurses (n=6). The top five most important benefits are shown in table 4-7, the least important benefits are shown in table 4-8, the most important costs/barriers are in table 4-9 and finally the least important cost/barriers can be seen in table 4-10.

As can be observed from the data, the points rated most important in round two are not the same points that were raised most frequently in round one. "Evidence of the effectiveness of EMDs is required" was raised on only four occasions in the first round of the survey, yet was given a rating of 9 or 10 by half of the sample, making it the most important cost/barrier facing EMDs, according to the results. In comparison, 'Cost of devices' was raised 32 times in survey one, but was not rated as one of the most important costs/barriers in round two. However, five participants did still give it a rating of 9 or 10 meaning it was still regarded as highly important by at least some of the sample.

Similarly, with benefits 'better asthma control and improved quality of life' was only raised on four occasions in round one, yet was rated as the most important benefit in round two. 'Aiding discussions between the clinician and patient e.g. visual evidence' was also rated highly in round two, and came up more frequently in round one with eleven occurrences.

Table 4-7 The five most important benefits according to ratings from the participants. Green arrows correspond to how many places each point has moved up in the original list from round one.

5 most important benefits (out of 29)	10s, 9s	10s, 9s, 8s
1. Better asthma control and improved quality of life ↑ 12	9	13
2. Aiding discussions between the clinician and patient e.g. visual evidence ↑ 2	8	15
3. The patient's awareness of monitoring by their clinician may improve their compliance ↑ 16	7	14
4. Increase patient involvement and motivation for treating their condition ↑ 7	7	12
5. More informed decision making for clinicians ↑ 7	7	11

Table 4-8 The five least important benefits according to ratings from the participants. Red arrows correspond to how many places each point has moved down in the original list from round one.

5 least important benefits (out of 29)	1s, 2s	1s, 2s, 3s
25. Helpful for identifying dose-dumping ↓ 1	3	4
26. Could be used with other monitoring techniques e.g. peak flow ↓ 3	4	4
27. Promote competition -	4	5
28. GPS would be beneficial in identifying triggers for a patient e.g. pollen, pollution ↓ 6	4	6
29. Long term - could be used to develop bio-feedback ↓ 3	10	11

Table 4-9 The five most important costs/barriers according to ratings from the participants. Green arrows correspond to how many places each point has moved up in the original list from round one.

5 most important costs/barriers (out of 32)	10s, 9s	10s, 9s, 8s
1. Evidence of the effectiveness of EMDs is required ↑ 10	9	11
2. Records actuation but not inhalation, technique, nor identifies if the canister is empty or the inhaler is shared ↑ 5	6	11
3. Whose responsibility is downloading, processing and interpreting the data and discussing with patients? ↑ 5	6	10
4. Could interfere with inhalation technique or not be compatible with spacer ↑ 10	6	9
5. Patient may forget to bring device with them to clinic ↑ 9	6	7

Table 4-10 The five least important costs/barriers according to ratings from the participants. Red arrows correspond to how many places each point has moved down in the original list from round one.

5 least important costs/barriers (out of 32)	1s, 2s	1s, 2s, 3s
28. Patient resistance or refusal to use the device ↓ 3	3	4
29. Concerns over the time and workload this would add to the consultation process ↓ 24	3	5
30. More benefits for researchers than patients, meaning patients may fail to see worth -	3	5
31. Are there better alternatives? E.g. Telehealth or Medication Possession Ratio (MPR)? ↓ 9	5	7
32. Bad for the environment – plastic and batteries ↓ 5	7	8

Viewing the arrows in Table 4-10, it is interesting that 'concerns over the time and workload this would add to the consultation process' moved down 24 places. In round one this point was raised by nine different participants, yet was the fourth most negatively rated point in round two. This may be explained by the fact that 'aiding discussions between the clinician and patient' was rated as the second most important benefit (see table 4-7). It is possible that the participants recognised the benefit EMDs could bring to the consultation process over the potential negatives.

Table 4-11 shows the 3 most important benefits and costs/barriers for the two largest participant groups – consultants (n=8) and nurses (n=6). Analysis for smaller participant groups was not carried out as they were found to be too small to establish a meaningful list of 'top' issues.

For consultants and nurses there was a difference between the points they rated as most important. The benefits rated as more important by the consultants appear to focus more on supporting the consultation process, through providing them with visual evidence to show patients - such as graphs on their adherence over a period of time, and by allowing them to make more informed decisions about a patient's care plan. In contrast, the benefits rated highly by nurses focus more on the patient and on their health, asthma outcomes and medication use. For costs/barriers, consultants 'rated evidence of effectiveness of EMDs is required' as most important, whilst nurses were more concerned with where responsibility would lie for downloading, interpreting and discussing the data with patients.

Table 4-11 The most important benefits and costs/barriers according to the two largest participant groups - consultants and nurses

	3 most important benefits	**10s, 9s**	**10s, 9s, 8s**
Consultants (n=8)	**1.** Aiding discussions between the clinician and the patient e.g. visual evidence	5	7
	2. More informed decision making for clinicians	5	6
	3. The patient's awareness of monitoring by their clinician may improve their compliance	4	5
Nurses (n=6)	**1.** Better asthma control and improved quality of life	4	5
	2. Improve compliance	3	5
	3. Relating an accurate record of a patient's inhaler use to their health outcomes and asthma control	3	3
	3 most important costs/barriers	**10s, 9s**	**10s, 9s, 8s**
Consultants (n=8)	**1.** Evidence of the effectiveness of EMDs is required	4	4
	2. Patient may not like being 'watched'	2	5
	3. Could interfere with inhalation technique or not be compatible with spacer	2	4
Nurses (n=6)	**1.** Whose responsibility is downloading, processing and interpreting the data and discussing with patients?	4	5
	2. An EMD may be required for more than one inhaler per patient	4	4
	3. Accuracy and reliability of the device, as well as potential technical issues	4	4

4.4.4 Round three results

In round three, the remaining ten participants reviewed the ranked list of benefits and costs/barriers formed from the ratings given in round two and provided their final comments and feedback.

For the five most important benefits, nine of the participants felt that the points were correctly rated highly, whilst the remaining one participant was a consultant who felt that 'Better asthma control and improved quality of life' was not necessarily *"…implicit in the use of smart inhalers (EMDs): it is what we hope will happen…"* The same consultant felt that a pro that was missing from the list and should be considered important would be *"Collecting data for making large scale decisions in terms of health services delivery and research."* Although the other nine participants were satisfied with the five most important benefits, they did suggest other benefits that could be regarded just as important, such

as 'increasing patient independence, accountability and self-management for their asthma'.

For the five least important benefits, six of the ten participants felt that they were rightly rated this low. One of the consultants felt strongly that the benefit 'GPS would be beneficial in identifying triggers' should be rated higher, stating "*GPS seems a very significant benefit, particularly for 1) children and less well educated individuals who find it hard to describe triggers and 2) identifying locations that trigger off lots of individuals."* When asked if there were other benefits that should be rated lower, one nurse felt that 'Useful to monitor adherence of different groups of patient on different treatments' should be lower, stating "*the device is unable to monitor some treatments, such as those delivered through a turbo-haler, where the drug is not available as an MDI."*

For the five most important costs/barriers, seven of the ten participants felt that they were correctly rated highly. Of the three participants who disagreed, one consultant felt that 'the device records actuation but not inhalation, technique, nor identifies if the canister is empty or the inhaler is shared' was actually device dependent *"so may be very important or less important depending on the smart device used".* When asked if there were other costs that should be regarded as more important, one GP stated "*Data overload. A genuine fear which needs to be addressed"* whilst a consultant stated that an important cost that hasn't been explicitly mentioned in the process so far is; "*institutional procurement processes: It is a complete pain to acquire things that aren't either drugs for a patient or equipment for the institute.*"

Finally, for the five least important costs, six of the ten participants felt that they were rightly rated this low. However, one consultant felt that 'Bad for the Environment' should be rated higher and added *"Green electric cars are very demanding to the environment in terms of construction costs, shipping, and disposal. Inhalers are small but people go through them quickly."* Elsewhere, a nurse felt that 'Patient resistance or refusal to use the device' should be considered more important as *"patient acceptance of the device is of importance or else the devices will not be utilised."*

When asked a final question about whether their attitudes had changed, many of the respondents spoke about how taking part had altered their views towards EMDs. For example, one consultant said that their attitude had moved from "*not*

at all interested (in using EMDs) to possibly interested for selected patients." Whereas a nurse stated that their views were different because they now had a "*…better understanding about how they work and the benefits to the patients."* However, another nurse who had previous experience with EMDs still had reservations about the devices, and believed they could often be prone to errors and faults, stating "*these can be frustrating for both patients and clinicians, and may cause problems when reviewing results."*

4.4.5 Impact of overseas participants

The eight participants from outside of the UK were made up of two consultants, two general practitioners, one pharmacist, two academics, and one where no occupation was given. Whilst omitted from the data here, their results were included in the three surveys given to participants and therefore impacted on points raised in round one, as well as the ratings given in round two.

This sample provided one additional pro:

- Identifying 'at risk' patients with low adherence'

As well as four additional cons:

- Patients may lose or break EMD - expensive to replace
- Patients may begin to over-rely on the device
- Some patients only want treatment for symptoms
- Some patients will only be adherent when they know they are being monitored

These responses affected the ratings participants gave in the second survey, with 'Identifying 'at risk' patients with low adherence' rated as the most important benefit, above 'Better asthma control and improved quality of life'. Whilst this point was raised by a healthcare provider outside of the NHS, it was still rated very highly by stakeholders within the NHS. Furthermore, identifying patients who are at risk from low adherence is a general benefit which would not be specific to one healthcare system, but would be applicable to patients with asthma globally.

4.5 Delphi results – Overall review

Benefits and costs/barriers were obtained which relate to the patient and their health, the job and workload of the clinician, advancing asthma research, and the practicalities of EMDs more generally. Many of the comments received from the participants were short and non-descriptive, simply stating the point without further explanation. However, participants did provide more in-depth comments in places. This section contains a review of the points raised, split into patient, clinician, research and practical factors and gives examples of the more descriptive comments that were received during the study.

4.5.1 Patient-related factors

Participants identified benefits and costs/barriers of EMDs that could directly affect the health and care of asthma patients. The full list of factors related to patients is outlined in Fig 4-2. The discussion afterwards focuses on the factors where detailed comments were received.

Patient-related benefits	Patient-related costs
• Reminding the patient to use their inhaler • Improve compliance • Patient can see their inhaler use from home and know if they are underusing/overusing • Patient has proof of their adherence to share with their clinician – increasing trust • Increase patient involvement and motivation for treating their condition • Better asthma control and improved quality of life • Adding the ability to alert when the inhaler is about to run out would be beneficial • Increasing patient independence, accountability and self-management for their asthma • Parents can check on their child's inhaler use • Patient's awareness of monitoring by their clinician may improve their compliance • 'Cool' technology may appeal to patients • Could reduce exacerbations • Increasing patient confidence in their care • Promote competition	• Bulkiness and appearance may put patients off • Patient may not like being 'watched' • An EMD may be required for more than one inhaler per patient • Ease of use – Another thing patients have to learn • Elderly patients may struggle with the technology or have a negative attitude towards it • May make no difference to already unengaged patients • May put patients off coming to clinic particularly if they have failed • Paternalistic approach • Patient may forget to bring the device with them to clinic • Patient resistance or refusal to use the device • Patient may find the reminders a nuisance • Could create potential conflicts between the patient and their clinician or parents • Many who get this device may do so as

	there are adherence concerns and this will show (inevitably) that adherence is poor • More benefits for researchers than patients, meaning patients may fail to see worth • This will not address intentional non-adherence

Figure 4-2 Patient related benefits and costs

The respondents often spoke about how EMDs could have the potential to improve adherence, with some continuing to describe how this could lead to improved asthma control and quality of life. Comments included "compliance enhanced", "effective use of treatment", "more likely to comply", and "improved care, because of increased adherence". Many of the respondents felt that the reminders an EMD could provide would have a direct effect on how often patients were using their inhalers. For example, one nurse stated "The EMD would be useful in patients who forget to take their inhaler, and acts as a reminder, and gets them into a habit of taking their inhaler regularly" whereas another nurse commented "Some children would love the fact that devices are being used to remind them…"

Participants also commented on the positive effect that EMDs could have for motivating patients and creating a sense of independence and accountability for their condition. A nurse commented that "The patients can individualise the EMD by selecting their own tune and time of the alarm, which by involving the patient in choice may increase adherence to medication" whilst a pharmacists and CCG member stated "Uploadable results may improve patient involvement and interest in their treatment." Some comments were also received from respondents who felt that the technology could be an attractive feature, such as "The device may appeal to patients who like the new technology and gadget feel".

Participants also felt that the data recorded by EMDs could foster a trusting relationship between the patient and their clinician. For example, one respiratory consultant stated "patients know that clinicians "believe" them re concordance" whilst a GP similarly said that it "may encourage asthma review as have 'done well' and will receive praise." Some respondents also felt that a patient simply being aware of their inhaler use being monitored could have a positive impact,

with a respiratory consultant commenting; "Positive observation effect: people won't know when they are being watched so are more likely to behave."

Whilst participants recognised the benefit EMDs could have for asthma patients, they equally had concerns for the potential barriers that may need to be addressed or overcome for benefits to come to fruition. Firstly, many comments pertaining to the bulkiness and size of the device were received. One GP and CCG member stated that the "EMD may make the whole inhaler bulky - not user friendly and may discourage patients to clip it onto their inhaler," whilst a respiratory consultant with first-hand experience of EMDs warned "they were not popular with patients, many liked the idea but found the reality of the device too bulky and cumbersome." Others additionally felt that the usability of the device could be a potential issue, with a nurse and CCG member commenting "this may be another device the patient has to get to grips with along with the various types of inhaler they may be using." This could be a particular problem in older patients, a GP and CCG member asked "Are they accessible to the older generation who may not be quite so ok with using technology?"

As opposed to the potential benefits for some patients in encouraging good adherence, respondents felt there was potential for EMDs to have a negative effect on a patient's attitude. A GP commented "Intrusion may not be well received - 'Big Brother'" and a nurse stated "people are highly resistant to being watched." Some felt this could even effect whether patients attend clinic visits, with a respiratory consultant stating "Patients may feel their clinician is checking up on them and may be put off coming for review." Comments were also received stating that this was a "paternalistic approach to medicine" and a "restriction of a patient's autonomy". However, this wasn't a universal opinion.

4.5.2 Clinician-related factors

With the data collected by an EMD having wide-ranging uses and implications for a clinician and their care of patients, the participants identified many different benefits and costs/barriers related to health-care providers. The full list of factors related to clinicians is outlined in Fig 4-3. The discussion afterwards focuses on the factors where detailed comments were received.

Clinician-related benefits	Clinician-related costs
• An accurate record of adherence for clinicians/nurses/GPs to use in auditing and review • For identifying patterns of inhaler use e.g. days, times, school, holidays etc. • Aiding discussions between the clinician and the patient e.g. visual evidence • Relating an accurate record of a patient's inhaler use to their health outcomes and asthma control • More informed decision making for clinicians • GPS would be beneficial in identifying triggers for a patient's asthma e.g. pollen, pollution • Helpful for identifying dose dumping • Useful data for emergency situations	• Concerns over the time and workload this would add to the consultation process • Whose responsibility is downloading, processing and interpreting the data and discussing with patients? • Data overload • Added cost/time/workload of training clinicians and staff on how to use device, how to teach patients and how to interpret results • Over-reliance on data – also need to determine reasons for non-adherence

Figure 4-3 Clinician related benefits and costs

Many of the participants spoke about the devices providing an accurate record of adherence that could be used by a clinician in their auditing of a patient. For example, one respiratory consultant said that EMDs would create "a tool to monitor actual adherence achieved against the goals previously agreed." Some respondents specifically mentioned how this would be a more accurate estimate of inhaler use than asking the patient directly, with one CCG member saying it would "improve assessment of compliance - rather than rely on a patient telling their clinician."

Participants then spoke of how this accurate record of adherence would be useful for identifying patterns of use, with one nurse and CCG member stating "Being able to demonstrate patterns of use… is particularly important for patients who forget to use their inhalers or are unsure of the frequency of use for 'as required' inhalers." Other participants then additionally spoke about how a true record of inhaler use could be related to health outcomes and asthma control, "the data could be used to establish if their asthma control is poor due to reduced adherence to medication or their medication requires escalation to improve control."

Furthermore, participants commented on how this detailed picture of a patient's medication management would ultimately lead to more informed decision

making, with one respiratory consultant stating it would provide "objective data for clinicians to make decisions, not report" and another consultant adding "Changes in medication…could be based on accurate reports of current medication regimen administered". There was also a shared feeling that the data could be used to aid discussions between a clinician and patient. One nurse provided the insightful comment that "We do practice open conversations, but seeing things written down or pictorially presented may be more effective in devising an action plan together."

Much the same as with factors related to the patient, the participants had concerns about the potential barriers EMDs may have to overcome to provide true benefit for clinicians.

Firstly, there were concerns expressed by participants about the time and added workload EMDs could create. One nurse said "The time to download and examine the data collected from the EMDs in clinic may be limited," whilst a GP and CCG member stated "Doctors don't have enough time to follow up adherence."

Questions were also asked about who should actually take responsibility for downloading, processing and interpreting the data and then discussing it with the patient. One participant stated "some clinicians may not appreciate that the time taken to discuss results together is actually saving time in the future. Who is the best professional to discuss data with patient/family? GP, nurse, specialist doctor or other?" Related to this was a comment about the cost of training; "clinicians will require training on the use and interpreting of the results".

4.5.3 Research-related factors

With a proportion of the recruited sample having strong ties to academic research, points were raised in relation to utilising EMDs for asthma research going forward, as well as further research required now. The full list of factors related to research is outlined in Fig 4-4. The discussion afterwards focuses on the factors where detailed comments were received.

Research-related benefits	Research-related costs
• Data for research • Can be used to identify inhaler types that are less likely to be used – to ultimately find the most widely accepted and use inhaler types • Long-term could be used to develop bio-feedback • Useful to monitor adherence of different groups of people on different treatments	• Evidence of the effectiveness of EMDs is required • Are there better alternatives e.g. Tele-health or Medical Possession Ratio (MPR)? • Non-adopters leads to selection biases

Figure 4-4 Research related benefits and costs

One respiratory consultant felt that EMDs could be useful "to monitor concordance of different groups of patients on different treatment regimens" to examine how adherence varies from medication to medication. Along a similar line, a GP commented that EMDs could be used to "identify devices which are less likely to be used and weed them out, and which ones are easier and more likely to be used."

Another GP spoke of the potential for location monitoring, stating it could be useful "to identify triggers…but may not be accurate if trigger is mobile". Elsewhere, a nurse recognised the benefit EMDs could have for research more generally; "to validate study results by showing compliance with a particular treatment."

Although research exists that demonstrates the accuracy of EMDs, some participants felt that more evidence is needed. One respiratory consultant asked "Has the data they collect been validated? Personal use with an older generation of these devices (on a research study) has been poor. Ranged from recording puffs for patients who had never used them to recording nothing at all when we knew they were definitely used." Another participant asked "does the EMD have a sustainable effect as a reminder?"

4.5.4 Practical factors

Many of the points raised by the participants were applicable to the healthcare industry in general and focused on the practicalities of the devices. The full list of factors related to practicalities is outlined in Fig 4-5. The discussion afterwards focuses on the factors where detailed comments were received.

Practical-related benefits	Practical-related costs
• Reducing costs through less wasted medication and less time in hospital • Could be used with other monitoring techniques e.g. peak flow	• Cost of devices • Accuracy and reliability of the device, as well as potential technical issues • Concerns if this is only compatible with MDIs • Records actuation but not inhalation, technique, nor identifies if canister is empty or inhaler is shared • How is data stored and who has access? • Cleaning and maintenance of the device • Concerns about the role of pharma companies • Could interfere with inhalation technique or not be compatible with spacer • Bad for the environment – plastic and batteries

Figure 4-5 Practical-related benefits and costs

Some participants recognised that better adherence and asthma control could lead to a reduction in hospital admissions, wasted medication and healthcare costs. One nurse and CCG member stated "Ensuring better adherence to inhaler treatment will have a positive effect on wider health economics e.g. - more patients being well managed."

Whilst the potential positive financial effects of EMDs was recognised by some participants, many had concerns about the initial cost of the devices. One nurse asked "How much do they cost? Is this cost incurred by the department, GP practise or patient?" whilst a GP stated "The cost of each EMD may be expensive and may be limited to the more severe asthmatics having them." The points were typically questioning of the cost rather than dismissive of it, highlighting a need for better clarity on initial costings versus potential savings.

There were also some concerns regarding the reliability of the devices, with a nurse asking, "How robust are they? They need to be up to being thrown around and chucked in bags or drawers & left in wet steamy bathrooms!" Participants also raised issue with the fact that the devices typically only record actuation and do not record inhalation, technique nor detect if the inhaler is shared. One

participant stated "I would want assurance that the device was not open to abuse e.g. removable in order to conceal overuse or inhaler sharing, or pressing device and not inhaling."

4.6 Discussion

Through identifying, accessing and engaging with a selection of stakeholders and key-decision makers in asthma care, a comprehensive list of the key benefits and costs/barriers associated with the introduction of EMDs has been established. The following section discusses how this supports the systems approach and also discusses challenges, limitations, potential future research, as well as recommendations for the future development of EMDs. Finally, it uses a traditional human factors onion model to bring the findings from the two research studies conducted so far in this thesis together.

4.6.1 Support for a systems approach

Whilst the previous chapter investigated the attitudes of patients towards EMDs, the perceptions of other key stakeholders in asthma care including consultants, nurses, GPs and members of CCGs were considered here.

The study demonstrates that these stakeholders have needs and requirements that are important to take into account in the future development of these devices. This provides support for the adoption of a systems approach in this thesis, as these requirements would have been missed if EMDs had been evaluated for patients in isolation, without considering the wider context (Carayon et al., 2006; Sharples et al., 2012).

The study showed how EMDs could potentially both support and disrupt the work of a clinician, meaning this research strengthens the need for considering the wider work system when evaluating new health related devices, software and procedures – as highlighted by the SEIPS model discussed in Chapter 2 (Carayon et al., 2014, 2006).

4.6.2 Recruitment challenges and lessons learned

Recruitment challenges were faced in this study for two main reasons. Firstly, the targeted sample consisted of clinicians who have little spare time. Secondly, using surveys to collect data meant that the study was in competition with other similar research studies that are regularly e-mailed and sent to clinicians to ask for their opinions and participation.

For these reasons, it was decided that multiple different recruitment strategies would need to be adopted in order to recruit sufficient stakeholders. Initially, based on an informed suggestion from the researcher's clinical supervisor, it was decided that e-mailing surveys would not be an effective approach as the survey would get lost amongst the other surveys circulated to clinicians and would mostly likely be ignored. It was therefore determined that surveys would be paper-based and would also include an incentive of a £3 donation to Asthma Research UK.

Based on previous research where it was found that post-it notes with personalised messages increased response numbers (Garner, 2004), the initial recruitment strategy used printed out surveys that were either posted or handed to potential participants along with personalised post-it notes. After this, surveys were distributed in multiple different ways, including handing them out to delegates at the East Midlands Asthma Day, e-mailing them to clinicians in Leicestershire and having a featured post on the Respiratory Futures website (respiratoryfutures.org.uk). A full list of recruitment avenues was shown in section 4.3.3.

There was no single strategy that worked considerably better than the others, and all contributed to the study sample size. It is difficult to accurately estimate which technique was most effective in terms of potential respondents compared actual number of respondents as for many of the strategies, particularly the online ones, the number of individuals the survey reached is unknown.

However, anecdotally it appeared that much of the recruitment relied on knowing clinicians and asthma stakeholders who could distribute the survey themselves and help persuade colleagues to complete it. This was the case in Nottingham and Leicestershire and also led to the survey being picked up by the Respiratory Futures website as well as shared on Twitter. Although the original strategy focused on providing printed out, personalised surveys to help try and attract attention and encourage participation - it ultimately appeared to be more important to network and communicate with individuals who could encourage others to respond.

4.6.3 Limitations

The sample used here was sufficient to gather a comprehensive list of the main pros and cons associated with EMDs, but was limited in the number of participants who gave ratings for each point's importance. This was due to participant drop-out with the sample size reduced considerably in both round two and round three. It is possible that this may have been due to the complexity and unfamiliarity of the method to many of the respondents - as this is a recognised pitfall of the Delphi technique which can increase workload for respondents and cause them to drop-out (Linstone & Turoff, 2002; Meyrick, 2003). Although instructions were clearly and simply explained in the study documentation, it may be the case that many of the participants were happy to provide their opinions in round one, but were less sure of the purpose in the latter rounds and did not have the time to read the instructions to find out what was required of them.

For the later rounds of the Delphi it is important to recognise the bias that may have been introduced by responses potentially coming from those with an interest in EMDs, rather than those with more negative opinions who may not have continued responding. This is particularly important to acknowledge when considering the order of the benefits and costs/barriers in the results for round two (see Tables 4-7 to 4-10). These ratings came from a smaller sample than in round one and could therefore be biased by whether the perceptions of these secondary responders are swayed more positively towards EMDs.

4.6.4 Recommendations for the future of EMDs

4.6.4.1 *Future Research*

Future research should look to distribute the lists of benefits and costs/barriers to a larger sample, such as a respiratory organisation, to gather a larger dataset for the issues stakeholders rate as most important and most crucial to address. The current study was concentrated largely around CCGs in the East Midlands, but distributing the surveys to a wider group where different pressures and priorities may exist should help provide validation to the findings.

Widely distributing the survey would also help counter the key limitation of participant drop-out and allow for further, more comprehensive exploration of which issues stakeholders rate as most important. It could additionally offer the

opportunity for other points to be raised, if there are any that were not thought of by the sample used in this instance.

Future research should also look to address data governance, as this is an important topic where there is still uncertainty (Al Ameen, Liu, & Kwak, 2012; Martínez-Pérez, de la Torre-Díez, & López-Coronado, 2015). Whilst participants here did question whose responsibility it would be to download, interpret and discuss the data with patients, this should be examined further. Working with stakeholders to establish how data could realistically be handled and managed within the NHS will help to reduced fears of 'data overload' and ensure that the data can be used appropriately and effectively to ultimately benefit patient care.

4.6.4.2 *Design and Development*

The stakeholders raised similar concerns to the adolescent participants in Chapter 3 regarding the bulkiness of current EMDs and felt that this could put patients off. This further supports the need for future developmental efforts to focus on reducing the size of the devices.

A key issue raised in this study was the fact that EMDs typically only record the actuation of an inhaler, rather than inhalation and technique. Stakeholders felt that this would be a key barrier to widespread use of these devices as patients may not actually be inhaling their medication, or could have poor technique. It is important that these capabilities are developed for EMDs, to help reassure clinicians and allow them to know just how effectively a patient is using their inhaler. This has previously been achieved in alternative devices such as the SmartMist (Julius et al., 2002) as well as the INCA (Inhaler Compliance Assessment) device (Sulaiman et al., 2016)

4.6.4.3 *Implementation*

Stakeholders here expressed concerns about the time these devices could add to the consultation process, as well as the training that would be required to use them. EMD developers should work alongside healthcare providers to ensure devices and accompanying software are simple and intuitive to reduce their impact on consultation time.

Further concerns were also raised regarding data governance and who should have responsibility for handling, discussing and acting upon the data recorded by EMDs. Developers should collaborate with healthcare providers to create a

formal protocol establishing where data is stored, who has access and under what circumstances (if any) would a clinician have a responsibility to intervene – such as if a patient is taking a dangerous amount of medication.

4.6.4.4 *Commissioning and Purchasing*

It is important that EMD developers provide greater clarity on how the devices could be funded as well as the potential savings they could create. Some of the stakeholders here recognised that EMDs could save money through reducing levels of wasted medication as well as helping keep patients out of hospital, but many more had concerns for the initial cost of the devices. Stakeholders rated 'Evidence of effectiveness of EMDs is required' as the most important issue – similarly to better clarity on costs, this highlights that there needs to be better dissemination of research studies that have demonstrated their clinical effectiveness, as well as further research to continue to build evidence in their favour.

4.6.5 Bringing the findings of the two studies together

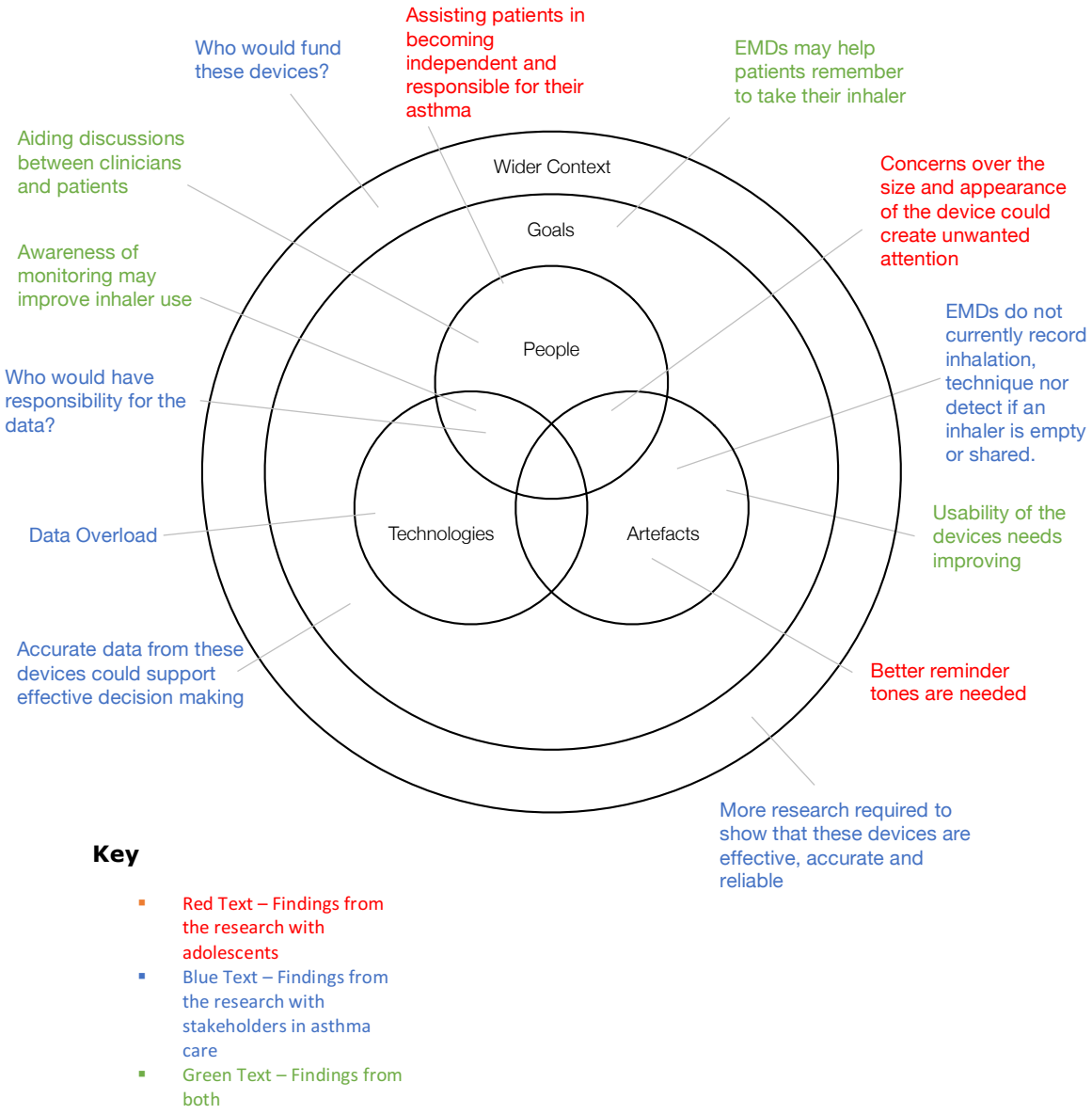

Figure 4-6 - A summary of the findings from the two studies using a simplified version of the onion model depicted in Wilson and Sharples (2015).

Figure 4-6 provides a summary of the key findings taken from the research with adolescents, as well as the research with stakeholders in asthma care. The findings are plotted onto a traditional human factors onion model which depicts the interactions and relationship between technology, artefacts, people, their goals and the wider context. Some of the findings came from both studies, such as EMDs aiding discussions between the patient and their clinician. This type of overlap means that the studies support each-other and helps show how EMDs could be mutually beneficial for both patients and healthcare providers.

The fact that separate points were raised by the adolescent patients and the stakeholders (shown using red and blue text) demonstrates the merit in assessing the perspectives of both of these user groups, as important points may have been missed if only one study was conducted. Ultimately, the findings contribute to a new understanding of asthma management from a human factors perspective and highlight the needs and goals of both the patient, as well as the clinician in relation to EMDs.

4.7 Conclusions

Through collecting the views of stakeholders with a direct interest in the future of asthma care, a comprehensive list of the pros and cons associated with introducing EMDs into the NHS has been obtained. The stakeholders raised points relating to the care and wellbeing of patients, the work of a clinician, research, and more practical factors such as device reliability and cost. Factors that particularly need addressing include assurances over the cost of the devices, data governance, further evidence for the effectiveness of EMDs, and an ability to record inhalation, not just actuation. The findings of the study provide a guide for where EMDs could add most benefit and additionally identify the key issues and challenges that need to be overcome for their introduction to be successful.

4.7.1 Implications for thesis

- Whilst Chapter 3 examined the perceptions of a sample of adolescents with asthma towards EMDs, this chapter gathered the views of stakeholders and healthcare providers.
- Chapters 3 and 4 together therefore provide the views of the two key user groups for EMDs - both of whom have needs and requirements that are important to consider for these devices to have a successful impact on asthma care and health outcomes.
- The two studies therefore support the need for a systems approach when evaluating medical devices - to understand the requirements of multiple user groups, as well as the impact the technology could have on the healthcare process as a whole.

Chapter 5 Exploring the future potential of EMDs

5.1 Introduction

This chapter describes the third and final research study of this thesis. Since the first research study, EMDs have developed new capabilities and can now integrate additional data sources such as location and exercise to supplement patterns of inhaler use. Bringing this data together helps build up an in-depth picture of a patient's asthma and helps identify the triggers most associated with their asthmatic symptoms.

So far, this thesis has investigated the perceptions of patients and healthcare providers towards EMDs. The fact that new capabilities for these devices have developed over the course of this short period of research demonstrates the rapid pace at which technology in this area is developing. Including these new sources of data raises new questions about attitudes to having this information monitored. In order to investigate perceptions towards the future capabilities of these devices, a study was conducted with a sample of healthy adolescents from a local sixth form. This included two workshops and a trial of monitoring personal location and activity information.

This chapter firstly covers the literature related to the advancing functionality of EMDs, followed by looking at previous research on attitudes to location and activity monitoring. Then the study design is described, including the tasks carried out in the two workshops as well as the procedure for the trial of monitoring technology. Afterwards the results are presented on what this sample of adolescents' attitudes were to location and activity monitoring.

5.2 Literature on location and activity data

5.2.1 Advancements in the capabilities of EMDs

Since the initial research conducted for this thesis, the functionality of EMDs has been subjected to new changes and developments that have implications for the attitudes of users (both patients and stakeholders). In addition to recording the date and time of inhaler use, new devices are now capable of recording the location of the inhaler actuation using global positioning system (GPS) technology.

The Propeller sensor (see Fig 5-1) is an EMD capable of recording the date, time and location of inhaler actuation and can sync this data with a dedicated smartphone application via Bluetooth (Chan, Harrison, Black, Mitchell, & Foster, 2015; Howard et al., 2014; Perez, 2015). Adding GPS data offers the potential for a patient and their healthcare team to gain insight into what triggers may be causing their symptoms, such as if they have need to use their rescue inhaler in a highly polluted area, or an area with a high pollen count (Hunter, 2013).

Figure 5-1 - The Propeller sensor attached on top of the canister of an MDI

There has been limited published clinical research with the Propeller sensor. However, in one study where patients with asthma used a propeller device and had access to the dedicated smartphone and web applications, they found that rescue inhaler use was reduced at study exit by 75% and the number of participants who reported an asthma free-day had risen by 39% (Van Sickle et al., 2015). Another similar clinical trial gained initial patient feedback and received comments to suggest that participants found the Propeller device useful

for identifying asthma triggers and helping them to take their medication on time (Smith et al., 2016).

5.2.2 Asthma research on integration of additional data sources

Over recent years, the reduction in the cost of micro-sensors and the increasing capabilities of smartphones has led to research that has looked to develop and test systems to collect and aggregate contextual data to support the management of asthma. Asthma can be triggered by environmental factors including dust, pollen, cold temperatures, damp, and pollution (Jackson, 2009), making recording data on these types of triggers important for understanding the condition and how best to manage it.

'AsthmaGuru' is a system developed to improve adherence to asthma medication by providing personalised guidance based on individual health data collected via sensors and a smartphone application (Biswas, Chang, Dharmasiri, Patel, & Sabharwal, 2013). The system collects three different sources of data; inhaler actuations, lung function from a portable spirometer, and local air quality. Whilst the study did not test whether the system impacted on patient adherence, it did test the accuracy of the three data sources and found it to be sufficiently reliable to begin trialling the system with patients (Biswas et al., 2013). The 'Eco-mini' is a similar new concept – a device which can be used without a smartphone and can capture environmental data including air quality, temperature and humidity and can also measure the user's activity levels (using a 3-axis accelerometer) and their GPS location (Fletcher, Oreskovic, & Robinson, 2014).

Another system called 'kHealth' focused on integrating data from sensors measuring pollen levels, air quality, air temperature and humidity, with a sensor measuring exhaled nitric oxide, and an EMD measuring inhaler use (Anantharam et al., 2015). In a preliminary trial of the system, the researchers found that pollen count and exhaled nitric oxide levels impacted on a patient's coughing, exercise levels and the effectiveness of their medication taking (Anantharam et al., 2015). Elsewhere, a recent trial collected the asthma status of patients using the Asthma Health Application (AHA) and correlated the results with air quality data (Gowda et al., 2016). Looking specifically at areas where wildfires occurred, they found a close correlation between air quality changes induced by wildfires and reports from asthma patients of air quality being a trigger for their asthma. The investigators recommend that the system could be used in the future to act

as a warning sign for patients with asthma when adverse environmental conditions could affect their health (Gowda et al., 2016).

Although not yet published, 'The Asthma Mobile Health Study' is a major new trial using Apple's new 'ResearchKit' that allows medical researchers to use iPhones as tools for collecting data about patients (Icahn School of Medicine, 2016). The researchers are using a dedicated asthma application to encourage asthma patients to record information about their inhaler use, triggers, symptoms and more. This information can then be integrated with data on local air quality and physical activity to build up a comprehensive picture of a patient's asthma and their own individual triggers, symptoms and medication taking behaviours (Icahn School of Medicine, 2016).

5.2.3 Location data – research on attitudes

With location being a potentially intrusive and personal source of data, a series of studies have investigated peoples' attitudes towards their location data, including how they feel about it being monitored, who it should or should not be shared with, and the potential uses for it.

Some of the earliest research on this topic used experimental economics to assess how much people value their location data (Danezis, Lewis, & Anderson, 2005). The researchers advertised for a study where participants would have their location monitored for one month. However, what they were actually interested in was how much compensation participants felt they would require for taking part – a question asked in the recruitment process. They found that the median valuation was £10 but this increased for participants who regularly travelled further (Danezis et al., 2005). A later study used a similar method and offered participants money over a smartphone application for randomly publishing their location (Barak, Cohen, Gazit, & Toch, 2013). They found that participants expected more money for publishing their location when they were at home than when they were at work, indicating that they saw information related to their home as more valuable and more personal (Barak et al., 2013).

The privacy preferences that people have for location sharing has often been studied using hypothetical or made up data. A questionnaire given to adults aged between 19 and 35 investigated the differences in peoples' attitudes for 'location aware' services that track a user's location and 'position aware' services that are based on the device's own knowledge of its surroundings - an example

being a mobile phone updating its clock based on the time-zone it is within (Barkhuus & Dey, 2003). They found that participants rated the usefulness of both types of service as the same, but rated position-aware services as less intrusive than location-aware services. The researchers suggest that this supports the idea that people have higher privacy concerns when their own location is being tracked, rather than their mobile phone simply reacting to its current location (Barkhuus & Dey, 2003).

A three-phase study went a step further than a simple questionnaire and gave 16 participants aged 24-64 a mobile device that asked them where they were and what they were doing at random times in the day for two weeks (Consolvo et al., 2005). They found participants were generally willing to hypothetically disclose their location to their spouse, partner or a family member, but were less willing to disclose information to a colleague or manager at work. When the participants were interview after the trial, nine mentioned privacy as a concern, e.g. *"It would be "a little creepy" for people to always know where I am"* (Consolvo et al., 2005). A similar study with 30 undergraduate students gave each participant a pager and a questionnaire booklet, and paged them at random times over a week to ask who at that exact moment they would be willing to disclose their location to (Anthony, Kotz, & Henderson, 2007). They found that some participants were always willing to share, some were never willing, and some were willing to share dependent on where they were at the time – often they were more willing to share when they were at home or at the library (Anthony et al., 2007).

Other more recent surveys on location sharing have found that participants rate themselves as 'extremely concerned' about having full control over who has access to their location (Tsai, Kelley, Cranor, & Sadeh, 2010). When asked for the benefits of location sharing these participants listed giving directions to friends and family and tracking loved ones as the main positives. For risks, they felt location data could be misused for marketing purpose or even for stalking (Tsai et al., 2010). In contrast to the studies that have examined hypothetical location sharing, one study investigated the reasons why people actually share their location in their everyday lives (Patil, Norcie, Kapadia, & Lee, 2012). They found that location sharing was typically carried out to connect with a person's friends, as well as to receive rewards for 'checking in' to certain venues such as restaurants or bars. Over 25% of their sample of 401 respondents stated they had regretted sharing their location on at least one occasion (Patil et al., 2012).

Only a few studies to date have actually tracked participants' location during a study. In a two-month trial, 32 participants aged 21-59 had their locations tracked using GPS (Brush, Krumm, & Scott, 2010). The researchers were interested in understanding user preferences towards different techniques for location 'obfuscation' where personal information is distorted or removed from location data. At the end of the trial, 21 of their 32 participants agreed to have an anonymous version of their GPS data published (Brush et al., 2010). Another study tracked adult participants living in diverse, urban areas using GPS to investigate acceptability, barriers and ease of use (Zenk et al., 2013). They found that most participants were comfortable with the location monitoring, but levels of comfort differed across age and ethnic groups. Younger participants tended to be more comfortable with the monitoring than older participants, and some African-American participants were less comfortable than White or Hispanic participants. The researchers suggest this may be due to their past experiences with profiling and discriminatory monitoring (Zenk et al., 2013).

The majority of studies on location sharing to date have used an adult population. Only one study could be found that had investigated the attitudes of adolescents – a trial with 15 female teenagers who were asked to carry GPS enabled phones for one week (Wiehe et al., 2008). They found that the participants were not concerned by the monitoring and didn't feel like it influenced their behaviour, with three of the participants additionally mentioning that they liked the fact their location could be traced if they were in danger. However, some friends of the participants felt threatened and wouldn't let them make calls from the phones in case it was being monitored and potentially reported to the police (Wiehe et al., 2008).

With much of the current research on location sharing focused on hypothetical scenarios or made-up data, there is scope for further research where participants have their location tracked via GPS. In addition to this, many of the studies so far have used adult populations. However, with adolescence associated with a drive towards being an independent, autonomous adult (Barrett, 1996) and a new generation of teenagers being classed as 'digital natives' – spending their lives growing up with technology (Palfrey & Gasser, 2013) - their attitudes to the concept of location monitoring may be different to those of previous generations.

5.2.4 Activity monitoring

As well as capturing data on location, there is potential for EMDs to also be integrated with data on a patient's exercise and activity levels. The 'Eco-mini' device described in 5.2.2 is an example of this, as it included an accelerometer to estimate how much time the wearer spent being active or resting (Fletcher et al., 2014). The Asthma Mobile Health Study has also been set up to collect data on physical activity levels from asthma patients - to help understand how exercise affects symptoms and triggers for individual patients (Icahn School of Medicine, 2016).

People with asthma can be prone to avoiding exercise due to experiencing shortness of breath and other asthma symptoms as well as fearing that exercise and sport may trigger or worsen their asthma symptoms (Chandratilleke, Carson, Picot, Malcolm, & Smith, 2012). However, there is evidence that lower-intensity or 'submaximal' exercise can be beneficial for patients – improving their aerobic fitness, exercise capacity and quality of life (Basaran et al., 2006; Chandratilleke et al., 2012; Hallstrand, Bates, & Schoene, 2000). This makes exercise a relevant and potentially insightful source of data to monitor, as it may be a trigger for symptoms, or alternatively could be recommended as an interventional measure to help improve the condition.

Unlike location monitoring, a selection of studies have used pedometers to monitor activity in samples of adolescents and children. There have been mixed results for whether they improve activity levels or not, with most reporting that they can have a positive short-term affect (Butcher, Fairclough, Stratton, & Richardson, 2007; Schofield, Mummery, & Schofield, 2005; Zizzi et al., 2006). It has been recommended that feedback of information on step count and ways to improve it can help increase activity (Butcher et al., 2007) and when students were questioned in one trial, 70% said their motivation towards health and fitness was positively impacted by the pedometer (Zizzi et al., 2006).

A recent survey conducted by the website www.healthline.com found that out of 3,679 responders, 25 percent said they had concerns about activity monitoring data (Mills, 2015). Another study explored how privacy concerns change over time during a workplace environment where employees have been given activity monitors and encouraged to exercise and compete with one another (Gorm & Shklovski, 2016). Initially, they found that the employees had little concern for disclosing their step counts to others. However, as time progressed it was found

that step counts were used as a mechanism for prying into the private social lives of other people through asking what they'd been doing on particularly step-heavy days (Gorm & Shklovski, 2016).

5.2.5 Summary

New EMDs are integrating additional data sources to build up an in-depth personalised picture of a patient's asthma that includes their symptoms, triggers, medication use and exercise. Previous research has indicated that people have concerns about the intrusive nature of location data and want control over who can access it. With location and activity data both beginning to be integrated into asthma management, it is important to understand attitudes towards them.

Little research could be found where the attitudes of adolescents towards location and activity monitoring have been investigated. With asthma most prevalent in this age group, there is scope to examine how adolescents feel about having their location and exercise monitored.

The goals of the study are as follows:

- Monitor the location and activity of a sample of adolescents using currently available technologies
- Present data back to the sample in an engaging format and use group and individual tasks to elicit feedback from the participants on their attitudes towards this type of data collection, as well as potential uses for this information
- Compare monitoring using technology and monitoring using a self-report diary - in terms of the data collected and attitudes to each method

5.3 Study Background

When initially designing a study where location and activity data would be monitored, it was decided that due to the difficulties associated with acquiring ethical approval to track this information in a medical context, adolescents with asthma would not be approached as the study sample. Instead, it was decided that healthy adolescents who could be recruited from a local school would be a suitable alternative, as they would be at the same stage of development and would have similar experiences and attitudes to equivalent adolescents with asthma of the same age.

With links with the university already established through prior research, Long Eaton School was approached for the study. According to the most recent full Ofsted inspection, the school is larger than average, with students achieving above the national average by the end of Year 11 (Ofsted, 2012). In the Sixth Form, teaching is good if not outstanding, meaning that the grades achieved are rapidly improving (Ofsted, 2012).

The researcher liaised with the Head of Sixth Form at the school and held discussions to help ensure that the research could be beneficial for both parties. The Head felt that the research would be both exciting and relevant for his students and would be an excellent opportunity for them to experience university research first-hand. It was decided that the research could be run in an extra-curricular lesson – a period each week where students are given the opportunity to learn or take part in activities outside of their usual curriculum.

He recommended that the most suitable students to carry out the research with would be his group of high-achievers – a group of twenty students whom he felt had the greatest potential to go onto university level education. Whilst this opens the research up to selection biases, it was agreed that this would be the most suitable approach as these students would be reliable and willing to share their opinions and would also benefit most from taking part by furthering their education and getting a taste for university research.

5.4 Workshop Rationale

For investigating the attitudes of a sample of healthy adolescents towards location and activity monitoring, it was decided that a workshop would be the most effective technique in encouraging the participants to provide their thoughts and opinions in an open and friendly environment.

Workshops allow for a multi-method approach, meaning the session can contain both group and individual tasks. For research with groups of children, this is a recognised approach that allows for the collection of data containing both group opinions as well as individual standpoints (Hill, 2006).

The exact details of the two workshops used in this study are described in the methods section (section 5.5). These workshops included participatory research techniques that are recognised as effective in children, such as idea generation,

ranking exercises and drawing tasks (Fargas-Malet, McSherry, Larkin, & Robinson, 2010).

5.5 Method

5.5.1 Design

Two workshops and a trial of location and activity monitoring technology were carried out with a sample of sixth form students. The first workshop was used as an introductory exercise to involve participants and inform them of the research area. Participants were then assigned either a paper diary, or a phone and activity monitor to record their location and exercise over five days. After five days, the participants swapped their methods of monitoring and continued the trial for another five days. In the second workshop, participants had their data presented back to them and were asked for their opinions on this type of monitoring technology. A breakdown of the stages of the study can be seen in Fig 5-2.

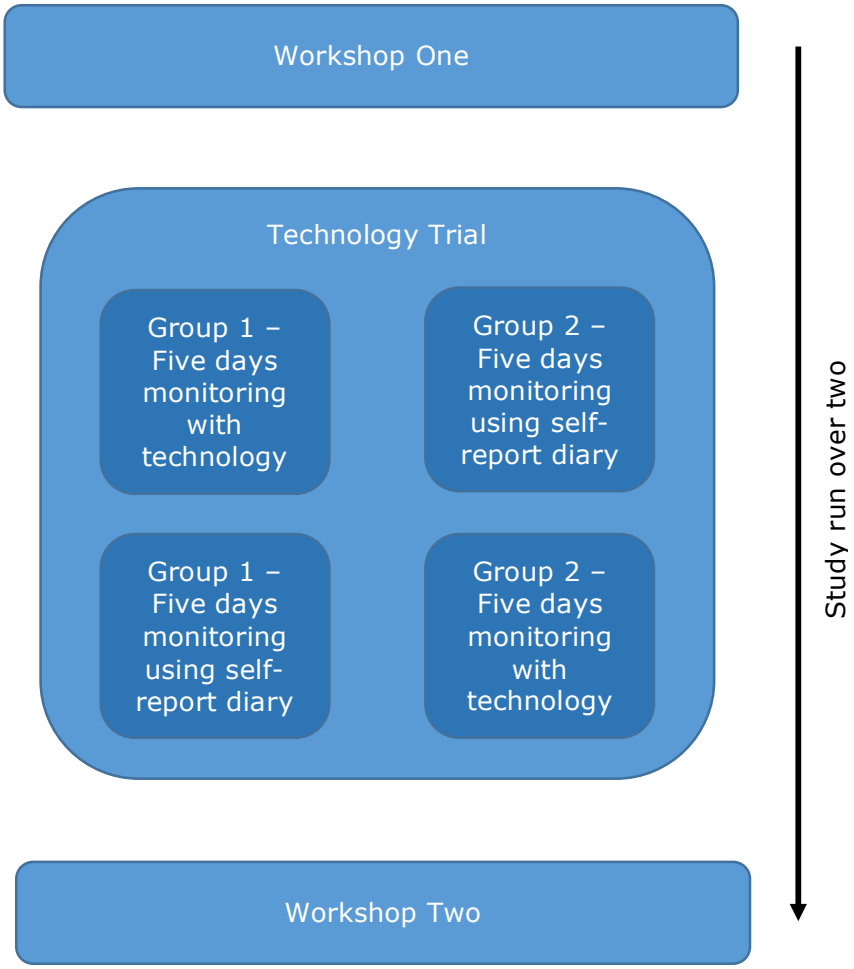

Figure 5-2 The stages of the study, with two workshops and a technology trial in between

5.5.2 Sample

Nineteen sixth form students aged 16-17 (4 male, 15 female) were recruited from Long Eaton School Sixth Form, Nottingham, UK.. The students were recruited after discussions were held with the head of sixth form, who recommended the group as the most suitable to carry out the study as they would be reliable, unlikely to drop-out and would be likely to provide insightful feedback. More details are given in 'Study Background', section 5.3.

5.5.3 Ethics

Ethical approval for this research was granted by the School of Engineering ethics committee at the University of Nottingham. The participants were all over 16 meaning they were able to provide their own consent to taking part. However, a letter was still sent to each of their homes to inform their parents/guardians of the research and to make them aware of what their child would be doing over the next few weeks (see Appendix 8).

As sensitive location data was being recorded, the names of participants were never recorded, only their first and second initials. Location and activity data were stored on the researcher's university computer in a password protected folder. All data recorded on paper throughout the workshops was kept in a locked filing cabinet in the researcher's office at the University.

Location and activity data was given back to the participants individually and they were then given the option of keeping this information private and not allowing other participants to look through it, or could discuss and compare their data with others if they were happy to do so.

5.5.4 Workshop One

The first workshop was conducted in a classroom at Long Eaton School Sixth form. Participants were provided with an information sheet (see Appendix 9) a week prior to the workshop along with a letter to be given to their parents to make them aware of the study. When participants arrived, they were firstly asked to read and sign a consent form, before the workshop could begin. A summary of the workshop is provided in Table 5-1 with more specific details provided after.

Table 5-1 Breakdown of activities conducted in Workshop One

Activity	Description	Purpose
Short Introductory Presentation **[10 minutes]**	An introductory presentation was given to the participants by the researcher. This included: • Information on the researcher's background: A PhD student from the University of Nottingham researching digital health technology • A brief outline of the research aims: what do people think of location and activity monitoring technology • A summary of what the benefit is for the participants: they get to experience university research first-hand, get to try out some new technology and can also use it as an opportunity to ask questions about university life and studying. • A summary of what's in it for the researcher – helping contribute towards their PhD.	To engage and involve the participants, explaining what the benefit could be for them and making sure they understand the purpose of the study.
'Blue Skies - Future Me' Workshop – Ice Breaker Exercise **[30 minutes]**	Immediately after the introduction, participants had the first activity explained to them. This was an 'ice-breaker' exercise where participants were encouraged to think about how fast technology develops and think how they might use technology in the future. The details of this exercise are explained in more detail in section 5.4.4.1.	To encourage the participants to think about how quickly technology develops and to think about their own relationship with technology. Participant input into this exercise could be used to demonstrate their engagement and involvement in the study.
Technology Trial Introduction **[20 minutes]**	For the final stage of Workshop One, participants had the upcoming technology trial explained to them. They were told how they would have their location and activity monitored and were given examples of what this data could be used for in the real world, for example: • Identifying triggers in health conditions such as asthma • Improving public transport systems • Car insurance companies tracking how safely people drive • Companies tracking if their employees are exercising enough They were told that they would have their data presented back to them individually and privately in the second workshop, so	To explain the trial to the participants and ensure they understood the relevance of capturing this type of data.

	that discussions could be held about what they thought of the data.	

5.5.4.1 *'Future Me' Activity*

For the 'Future Me' exercise, a presentation was initially given to demonstrate how quickly technology develops. This presentation included:

- A summary of technology in 2007 when the researcher was the same age as the participants now. Technology was shown including the first iPhone and the iPod classic. Crucially, it was explained to participants that very few things were directly connected to the internet at this point.
- A summary of technology in 2015. This included the latest iPhones, iPads, the Apple watch, 'smart' TVs, Netflix, Fitbits, and internet connected home appliances including a fridge, toothbrush and a thermostat. These were used to highlight to participants how we are living in the age of the 'Internet of Things'.
- A demonstration of how iPhones keep a hidden record of 'frequent locations' even if location services are turned off (Adamczyk, 2015)
- A short summary of the Propeller sensor and how it could use location information to identify triggers for asthma (Hunter, 2013).
- The fact that we generate 2.5 quintillion bytes of data every single day (Wall, 2014).
- Finally, participants were asked what they think technology will be like when they are the same age as the researcher in the year 2023.

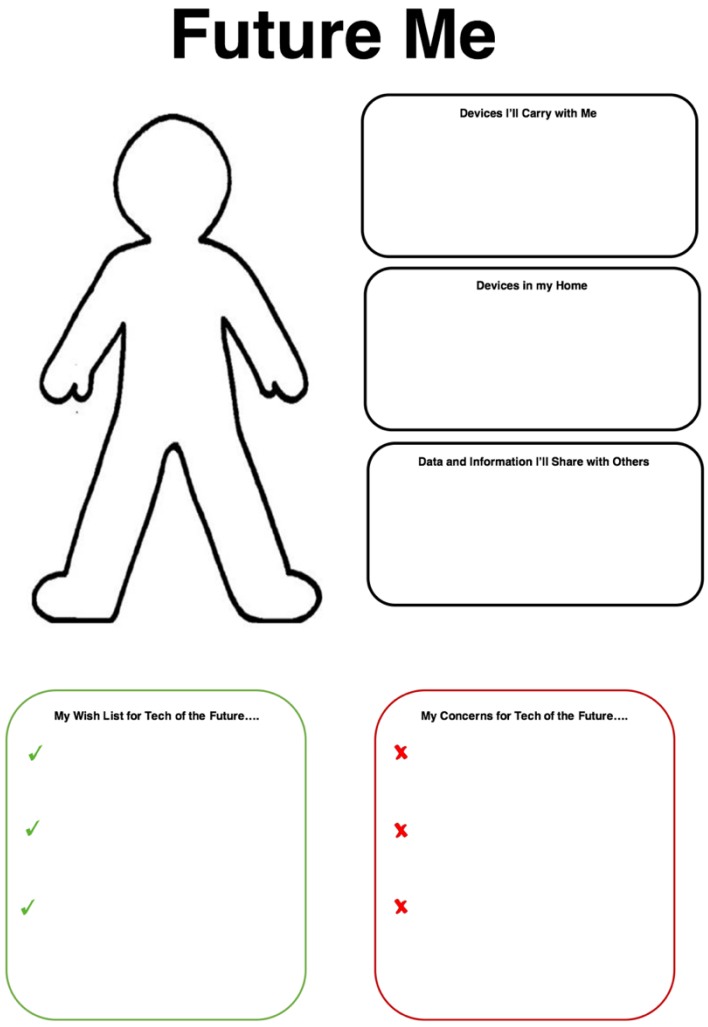

Figure 5-3 'Future Me' template sheet given to the participants

After the presentation, participants were provided with a 'Future Me' template as shown in Fig 5-3. They were provided with coloured pens and were asked to draw and write about how they think they will use technology in the year 2023. The boxes on the template were used to help participants think about what technology they might use, who they might share information with, as well as their main wishes and concerns for the future of technology.

5.5.5 Technology Trial

Immediately after workshop one the technology trial started. Here, participants had their location and activity levels monitored using technology for five days. They then monitored this information manually for a further five days using a self-report diary.

Having the participants record their location and activity information manually for five days was included in the study in order to get the participants thinking about the differences in accuracy between the data they can record themselves and the data captured by the monitoring technology, as well as the control they have over each method. Details of the two methods of data capture are provided below.

5.5.5.1 *Monitoring Technology*

Nexus 4 and Samsung Galaxy S4 Android smartphones were used to run a GPS logging application called 'Ultra GPS Logger' (http://ugl.flashlight.de). This application was chosen as it had a wide range of customisable settings that allow for long-term GPS monitoring without rapidly draining the battery life of the phones (see Fig 5-4).

The application was set up to log GPS whenever the phone was switched on (meaning it would automatically start up again if battery ran out during use) and was set to log a point on the map whenever the user stayed in the same location for more than 5 minutes. Although this creates some loss of data if the individual is moving from place to place quickly, in pilot testing of the application this was found to be the best balance between maintaining battery life and gathering a good data set.

The phones were locked with a security lock screen password. This was set up in order to ensure the participants could not use the phone for anything other than to record their location. They were asked to charge the phone every night and carry it with them throughout the day. If they ran out of battery, they were told to charge the phone and reboot it, so that the application could automatically start logging their location again.

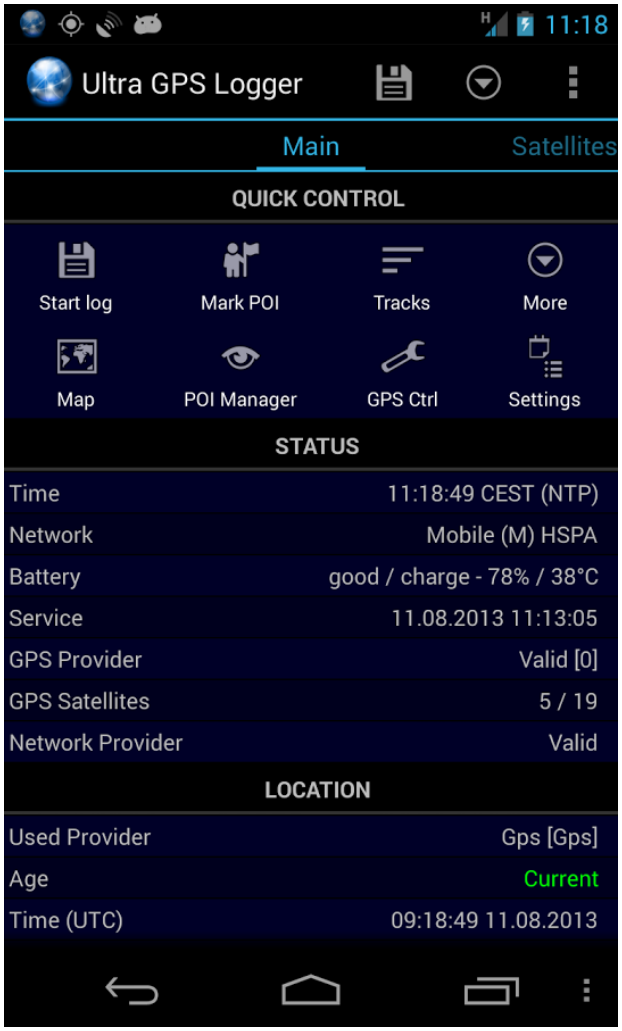

Figure 5-4 A screenshot of the Ultra GPS Logger application

For monitoring activity levels, participants were assigned a Fitbit Zip (see Fig 5-5) (https://www.fitbit.com/uk/zip). The Zip device is worn on the waist like a traditional pedometer and can record data on the number of steps the wearer completes over a day (Fitbit, 2016). Previous research has shown that the Fitbit Zip can be used a valid measure of activity levels (Tully, Mcbride, Heron, & Hunter, 2014). As the battery life of the device is 4-6 months, participants did not need to charge the device over the trial and were simply told to wear the device throughout each day in order to capture their activity.

Figure 5-5 Fitbit Zip activity monitor

Data was uploaded from the phones and Fitbits at the end of the trial. This meant each device contained data for two participants (due to the swap over after five days), but this was easily separated as the researcher knew the days each participant had used the devices for.

5.5.5.2 *Self-Report Diary*

Table 5-2 An example day using the location and activity diary

Locations		
Location	**Arrival Time**	**Departure Time**
Home	-	8:45
School	9:00	15:30
Shop	15:45	15:55
Home	16:00	18:00
Friends House	18:10	21:30
Home	21:45	-
Daily Activity		
Type of Activity (Walk, Run, Type of Sport etc.)	**Start Time**	**End Time**
Walk	8:45	9:00
Football (Lunchtime kickabout)	12:00	12:30
Walk	15:30	15:55

For the five days where participants were manually recording information on locations they visited and activities they carried out, they filled out a table like the one shown in Table 5-2. Unlike the technology which could record specific

information on GPS location and step count, the self-report diary was more simple. Participants were asked to record the time they arrived and departed from key locations throughout the day and the times they started and finished activities such as walking or sport.

5.5.6 Workshop Two

The second workshop was conducted a week after the tech trial had ended, in order to allow the researcher time to upload and process the data collected by the phones and Fitbits. Like the initial workshop, this was held in a classroom at Long Eaton School Sixth Form. A summary of the workshop is provided in Table 5-3 with more specific details provided after.

Table 5-3 Breakdown of activities conducted in Workshop Two

Activity	Description	Purpose
Short Refresher Presentation **[5 minutes]**	A brief refresher presentation was firstly given to the participants to remind them of the potential uses of location and activity monitoring technology.	To refresh the minds of the participants and get them thinking about this type of monitoring.
Data Reports **[5 minutes]**	Participants were individually given a report of the data that had been recorded by the technology. This report included a map of their locations for each of the five days, as well as a daily and overall step count. Further details of the data report can be found in section 5.4.6.1.	To allow the participants to see the data the monitoring technology had captured about them
Worksheet and Discussions **[50 minutes]**	As there were 19 participants, it was determined that it would be difficult to gather input from every individual if there was only an open discussion. Therefore, a worksheet was created which contained open-ended questions and activities for participants to complete in groups of four or five people (see Appendix 10. This way, comments and feedback could be gathered from every participant, whilst still having open-discussions whilst the worksheet was completed. Further details of the content of this worksheet are provided in section 5.4.6.2.	To gather feedback and comments from the participants in order to elicit their attitudes towards location and activity monitoring

5.5.6.1 *Data Reports*

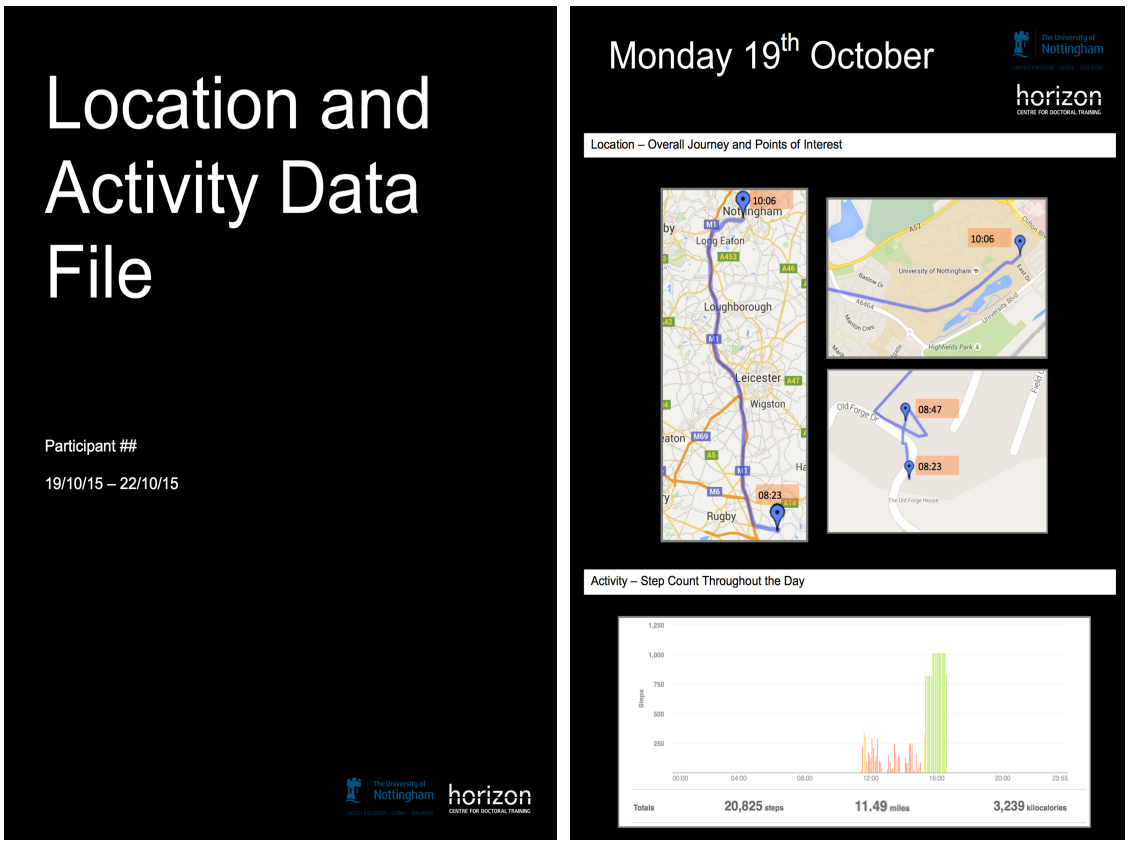

Figure 5-6 The front page and an example day from the Data Reports given to the participants

The data reports given to participants presented locations they had visited as well as a graph of their step counts (see Fig 5-6). The location data presented in the reports was manually sorted by the researcher and in some cases individual sections of a map were shown in order to succinctly represent everywhere the participant had visited that day. This was framed as their 'overall journey and points of interest'. Above each point on the map, a time of when this location was recorded by the GPS logger application was provided.

For activity data, graphs were manually taken from the Fitbit online dashboard (https://www.fitbit.com). These graphs displayed a representation of the number of steps the participant had taken each hour, as well as a total for their steps, distance travelled and calories burned.

Participants were given their data reports individually and were told to look through them privately initially. They were then given time to discuss their

reports with the other participants on their table and share their reports with others if they felt comfortable doing so.

5.5.6.2 *Worksheet*

The worksheet (see Appendix 10) was given to the participants after they had looked through their personal data reports in order to gather comments and feedback from every individual. Participants sat on tables in groups of four and five and were encouraged to discuss their thoughts with others. Whilst the worksheets were being completed, the researcher walked around and spoke with participants to ask additional questions on the fly based on the discussions being held (spoken discussions were recorded with a Dictaphone).

The worksheet was split into four sections:

1. Data Reports – First Thoughts
Participants were told to look through their data report carefully and then asked to answer the following questions:

1) Please describe your initial reaction after looking through your location data. Is it as you expected? Has anything about it surprised you?
2) Now please do the same for your initial reaction to your activity (step count) data…
3) Please describe how aware you felt of being monitored during the trial. Did this affect or change your behaviour at all? Give examples if possible.
4) Have your attitudes towards location monitoring changed after viewing this data? If so, how?
5) Have your attitudes towards activity monitoring changed after viewing this data? If so, how?

2. Participant X

The second section of the worksheet was a 'detective activity' where participants were given an extra data report for 'Participant X' (see Appendix 11). This report contained five days of simulated data in similar locations to Long Eaton School and the surrounding area. Participants were also presented with three different personas of 'made up' students from their sixth form (see Table 5-4) and were

asked to read through the personas and decide whom they thought the data belonged to. This activity was designed as an engaging exercise for the participants to enjoy completing, but was also used to help encourage the participants to think about what their own data might say about them.

Participants were encouraged to discuss this with the other people on their table and were then required to answer the following questions:

1) Which student do you think the data belongs to?
2) Please explain what it was in the data that made you decide that it belonged to the student you chose above:
3) Now look back over your own personal data report… how much does it say about you? Would you have concerns if someone was to look through your own location and activity data?

Table 5-4 The three personas presented to the participants during the activity

Persona Name	Persona Description
Amy	Amy is in upper sixth form and studies Biology, Geography and Psychology. She hopes to go to Loughborough University once she leaves school to study Biomedical Sciences. She likes Loughborough in particular due to the outstanding sports facilities on campus. Amy is a keen runner, competing in county athletics competitions since an early age. She regularly trains during her spare time to keep her fitness levels up.
Daniel	Daniel is an upper sixth form student who is currently unsure about whether University is for him. He intends to take a year out once he has left school and plans to increase his days and hours for his current weekend job in order to save up sufficient money to go travelling for a few months in the latter half of the year. Daniel doesn't particularly enjoy sixth form and is struggling to stay motivated with his studies, coming into school late and often leaving early.
Claire	Claire is an upper sixth form student studying Drama and Theatre, English Literature and Media Studies. Whilst struggling to apply herself to her education at a younger age, Claire loves her subjects in sixth form and achieved highly throughout her AS levels. Claire recently passed her driving test and is enjoying the freedom of being able to drive her own car. She now regularly gives her friends lifts into town - to go shopping, for dinner or to go to the cinema.

3. Tech vs Diary

This section was designed to investigate the different attitudes participants had for monitoring their location and activity manually and using technology. The following scenario was presented…

"Imagine you suffer from severe asthma and your Doctor would like to monitor the places you visit and the places you use your inhaler to investigate what might be causing your attacks (e.g. pollen, pollution), and your exercise/activity levels to see how these could also affect your health…"

They were then required to answer the following questions:

1) Explain the potential benefits of recording this data manually in a diary
2) Explain the potential costs/negatives of recording this data manually in a diary
3) Now explain the potential benefits of having this data recorded automatically using technology
4) Finally, explain the potential costs/negatives of recording this data automatically using technology

4. Location and activity data

For the final section of the worksheet, participants were asked in their groups to come up with positives/negatives of location tracking, and positives/negatives of activity tracking and to write them down on post-it notes to place on their tables. The researcher used this time as another opportunity to walk around the room and speak to participants individually and in their groups to talk to them about their opinions.

Once participants were satisfied with the points they had come up with, the researcher asked each group to pick one positive and one negative of both location and activity monitoring to be written on the board at the front of the room. This allowed participants to see what other groups had thought about and potentially change their own opinions based on the comments made by others.

Once each group had provided their points, participants were asked to individually write down on their worksheet their own five most important

benefits and five most important costs for both location and activity monitoring. They were told this could be done using the points that had been written on the board, points written on post-it notes on their table, or new points they had only just thought of.

5.6 Results

The results of the study fall into three main parts. First, a description of the data that was captured over the trial is provided. Then for the main section of the results, a thematic analysis was carried out on the comments received from the participants in their worksheets as well as the spoken conversations that were recorded by the researcher during the workshop. Finally, the benefits and costs participants gave for both location and activity monitoring are presented. Although not included in the main results, two examples of 'Future Me' responses can be found in Appendix 12.

5.6.1 Data Capture

During the ten-day monitoring trial, each participant spent five days having their location and activity monitored using technology and five days recording this information manually in a self-report diary.

Although the purpose of this was to allow participants to experience both types of monitoring and to present their data recorded by the technology back to them. It is still of interest to compare the data that was captured by the two different methods, as well as how good participants were at either remembering to fill out the diary, or to carry the technology with them.

For the diary, 16 of the participants completed all five days successfully. One participant lost a page so only completed four days, whilst the remaining two participants did not return their diary meaning they may not have completed any of it, or simply forgot to hand it back in.

Table 5-5 shows the number of days where both location and activity data were recorded by the technology for the 19 participants. As can be seen, a full data-set was only captured in ten of the participants. However, it is difficult to know how much this was down to the participants forgetting to take the phone and Fitbit with them each day, and how much it is down to the technology failing or the phone losing charge.

Table 5-5 Breakdown of the number of days where both location and activity data were successfully recorded by the technology

Number of days where both location and activity data were recorded by the technology	Number of participants (N = 19)
5 days	10
4 days	5
3 days	1
2 days	1
1 day	1
0 days	1

Also of interest is the quality of the data participants manually recorded in their diaries. Although 16 of the participants completed this on all five days, the level of detail they included varied. As can be seen in Fig 5-10, one participant simply wrote 'Home' with no arrival or departure time on one of their days, whilst the other participant shown provided precise timings as well as added detail on the types of exercises they carried out. Naturally, the level of detail that could be included is limited by whether the individual has been anywhere or done anything, so under some circumstances 'Home' may be all that could be written.

Sunday 22nd November

Locations		
Location	**Arrival Time**	**Departure Time**
Home	-	-
Daily Activity		
Type of Activity (Walk, Run, Type of Sport etc.)	**Start Time**	**End Time**

Tuesday 24th November

from when I received log. →

Locations		
Location	**Arrival Time**	**Departure Time**
Sixth Form	12.45	~~12.59~~ 13.8
Music	13.00	13.30
Physics	13.35	14.30
Sixth Form	14.35	~~14.59~~ 15.00
Music	15.00	15.20
Home	15.30	17.20
Dancing (Lower Intensity Training)	17.30	19.30
Home	8.00	—
Daily Activity		
Type of Activity (Walk, Run, Type of Sport etc.)	**Start Time**	**End Time**
Walk around School	13.30	13.35
" " "	14.30	14.35
—		
Cycle Home	15.20	15.30
Dancing; technique class (Strengthening)	17.30	18.00
Top Class (anaerobic & at high speed)	18.00	18.45
Freestyle Class (anaerobic, jumping & kicks)	~~18.45~~ 18.45	19.30

Figure 5-7 Examples of self-report days recorded by two different participants

5.6.2 Thematic Analysis

Figure 5-8 The thematic analysis process, with hand written post-it notes for the comments from the participants

Data collected from the participant worksheets as well as transcriptions of the spoken conversations were compiled in preparation for a thematic analysis. Thematic analysis was chosen as the method of analysis as it is a generic and widely used technique that can be used to report on the experiences and realties of participants (Hignett & McDermott, 2015). As a first stage of this process, the researcher manually extracted comments from the worksheets and transcriptions and then hand-wrote them onto individual post-it notes (see Fig 5-11). Whilst this was a time-consuming task, it served as an opportunity for familiarisation (Grey, 2009) as well as a chance to reduce and organise the data so that it was ready for more in-depth analysis (Hignett & McDermott, 2015).

Coding the data was then initially informed by memos that were written down by the researcher as he read through the data. This is a recognised technique, where ideas are written down as they strike the researcher (Glaser, 1978; Hignett & McDermott, 2015). A further round of coding then took place, with post-it notes of comments grouped under initial themes (Braun & Clarke, 2006). Once the coding and groupings had been reviewed and the researcher was satisfied, the themes were then expanded into sub-themes in order to accurately reflect and describe the data and the experiences and attitudes of the participants (Braun & Clarke, 2006). Four main themes were found from the analysis, each with either two or three subthemes. These are described next, with example quotes to demonstrate the attitudes of the participants.

5.6.2.1 *Impacts and effects of being monitored*

The participants often spoke about the impact that being monitored had on their everyday life and the changes they made to their daily routine because of it.

5.6.2.1.1 Finding insight in their own data and utilising this information to improve their health

One of the most noticeable observations from the participant feedback was that they took an active interest in looking through their own data and finding meaning in it. They were interested in reviewing the places they had visited over the five days and were also intrigued to view their daily step counts and calorie counts and think about what this said about their levels of exercise. For example, one participant stated:

"I actually met my daily calorie count which was surprising but I realise I am not moving enough throughout the day as my day step count was only half of the recommended. Also, I realised I don't really go many places." (P19)

This participant has reviewed their data and inspected each aspect of it – the places they have visited, their step count on each day, as well as their calorie count. From this they have determined that whilst they are burning more calories than they thought, they are not walking as far as they think they should and are also not visiting enough places. A similar quote comes from P13 who stated:

"It has surprised me about how many places I actually visit throughout the day. Also I am surprised about how many calories I actually burn from walking throughout the day." (P13)

Interestingly, three of the participants commented on how recording the data manually rather than being monitored by technology, could make them more aware of certain environmental triggers that could affect their health. For example:

"It could make you aware of things you usually don't notice so you could figure out what the triggers are and thus make a conscious change" (P3)

"You may be more aware of the potential dangers of certain areas if you manually recorded your data and corresponded your health condition to each" (P14)

These participants appear to be suggesting that by manually recording the data you would be more likely to look through it and therefore more likely to find useful and actionable information within it to help improve your health outcomes.

5.6.2.1.2 Awareness of monitoring has varying levels of influence on behaviour and levels of discomfort

Thirteen participants spoke about how aware they felt of being monitored during the trial and the influence that this had on their behaviour. The majority of the participants reported that they had felt aware, but this hadn't changed how they acted or influenced where they went. For example:

"I mostly forgot about it but when I went out I was aware of the phone and thinking about where I was being recorded as going. However, it didn't stop me from going anywhere. I think if I was monitored all of the time I wouldn't notice." (P15)

"It did make me feel a bit more aware of being monitored, but it didn't change how I acted or where I went." (P8)

Some of the participants indicated that they had felt more uncomfortable with the monitoring, with some reporting that it felt like they were being 'followed':

"Did not affect behaviour at all, but was remotely aware of being 'followed'" (P9)

"It made me feel a bit anxious as it made me feel like I was being constantly followed" (P6)

One of the participants stated that their awareness of being monitored had influenced their behaviour, through encouraging them to find ways to stay active.

"I was aware of being monitored and it made me very aware of how little I travelled during that week. It encouraged me to find ways despite this to stay semi-active, so I didn't completely forget." (P14)

5.6.2.1.3 Perceived efficacy of activity monitoring improved with experience of the technology

Nine of the participants spoke about how the activity monitoring had encouraged them to do more exercise and become more active. For example:

"I walked around the long way to school to get more steps in" (P7)

"It affected how many steps I did. As it made me feel like I was really inactive and therefore throughout the day it made me feel as if I should go out for more walks/walk more places." (P13)

Some of the comments received suggest that the opinions of participants towards activity tracking were improved through taking part in the trial. Whilst they were previously unsure of the benefit, four of the participants commented

on how they thought activity tracking was a good idea for encouraging them to exercise. For example:

"I think its actually a lot more useful than I would have thought in terms of encouraging me to exercise." (P15)

"My attitudes have changed as I feel that it encourages you to be more active as it keeps you aware" (P13)

5.6.2.2 *Attitudes to being monitored*

In both the worksheets and the recorded conversations with the participants, privacy was a common theme. Participants appeared to fall into three general categories; those who had concerns for the specific, intrusive nature of the data, those who were not concerned, and those who were resigned to having no privacy and felt helpless to do anything about it.

5.6.2.2.1 Acknowledging potential uses for the information, yet having concerns for the personal, intrusive nature of the data

The concerns that participants had for their privacy varied in severity. Five of the participants suggested that they were uneasy about being monitored, but equally appreciated that the data could be useful under certain circumstances. For example:

"It hasn't changed my view; I still think it has its uses for personal health, though it makes me a little uneasy being able to view my address and things like sleeping schedule" (P14)

"I still don't think its ok to track people without their knowledge; but I realise it can be really useful in certain situations" (P19)

Others had a more negative and concerned opinion for location monitoring, suggesting that it was 'scary' or 'creepy' to have personal information recorded in this way, particularly if it were to get into the wrong hands. For example:

"It has scared me how specific it is and where it knows your every move and timings" (P2)

"You don't know what it is recording, it removes a sense of security and privacy" (P4)

One participant took a very blunt view and stated that they would intentionally try and avoid having their location tracked as much as they could:

"I will try to avoid having my location monitored as much as possible" (P8)

5.6.2.2.2 No privacy concerns because the data isn't revealing nor incriminating

In opposition to the participants who had concerns for their privacy, ten of the participants provided comments to suggest that they felt the data that had been captured about them was not necessarily an invasion of their privacy and they would not have concerns about who could have access to it. Some felt that their data didn't give away much personal information about them, didn't show anything bad, and one participants even suggested they were comfortable with it as it is 'past tense':

"I wouldn't have concerns as my week appeared quite boring and I feel it doesn't reveal too much about me personally" (P13)

"I've already been and nobody can follow me, its past tense" (P18)

An interesting contrast comes from P2, who provided one quote mentioned in the previous section stating ""*It has scared me how specific it is and where it knows your every move and timings"* yet also provided a comment stating they would not have concerns for anyone to look through their data as it doesn't show anything incriminating or personal about them:

"It doesn't concern me if someone was to look through this as it doesn't show anything bad" (P2)

From this it could be argued that the data captured during the trial was acceptable and some of the participants would feel comfortable letting others see it as it 'doesn't show anything bad'. However, the privacy concerns other participants had may be more related to the ***potential*** of the technology to record personal information, rather than the actual data that had been recorded about them during the study.

5.6.2.2.3 Resigned to having no privacy, despite concerns

A sub-section of participants expressed views to indicate that although they felt the monitoring was an invasion of their privacy, they felt helpless to do anything about it and believed that worse things are being recorded about them anyway. Six participants gave these opinions, with four comments coming during the recorded conversations with the researcher. Example statements of this type of resignation to having no privacy include:

"There are other things being tracked that are more worrying, like the messages you send to people. Walking around, with your name not attached to it, that's not that bad. But when its personal stuff being tracked that's worse." (A3 - From auditory recording – participant undetectable)

"The technology is hacked to track you without you knowing or being able to switch it off so I can't do anything about it anyway." (P19)

"I would have concerns if my name was attached to it and I wasn't aware that this data was being recorded. However, I think there are worse things that are being tracked about me against my consent, so I don't think this is truly worrying." (P3)

These comments suggest that these participants are aware that other aspects of their lives are potentially being monitored – such as their conversations with friends via instant messaging. Because of this, these participants appear to be resigned to the fact that this monitoring does happen and location/activity monitoring would not be of greatest concern for them.

5.6.2.3 *Data Issues*

After viewing the data that had been recorded about them during the trial, the participants made comments about both the quality and accuracy of location and activity monitoring – both when it is recorded via technology, as well as when it is recorded manually in a self-report diary.

5.6.2.3.1 Data can be too accurate or not accurate enough, depending on individual experiences and expectations

The data reports given to participants varied in accuracy and this was reflected in the comments received. Some participants felt that the technology had very accurately recorded information about them, for example:

"The specific timings and the accuracy of my location surprised me." (P16)

"I was very surprised as there were some places that I had only walked past but it still recorded it." (P6)

However, other participants felt that the monitoring had not been as specific as they would have expected:

"I now know that they sometimes aren't 100% accurate." (P4)

"I thought the location tracker would be more specific and more accurate about where I was travelling." (P11)

There were also conflicting opinions on the accuracy of recording the same data manually in a diary. Two participants believed manually recording the data would actually be more accurate than through technology as you could record the exact location rather than a 'nearby' location:

"Location data is more accurate and you are in control of which location you do and don't record" (P8)

"It can be more accurate as the specific location would be recorded rather than the nearby location" (P17)

However, P8 also conceded that recording the data manually would make it easy to fabricate results – particularly if you wanted to make yourself look more active than you really are:

"It is easy to make up activities and location to make yourself look more active than you really are. Also, you won't get an accurate step count." (P8)

5.6.2.3.2 Adding notes to supplement and provide context to the data

The quality of the data recorded was also discussed. When talking about manually recording the data, three participants spoke about how this allows for

the addition of notes and comments to provide context to the data. For example:

"Able to include notes and points of interest" (P9)

"You could exclude anomalous data. Can include extra notes." (P15)

However, two other participants noted that a negative of manually recording the data is that it can lack detail and quality about specific locations:

"It didn't show/tell your specific location as if you put 'home' the person reading doesn't know where this actually is." (P2)

"It can take a while to continuously update the diary and it doesn't show specific locations which may be wanted for any reason." (P16)

5.6.2.4 *Role of Technology*

When discussing the role of technology in recording location and activity data, many of the participants considered how the level of user involvement required would be different compared to if the data were to be recorded manually. Some also spoke about the technology itself, the issues a user may face, as well as a consideration of potentially better alternatives.

5.6.2.4.1 Technology removes human error and chances of forgetting

Participants spoke about how using technology would reduce the level of involvement required, creating an automatic process of data collection. Some spoke about how this would reduce the need to try and remember everywhere you had been that day:

"You could forget some of what you did that day - or forget to write it down on one day and mess up." (P11)

"You don't have to think about it and try to remember your locations and times you've been there." (P3)

"It is easier for the user. Can record things manual methods cant. Removes human error." (P4)

Others spoke about how using the technology would remove the chance of the user fabricating or lying about where they have been or what they have been doing:

"People may be subject to demand characteristics and social desirability, so they will exaggerate or falsify their results making them not valid." (P7)

5.6.2.4.2 Technology can be lost or broken and may not be suitable in certain contexts

Five of the participants provided opinions about the technology itself. Two felt that it could easily be damaged, lost or could fail to work properly. For example:

"It can be easily damaged/forgotten and technology can glitch" (P8)

One participant stated that the Fitbit wasn't practical for capturing all of their activities, as there were certain situations where they were unable to wear it:

"I couldn't wear it for activities I do, like karate, as it isn't regulation and can't be worn during fights." (P5)

Another participant suggested that the Fitbit would be better in a different form, worn on a different part of the body:

"I think the device itself may not be the best way to monitor activity - a more regularly usable device like a watch or app might be more useful" (P11)

5.6.3 Benefits and costs of location and activity monitoring

The final activity in the second workshop required participants to get into small groups and come up with benefits and negatives of location and activity tracking. After a whole-class discussion, participants were required to fill out their worksheet with their own five most important issues for each category.

To analyse this data, the researcher collected and combined all of the issues that participants had written into their worksheets and merged cases where two or more participants had put down the same point. In doing so, an exhaustive list was created of every unique point raised during the workshop.

The points raised are presented below. Data on the number of times each point was raised has been omitted, as some of the participants simply wrote down the issues that had been written on the board at the front of the class during the group discussion – suggesting they had not given the task sufficient personal thought. However, the lists still demonstrate the breadth of advantages and disadvantages the participants believed location and activity monitoring could have.

Benefits of Location Tracking

- Finding missing people (or objects)
- Useful for businesses to see popular locations
- Health reasons
- Automatic process (self-filling diary)
- Keep track of where you've been
- Parents will know about their children's location
- People's alibi in crime investigations
- Government uses
- People can see personal fitness
- Safer for the person
- Some may find their data interesting

Negatives of Location Tracking

- Tracked by the wrong person
- Impractical
- Expensive – device and tech costs
- Can get damaged, tech often doesn't work, missed data
- Paranoia
- Spied on
- People don't know who sees the data
- Some may find it uncomfortable to be tracked
- Invasion of privacy
- Makes you obsessed with tracking yourself
- 'Big Brother'
- Could be used to intercept people (kidnapping)
- Obtrusive
- Hackers

- Stalkers
- Privacy issues – where you go what you do
- Very specific, may be too specific

Benefits of Activity Tracking

- Can make and recommend products specific to people – tailor products to suit customers
- Medical research
- People aware of their activity – improve health
- Gives sense of achievement
- Doctors can track patient exercise
- Encourages you to be active
- If people know who sees the data, its fine
- Can see how active you are
- Can track patient compliance to treatment
- Motivation
- Personal use for fitness
- Asthma triggers etc.
- People know what sports they've done/track progress
- Help diagnose conditions

Negatives of Activity Tracking

- Invasive
- Monitoring may affect behaviour
- Paranoid
- Uncomfortable to wear
- Data could be inaccurate/imprecise
- Some may find it uncomfortable to be tracked
- Overdoing it
- Not happy to give data away
- Charging it/Maintaining device
- Discouraging when data is poor
- Sometimes too intrusive

5.7 Discussion

To begin investigating attitudes towards new monitoring capabilities that the latest models of EMDs are beginning to include, this study sought to elicit the attitudes of a sample of adolescents towards location and activity monitoring technologies. Through two workshops and a trial of monitoring both manually and using technology, the opinions of this sample have been collected. This discussion will firstly cover the findings that were related to location monitoring and assess their contribution to the literature as well as their support for previous research. The same will then be covered for activity monitoring. Afterwards, the findings that relate to the comparison between monitoring using technology and manual monitoring using a diary will be considered, before assessing the limitations of the study, future research, as well as recommendations for the future development of EMDs.

5.7.1 Location monitoring – findings and support for previous research

Participants had mixed attitudes for location monitoring. Whilst they recognised the benefit this type of monitoring could have – particularly for health conditions, as well as for finding missing people and tracking loved ones. They also showed concerns for the intrusive nature of this type of monitoring, with many pointing out the dangers if this information were to become available to the wrong people.

It was found that participants had varying privacy concerns. Some showed high levels of concern, highlighted by comments such as *"I will try to avoid having my location monitored as much as possible".* Some were less concerned and felt that their data gave away very little personal information about them and they therefore would not have an issue with someone looking through their data. A small sub-section appeared to believe the data was an invasion of their privacy, yet felt there were other instances such as monitoring of private messages with their friends that were of more concern. These participants seemed resigned to the fact that their privacy was being invaded, yet there was nothing they could do to stop it.

These varying attitudes support previous research that similarly found that some participants were always willing to share their location, some were never willing and for others it depended on their location at the time (Anthony et al., 2007). However, in the current study many of the participants who showed little

concern for their privacy did appear to be thinking purely about the data that had been recorded about them over the five days of the trial. For example, one participant stated *"I wouldn't have concerns as my week appeared quite boring and I feel it doesn't reveal too much about me personally".* It may therefore be the case that these participants hadn't considered whether this data would be a privacy concern if the data was recorded at a different time and potentially included location information they wouldn't want others to see.

The phrasing participants used when describing their feelings towards location monitoring supports a previous study where participants reported finding the location tracking 'a little creepy' (Consolvo et al., 2005). Here, the participants used terms such as 'scary', 'uneasy', 'creepy' and 'weird' when describing the monitoring, and also brought up negatives of location monitoring including 'spied on', 'hackers', 'stalkers' and 'big brother'.

In another study with adolescents who had their location tracked, it was found that the participants liked the fact they could be tracked if they were in danger (Wiehe et al., 2008). This was also raised as an important benefit of location monitoring in the current study. Participants felt the technology could be used to find missing people and could also increase safety.

5.7.2 Activity monitoring - findings and support for previous research

Compared to location monitoring, attitudes to activity monitoring were more positive. Comments from the participants indicated that they found it to be better than they expected and several stated that they enjoyed being able to check up on their exercise levels to attempt to improve them.

Although the participants did come up with a selection of negatives for activity tracking, such as it potentially being invasive, intrusive and making them paranoid. These did not appear as severe as for location tracking where the participants used more drastic phrasing such as 'hacking' and 'spied on'. Furthermore, they came up with a good selection of potential benefits for activity monitoring including medical research, encouraging you to exercise and be active, motivating, and for tailoring products to suit individual customers.

Comments were received from the participants which suggest that they found the activity tracking useful and encouraging in helping them to exercise more. For example, one participant stated *"It affected how many steps I did. As it*

made me feel like I was really inactive and therefore throughout the day it made me feel as if I should go out for more walks/walk more places." Some of the more negative comments for activity tracking included the fact that the Fitbit could easily be lost or damaged and was inappropriate to wear for certain activities.

The findings appear to be in line with previous research which found that participants had minimal privacy concerns for activity monitoring short-term (Gorm & Shklovski, 2016). This study found that privacy concerns for sharing data on step-counts only developed over time as people started using it to pry into people's activities outside of work (Gorm & Shklovski, 2016). It would therefore be of interest to see if the participants in the current study would have had different attitudes if the study had gone on for longer and there had been actual sharing of step-count data between the participants.

5.7.3 Technology versus diary

Through testing the two different methods of monitoring for five days each, participants were able to compare and contrast both techniques and provided a valuable critique of both. There were varying opinions on the accuracy of the technology, particularly for monitoring location. Some participants reported being surprised at how accurate the technology was at recording where they had been, e.g. *"The specific timings and the accuracy of my location surprised me."* However, other participants seemed less impressed, providing comments such as *"I thought the location tracker would be more specific and more accurate about where I was travelling."* These different attitudes are likely to reflect the different experiences participants had. For some, the phone battery lasted well and the application reliably recorded their location. However, for others it was more temperamental and there were cases where data was lost or fragmented.

An interesting finding was that more participants completed the full five days of monitoring using the self-report diary than the five days with technology. However, it is unknown whether participants filled out their diary each day or all at once and whether the records they kept accurately reflected where they actually went. Similarly, it is hard to know how many missed days with the technology were down to the participants forgetting to take the technology with them, or the technology failing. The participants themselves acknowledged that one of the drawbacks of the self-report method was that it relied on the user remembering, whilst the technology removed human-error.

Participants seemed to appreciate the added accuracy the technology could provide in recording specific locations and providing an accurate step count. However, it was also pointed out that a benefit of the self-report method was that you could include extra notes and additional information to supplement the data if added context was necessary.

5.7.4 Reflections on workshops

The most challenging part of the workshops was determining the best way to gather comments from the participants. Initially, it was expected that open discussions could be held which could be recorded using a dictaphone and later transcribed by the researcher. However, with a large sample of 19 participants, it quickly became clear that a select few were willing to talk whilst others were more comfortable listening and not voicing their own opinions. Fortunately, this was noted in the first workshop where data was not collected, meaning there was time to adjust the second workshop. To better collect participant comments, a worksheet was made which allowed for each participant to write their opinions down, meaning feedback could be gained from the full sample.

Whilst the workshops were successful in eliciting the attitudes of this sample, a more effective method may have been to carry out multiple workshops with the sample split into smaller groups. This might have allowed for more natural, open discussions and more debate between the participants. This was not achievable in the current study due to the constraints imposed by the school, but if the study were to be replicated, smaller workshops might be preferable.

5.7.5 Limitations of the research

Although this study was successful in eliciting the attitudes of a sample of adolescents towards location and activity monitoring, it has limitations which are important to acknowledge. Firstly, the sample consisted of nineteen 'high-achieving' students. Although this meant that the students were reliable, willing to take part and happy to contribute, it also means that they represent a small sub-section which may not be representative of adolescents as a whole. It is apparent from the comments the students provided that they are well informed, educated individuals capable of providing balanced opinions. Although this provided major benefit for the researcher in terms of running the study and receiving feedback, it is important to recognise that another group of adolescents could have different attitudes.

Another limitation could be that the sample consisted of healthy individuals, rather than individuals with a health condition such as asthma where location monitoring could provide benefit. This could mean that the sample were less likely to see the benefit of this type of monitoring in their own personal lives. Attempts were made to account for this, through providing the participants with examples where this type of monitoring would be useful, but they may still have answered questions purely based on the benefit of this technology for their own personal life.

5.7.6 Recommendations for the future of EMDs

5.7.6.1 *Future Research*

Future research should look to directly assess the attitudes of patients with asthma (both adolescents and other age groups). Whilst the current study gave a good preliminary overview of adolescent attitudes towards this type of monitoring, it is important to more specifically investigate perceptions towards this type of monitoring in the context of asthma management.

5.7.6.2 *Design and Development*

The findings from this study indicate that it is important to make location and activity data visible, so that the individual is aware of what is being recorded about them and can benefit from using the data to discover their own insights. It is important that EMD developers allow patients to view the information that is being recorded about them – particularly in the case of location data, as some found this to be an invasive form of monitoring but were comforted when they saw what was actually recorded about them.

Furthermore, participants here felt that it was important that they would be able to include their own notes and comments to add context and meaning to the data. EMD developers should also consider adding this kind of functionality – particularly if the device is accompanied by a smartphone application, where a user may be able to check up on the data that has been recorded and provide additional contextual information.

5.8 Conclusion

This research aimed to elicit the attitudes of a sample of healthy adolescents towards location and activity monitoring in order to begin to understand whether this could feasibly be integrated as functionality for new and future EMDs. The results suggest that the participants felt more positively about activity monitoring and saw it as a way to monitor their exercise and a motivation for becoming more active. In contrast, whilst the participants recognised the benefit that location monitoring could have for certain health conditions and for additional reasons including finding missing people, there were concerns for privacy. The findings support previous research and suggest that developers should work closely with users to establish mechanisms for secure location monitoring where the user feels comfortable with both the information being recorded as well as who has access to it.

5.8.1 Implications for thesis

- With EMDs developing new capabilities since the research in Chapters 3 and 4 were conducted, this chapter explores the attitudes of a sample of adolescents towards location and activity monitoring
- The findings provide insight into how patients with asthma may respond to having their location and activity monitored if this functionality were to be integrated with current EMDs
- The findings also highlight the potential patient-related challenges and issues that the developers of EMDs may need to overcome if this type of data is to be recorded

Chapter 6 A systems model of asthma care – impacts and future requirements of EMDs

6.1 Introduction

This chapter firstly relates back to the 'systems' perspective that has been adopted throughout this thesis when both planning and conducting the three research studies. With a recent clinical paper providing a new model of the asthma care process, this chapter considers how this model can be adjusted and expanded to use as a framework for discussing the potential impacts and the requirements of EMDs for asthma care. It does so through combining the findings of the research conducted in this thesis with literature on determinants of patient behaviour, guidelines on behavioural care, as well as procurement and purchasing processes.

After explaining the development of a new systems model of asthma care (SMAC), the potential impacts that EMDs could have are outlined - based on knowledge gathered from both the literature and the research studies conducted for this thesis. Each point is related back to the model, to help demonstrate how EMDs could impact on both the patient and the healthcare provider.

After plotting the potential impacts, the requirements that EMD developers need to meet for those impacts to be realised are discussed. These requirements are drawn from the findings of the three research studies from chapters three, four and five. Again, these are related back to the SMAC in order to show how requirements need to be fulfilled for both patients and healthcare providers for EMDs to fully influence the asthma care pathway.

6.2 Systems approach to asthma care

In the initial literature review in chapter two it was stated that a 'systems' approach would be adopted for conducting the research included in this thesis. This systems approach emphasises the fact that when evaluating a medical device, it is important to not just consider the patient, but also consider the complex environment in which the device will be used, as well as the other user groups and stakeholders whom may also interact with it (Carayon et al., 2014; Sharples et al., 2012).

This systems perspective is a useful and important framework for encouraging researchers and healthcare providers to adopt human factors research methods in the healthcare domain. However, models such as the SEIPS (Systems Engineering for Patient Safety) (Carayon et al., 2006) focus on high-level concepts that are applicable across healthcare. Whilst a model such as this can be essential in both guiding research and assessing patient safety events, it does not tell us anything about a system of asthma care specifically.

A systems model of asthma care would be useful for two main reasons. Firstly, to appreciate the impact that EMDs could have on asthma care and understand where their use could produce the greatest change and effects. Secondly, to highlight the requirements that have been elicited from the research conducted in this thesis and consider the impact that meeting those requirements could have on the asthma care process as a whole.

In September 2016 after the research for this thesis had been completed, a new clinical paper was published that adopted a methodology bearing similarities to the systems approach used in human factors and healthcare research. The authors intended to map the asthma care process - stating that asthma control is not just determined by effective medication - but is dependent on a variety of both patient and healthcare provider behaviours, all of which interact and can influence and determine health outcomes (Dima, de Bruin, & van Ganse, 2016). Similar to the systems approach used in human factors research, they comment that asthma research rarely considers how different factors interact and this can often make it difficult to use evidence collected from studies and ensure it creates the desired changes in clinical practise (Dima et al., 2016)

In order to develop a pathway of asthma care they reviewed asthma treatment guidelines, previous related studies and interviewed patients, parents as well as

nurses and GPs. By combining the collated evidence, they formed a model of asthma care, shown in Fig 6-1 below (Dima et al., 2016).

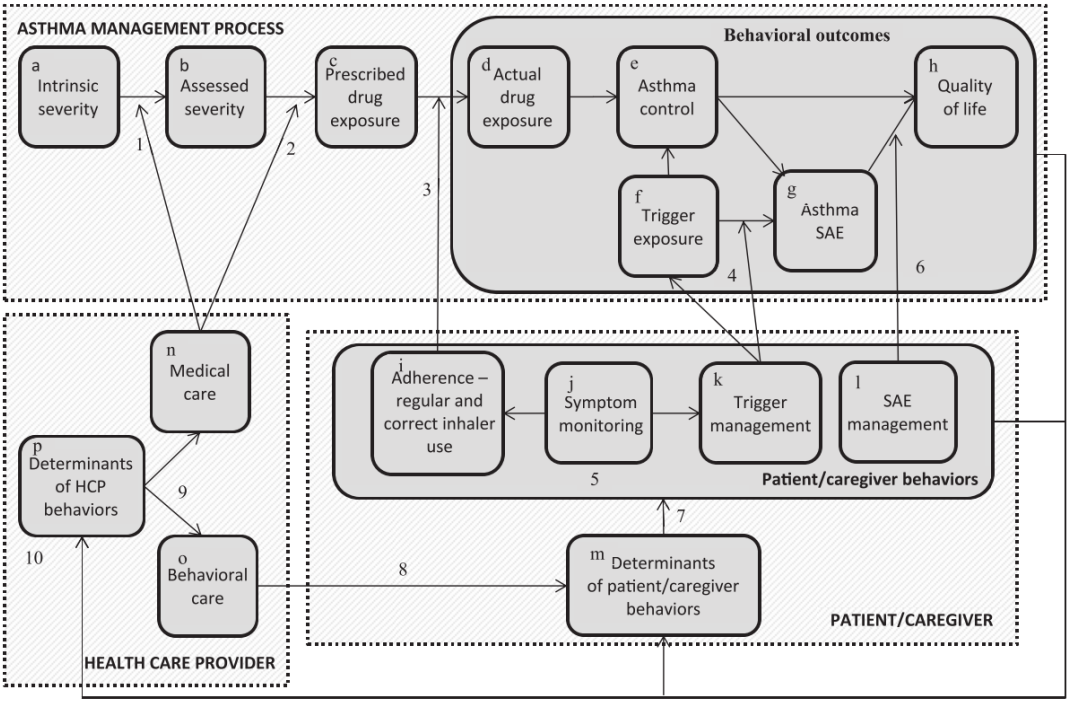

Figure 6-1 Model of asthma care (taken from Dima et al, 2016)

The model of asthma care contains three main components related to the patient, the healthcare provider, and the asthma management process (Dima et al., 2016). Each of these components contains a sequence of processes, with both the patient and healthcare provider sections encompassing behavioural factors, whilst the asthma management process section contains sequential steps of respiratory care, as well as behavioural outcomes (Dima et al., 2016). The components of the model and the relations between them are explained later, in section 6.2.2.

As the model contains factors and processes related to both patients and healthcare providers, it fits well with the research strategy used in this thesis. It provides a useful framework for both mapping the potential points of impact for EMDs, as well as identifying the areas where there are requirements that need to be met. However, as the model is intended for use in clinical research, there are certain contextual and behavioural aspects that currently lack clarity. The following section discusses how the model can be adjusted and expanded to form a model that is more in line with the systems approach used in human factors research.

6.2.1 Systems model of asthma care (SMAC)

The model produced by Dima et al (2016) is a useful systems approach to the asthma care process. However, it was felt that for the benefit of this chapter there was an opportunity to integrate additional factors and guidelines.

The National Institute for Health and Care Excellence (NICE) provides a pathway of patient experience in the NHS which includes guidelines on everything a healthcare provider should take into account when giving clinical expertise and care to their patients (NICE, 2015). This includes tailoring health services to the patient, ensuring they know each patient as an individual, and enabling the patient to be an active member in their care (NICE, 2015). This pathway is an expanded version of the 'behavioural care' box for healthcare providers in the model in Fig 6-1. This therefore opens up an opportunity to integrate the two to provide added depth and better describe the factors that are important for building a relationship between the healthcare provider and patient.

Furthermore, it was felt that adjustments could be made to the patient component of the model to better reflect the various factors that can affect a patient's health related behaviour. In the literature review in Chapter 2, the Health Belief Model (HBM) was introduced as a widely used framework for predicting and explaining health behaviours (Besch, 1995; Glanz et al., 2015; Rosenstock, 1966). The model includes modifying factors such as the patient's age and socioeconomic status, as well as individual beliefs about their condition or treatment, to help explain how health behaviours are formed (Glanz et al., 2015). These modifying factors and beliefs are currently lacking from the model in Fig 6-1, yet could be integrated to better reflect how the behaviours of a patient with asthma are formed.

It is important to note that many of the factors included in the NICE pathway and the HBM are touched on in the paper by Dima et al (2016), but are not as clearly reflected in the model as they could be. It was therefore decided that the model of asthma care would be expanded to include both the NICE pathway and the HBM, to create a systems model of asthma care (SMAC) that is more in line with the systems approach used in human factors research.

As the adjusted model is to be used in relation to EMDs, a third additional section was included to cover the purchasing and procurement process which

would be required for EMDs to be commissioned and used within asthma care. This was added to help position EMDs within the model and to understand how they could be introduced and was based on information from a 2011 report that outlined the routes by which NHS trusts can purchase consumables (National Audit Office, 2011). The newly adjusted model containing the HBM, NICE and Procurement can be viewed in Fig 6-2, with each component described and explained in more detail in the following section.

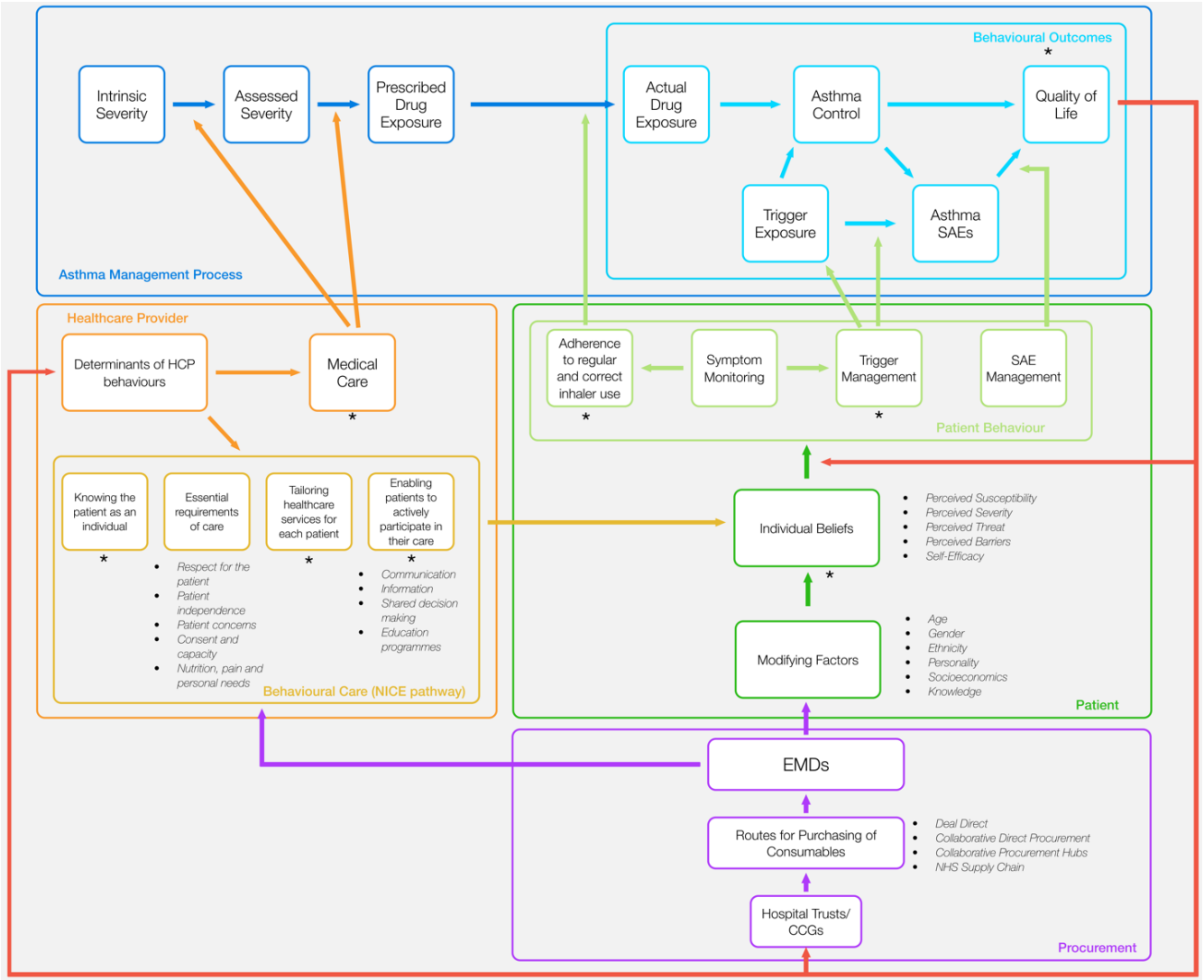

Figure 6-2 Systems model of asthma care (SMAC), combining Dima et al (2016), NICE guidelines, the Health Belief Model (HBM), and Procurement (National Audit Office, 2011) – An asterisk is placed under each of the sections where EMDs could have an impact (discussed in section 6.3)

6.2.2 Components of the asthma care model

This section describes the components of the SMAC displayed in Fig 6-2. Each of the four main components is outlined in turn, with a description for each of the boxes within it, as well as the relationship with other sections as indicated by the arrows on the diagram. The descriptions throughout this section are based on the information provided by Dima et al (2016), the NICE pathway (NICE, 2015), the HBM (Besch, 1995; Glanz et al., 2015; Rosenstock, 1966), as well as the report on procurement and purchasing within the NHS (National Audit Office, 2011).

Whilst this section is not informed by the research conducted in this thesis, it is still important to describe each section of the model and the links between them. Through understanding the flow through the model, as well as the feedback loop, we can understand how EMDs could be introduced into the system, helping to make the later sections of this chapter which discuss the impacts and requirements of EMDs clearer. Colour coding each section provides additional benefit as it makes the relationship between the SMAC and the impacts and requirements included in sections 6.3 and 6.4. easier to follow.

Asthma Management Process

The asthma management process starts with a patient experiencing asthma symptoms such as wheezing, shortness of breath and coughing, all indicative of their asthma's *Intrinsic Severity*. They consult a healthcare provider for these symptoms, who diagnoses and gives an *Assessed Severity* level for their asthma. Based on this assessment, the patient is prescribed medication to control their symptoms (*Prescribed Drug Exposure*).

Behavioural Outcomes

Based on patient behaviours (covered later), the patient will take a level of their prescribed medication (*Actual Drug Exposure*) which along with their exposure to certain triggers for their asthma such as pollen or exercise (*Trigger Exposure*) will determine their *Asthma Control.* Their asthma control then affects their likelihood of experiencing a severe asthma exacerbation (*Asthma SAE*) which along with asthma control, comes together to influence the patient's *Quality of Life*.

Patient

As opposed to the model of asthma care produced by Dima et al (2016), the patient component of the SMAC starts with the two core features of the Health Belief Model (HBM). The first of these is *Modifying Factors* which takes into consideration the patient's age, gender, ethnicity, socioeconomic status and more. These are called modifying factors as they can all influence the patient's *Individual Beliefs*. These beliefs are all covered by the HBM and include the patients perceived beliefs about how effective their advised treatment would be (*perceived benefits*), as well as the potential costs of adhering to that advise (*perceived barriers*).

The model shows how *Individual Beliefs* can also be influenced by the *Healthcare Provider* whose behaviour can influence how confident the patient feels about their treatment regime and how well they understand it. The red arrow also shows how the patient's *Quality of Life* also determines their behaviour and can be a cue to action if health is poor or deteriorating.

Patient Behaviour

Included in the model are four types of patient behaviour that are necessary for the management of asthma. Firstly, *Adherence to Regular and Correct Inhaler Use* determines how much medication the patient is actually exposed to (*Actual Drug Exposure*), compared to their *Prescribed Drug Exposure*.

Trigger Management then relates to how exposed the patient makes themselves to triggers for their asthma and also moderates the link between *Trigger Exposure* and *Asthma SAE* if a reliever inhaler is used effectively. *SAE Management* is then related to behaviours that can reduce the severity and length of an SAE, such as reliever medication and use of emergency services.

Finally, *Symptom Monitoring* is based on feedback from previous behaviours - the patient monitors how they are feeling and this influences their future *Adherence to Regular and Correct Inhaler Use* and *Trigger Management.*

Healthcare Provider

Determinants of Healthcare Behaviour can be influenced by the patient's *Quality of Life,* as shown by the red arrow. Dima et al (2016) also note in their paper

that a healthcare provider's behaviour can be influenced by their medical knowledge, training, speciality, age and gender.

The healthcare provider can then influence the asthma management process in two main ways. Firstly, through *Medical Care* they can assess the severity of the patient's asthma (*Assessed Severity)* and from this determine a level of *Prescribed Drug Exposure.* Secondly, *Behavioural Care* relates to the support and communication a healthcare provider has with a patient.

Behavioural Care (NICE Pathway)

The NICE pathway consists of four core sections. The first of these is *Knowing the Patient as an Individual* which recommends that the healthcare provider should develop an understanding of their patient, taking into account how their condition affects them and how their circumstances affect their condition. It is recommended that they should listen to any health beliefs and concerns that the patient may have and address these appropriately.

Second is *Essential Requirements of Care.* This states that patients should be treated with respect, kindness and with their right to confidentiality upheld. Patients should also be supported in maintaining their independence - giving them the opportunity to manage medicines for long-term conditions themselves. Patient concerns should also be listened to, consent should always be gained and the healthcare provider should always ensure that the patient has a suitable level of nutrition and hydration and is not in unnecessary pain.

Third is *Tailoring Healthcare Services for each Patient.* Similarly, to knowing the patient as an individual, this recommends that a patient's treatment plan should be tailored to their own individual needs and circumstances. It's important that the healthcare provider discusses treatment options with the patient, listens to their views and reviews their understanding of their condition as well as their views on whether they need treatment.

Last is *Enabling Patients to Actively Participate in their Care.* This recommends that it is important to communicate effectively with the patient - through maintaining eye contact, sitting at the same level and exploring ways to improve communication such as using pictures. It is also important to provide the patient with sufficient information about their condition, their treatment, as well as any

future clinic visits. It is also important to promote shared decision making, giving the patient the opportunity to discuss their treatment options and be informed of their risks and benefits. Finally, the patient should be given the opportunity to learn about self-management of their condition through taking part in relevant educational programmes.

Procurement

The procurement pathway provides a brief summary of how EMDs could be introduced into the asthma care system. *Hospital Trusts/CCGs* have a number of different *Routes for Purchasing of Consumables* to improve the quality of the care they provide. They can deal directly with suppliers (Deal Direct), collaborate with independent distributors (Collaborative Direct Procurement), use a Collaborative Procurement Hub – regional groups used to improve procurement strategy and save trust money, or they can use the NHS Supply Chain – a national organisation aimed at saving trusts time and money.

If *EMDs* were to be purchased by the healthcare system, it is likely they would be procured through one of these routes. This section therefore highlights how these devices could be introduced and could then go on to impact health management and outcomes for both the *Patient* and the work of the *Healthcare Provider*. The impacts that EMDs could have if they were to be introduced are covered in section 6.3, but the recommended developmental steps required if those impacts are to occur are covered in section 6.4.

Feedback Loop

The red feedback loop stems from the patient's *Quality of Life* and influences both the *Patient's* behaviour, as well as the behaviour of the *Healthcare Provider.* This creates a loop throughout the entire model, as the behaviour of the healthcare provider can affect the behaviour of the patient, which in turn can affect the asthma management process, affecting the health of the patient.

The red feedback loop also flows back into the *Procurement* section. This is to highlight how for *EMDs* to initially be purchased, there has to be a need for them and this would likely be based on patient *Quality of Life* being lower than expected - indicating faults or weaknesses in the system and resulting in higher hospital admissions. *EMDs* could be purchased in an attempt to improve the

asthma management system and impact on several aspects of it. If *Quality of Life* improves and feeds back again to the *Procurement* process, more devices may be purchased.

6.3 Mapping the potential impacts of EMDs

Expert knowledge of the functionality and capabilities of EMDs has been gained through examining and understanding the literature on these devices to date, as well as through investigating the perspectives of patients and healthcare providers towards them.

Using this knowledge, it is possible to identify the areas of the systems model of asthma care (SMAC) where EMDs could have the most pronounced effect if they were to be commissioned and used within the asthma care system. Table 6-1 briefly summarises these potential impacts. Section 6.4 will then look at the requirements that can be drawn out from the research conducted in this thesis -- to indicate what needs to be addressed for the impacts shown in Table 6-1 to be realised.

Table 6-1 The potential impacts of EMDs, described using sections of the SMAC.

Section of Model	Potential Impact
Adherence to regular and correct inhaler use	EMDs can support adherence to regular inhaler use through providing audio-visual reminders when a new dose is due. An awareness of inhaler use being monitored by a caregiver or healthcare provider may also promote good adherence.
Trigger Management	EMDs could support a patient in trigger management through combining contextual data on location, pollen count, pollution and humidity with reliever inhaler use - to provide insight into the main triggers for a patient's asthma. This could be discussed with their healthcare provider who may provide support in interpreting the data and suggesting future actions.
Individual Beliefs	EMDs may reduce 'perceived barriers' for some patients who may often forget to take their medication (unintentional non-adherence) and can use the reminder tones to help them remember. Using an EMD to promote good adherence may also lead to an increase in the 'perceived benefits'

	a patient feels their inhaled medication could have – if they have been regularly using their inhaler and have experienced a period of good asthma control. EMD's may also promote a patient's 'self-efficacy' about their ability to take their inhaler regularly. Particularly if they find the reminders useful for helping them to remember to take their inhaler on time.
Knowing the patient as an individual	The data collected by an EMD could help a healthcare provider in understanding a patient's asthma on an individual level – through understanding how well they adhere to their prescribed medical regimen, how their asthma responds to medication, as well as the triggers that affect the patient's asthma most.
Tailoring healthcare services to each patient	By using EMDs to understand a patient better as an individual and learning how well they manage their asthma, how severe their asthma is, how they respond to medication, and the key triggers for their condition, a healthcare provider could tailor health services to each individual patient. With access to data about a specific individual patient, a healthcare provider could make more informed decisions about what would be the best course of action for a patient's asthma going forward.
Enabling patients to actively participate in their care	The data collected by EMDs could be used to promote open discussions between a patient and a healthcare provider. Using graphs and figures to show inhaler use over time may help communicate information to a patient more effectively. Promoting open discussions about a patient's asthma management could then lead to more effective shared decision making about future inhaler therapy.
Medical Care	A healthcare provider could use the data collected by an EMD to understand if a patient is experiencing asthma symptoms because their medication is not as effective as it should be, or because they are not taking their medication as prescribed. This would reduce the amount of wasted medication and could also help a healthcare provider know when an interventional

	measure is necessary to help a patient become more adherent.
Behavioural Outcomes	Ultimately, the impacts that EMDs could have on both the patient and the healthcare provider could influence all aspects of behavioural outcomes. If the patient uses more of their prescribed medication and is exposed to fewer triggers, they may experience better asthma control, have less SAEs and therefore experience a better quality of life. The feedback loop of the model means that this could then relay back to the patient and the healthcare provider, potentially improving the health and asthma management of the patient further.

6.4 Requirements of EMDs going forward

The previous section outlined the sections of the asthma care process where EMDs could have the most impact. Drawing on the findings from the three research studies conducted in this thesis, the current section outlines the requirements that should be met to help ensure that the devices can be successfully introduced and used in asthma care.

Whilst medical device developers are currently required to comply with ISO 62366 and complete a 'Usability Engineering Process' - this only requires the developers to identify primary user functions and design a user interface to accommodate them (ISO62366). The standard does not require developers to consider other aspects of design – such as how socially compatible the device is, how easy it is to transport in everyday life, and whether users feel it supports and benefits their health management. The requirements in this section go beyond the criteria of ISO 62366 and draw on the findings from the research included in this thesis to consider how EMDs could be successfully integrated into asthma care and used to support a patient's health management as well as the work of a clinician.

Table 6-2 firstly outlines the requirements and states which sections of the SMAC each point relates to, as well as which thesis chapter the requirement has been drawn from. Afterwards, a short description is provided for each

requirement, explaining how the findings from the research in this thesis support it.

Table 6-2 A list of requirements drawn from the three research studies conducted for this thesis

			Related thesis chapter		
#	**Requirement**	**Related sections of the SMAC**	**3**	**4**	**5**
1.	Establish the most feasible purchasing pathway for procurement of these devices	*Procurement*		x	
2.	Formally identify patient types the device would be most appropriate and beneficial for	*Procurement* *Knowing the Patient as an Individual*	x	x	x
3.	Reduce the size of the device	*Adherence to regular and correct inhaler use* *Individual Beliefs*	x	x	
4.	Improve the choice of reminder tones and add in functionality for the user to import their own	*Adherence to regular and correct inhaler use* *Individual Beliefs*	x		
5.	Enable customisation of the device, e.g. choice of colours	*Adherence to regular and correct inhaler use* *Individual Beliefs*	x		
6.	Improve the usability of the device by making the function of buttons on the device clearer and the visual display larger	*Adherence to regular and correct inhaler use* *Individual Beliefs*	x	x	
7.	Consider ways to make data visible to the patient and to give them control over whom data is shared with e.g. via a smartphone application	*Individual Beliefs* *Enabling patients to actively participate in their care* *Medical Care*	x		x

8.	Work with health service providers to establish who should have responsibility for the handling and interpreting of data, as well as for discussing it with a patient	*Behavioural Care* *Medical Care*		**x**	
9.	Integrate the ability to monitor inhaler technique and inhalation	*Adherence to regular and correct inhaler use* *Medical Care* *Actual Drug Exposure*		**x**	
10.	Establish how data can be stored securely and confidentially, and determine who should have access to it	*Essential Requirements of Care*		**x**	
11.	Ensure software for downloading and interpreting data is both intuitive and usable, to reduce time burden on the consultation process	*Medical Care* *Tailoring healthcare services to each patient*		**x**	
12.	Ensure EMDs are compatible with a range of inhaler types	*Individual Beliefs* *Tailoring Healthcare Services for each Patient*	**x**	**x**	
13.	Make location monitoring and activity monitoring data visible to the user, to allow them to find their own insights.	*Trigger Management* *Enabling patients to actively participate in their care* *Behavioural Outcomes*			**x**
14.	Allow users to add contextual information and notes to their data	*Enabling patients to actively participate in their care* *Symptom Monitoring*			**x**

1. *Establish the most feasible purchasing pathway for procurement of these devices*

When stakeholders in asthma care were asked for their thoughts on the key benefits and barriers for the introduction of EMDs, cost was repeatedly raised as a major issue that needs addressing. For example, one stakeholder asked *"How much do they cost? Is this cost incurred by the department, GP practise or patient?"* whilst another stated *"Chesterfield CCG has to save £10m - not a hope in persuading them to spend more…".* It was clear from this research that there was a common consensus that how these devices should be funded is unknown and this is a critical issue to address, particularly due to the current pressures on the healthcare service to cut costs and find new money-saving initiatives.

With the NHS Supply Chain tasked with improving procurement to save a total of £700 million by the end of the 2020/2021 financial year (NHS, 2016), there is a clear need to establish the most realistic and feasible route for these devices to be purchased through. This will be highly related to the next requirement listed below, as in order for EMDs to be commissioned it is important to establish who the devices would be most beneficial for - to help reduce the chance of over-purchasing, or the provision of a large quantity of devices to patients with less of a need.

2. *Formally identify the types of patient the device would be most appropriate and beneficial for*

With cost highlighted as a key barrier by stakeholders, it is important to refine the approach used for introducing these devices into asthma care. Researchers and developers need to establish the types of patients who would benefit most from EMDs. This will help to reduce financial risks associated with purchasing them and will help to ensure that they are used by the individuals most likely to experience improved asthma control and quality of life as a result.

As stated in Chapter 3, Seretide is the costliest drug for the NHS with an annual financial burden of £170 million (NHS Information Centre, 2011). It may be the case that EMDs are most appropriate for patients with severe asthma who use a seretide inhaler, as targeting these patients may result in the largest savings.

3. *Reduce the size of the device*

Participants in the first study commented on how the size of the SmartTrack device could be a problem - particularly if it was attached to their reliever inhaler which they would tend to carry around with them in a trouser or jacket pocket. They also felt that the devices current appearance could draw unwanted attention to them because it looks different to a normal inhaler. Similarly, the second most frequently brought up 'cost/barrier' for EMDs in the second study was that healthcare providers felt that the bulkiness of the devices might put patients off using them. EMD developers should look to reduce the size of devices, to make them easier to transport and also to make them less conspicuous and attention grabbing.

4. *Improve the choice of reminder tones and add in functionality for the user to import their own*

The participants in the first study felt that there should be a better choice of ringtones available to alert them when their next dose is due. Some suggested they would like to be able to add their own music and tones to the device, whilst others felt that this would be too complicated for them to do and would just like a greater selection of pre-loaded tones. EMD developers should improve the selection of ringtones available on the device and also allow users to import their own tones onto the device when it is connected to a PC.

5. *Enable customisation of the device, e.g. choice of colours*

In the first study, some of the participants felt that the SmartTrack device could be improved by adding a range of colours. However, others felt that black was a good colour for the device and they wouldn't be interested in customising it. EMD developers should look to introduce methods of customising the device for users where this would be appealing, whilst still giving other users the option to have a standard device.

6. *Improve the usability of the device by making the function of buttons on the device clearer and the visual display larger*

Participants in the first study commented on how the SmartTrack's display and buttons were easy to use once it had been explained to them, but initially they

were unsure how to use the device as all four buttons look the same. They also felt that the display could be larger, as the text on the screen was quite small and some people may struggle to read it. Similarly, three of the healthcare providers in the second study raised 'ease of use' as a potential problem, stating that using the device would be another thing that patients have to learn.

EMD developers should make the purpose of buttons on the device easier to understand by using icons. Alternatively, they should look to incorporate a touch-screen interface which is both larger, and easier to interact with as the user can directly press on menu options and functions.

7. *Consider ways to make data visible to the patient and to give them control over whom data is shared with e.g. via a smartphone application*

In both the first and third study participants spoke about controlling who they share their data with. It is important that EMD developers make the data that is being recorded visible to the user, so that they are both aware of the information being monitored, as well as who this information is being shared with. In the first study it was suggested that a smartphone application would be the most useful method for checking on adherence data and deciding whether to share it with parents or a healthcare provider.

8. *Work with health service providers to establish who should have responsibility for the handling and interpreting of data, as well as for discussing it with a patient*

In the second study the stakeholders expressed concerns about who would have responsibilities for data handling and discussing it with patients. It is important that EMD developers work with health service providers to establish the most appropriate way for the information provided by EMDs to be incorporated into the asthma care process, in order to ensure that the data can be used to benefit consultations and increase a healthcare providers understanding of a patient's asthma.

9. *Integrate the ability to monitor inhaler technique and inhalation*

Stakeholders rated the fact that EMDs cannot monitor inhaler technique and inhalation as the second most important barrier/cost affecting these devices. As

EMDs tend to only record actuation, this means that there is no way to detect if a patient is actually inhaling their medication and no way to know if their technique is inhibiting the effectiveness of the drug. EMD developers should therefore explore ways to monitor technique and inhalation in order to record data that healthcare providers feel more confident using. By doing so, a healthcare provider may be able to determine if poor asthma control is down to the wrong medication, poor adherence, or poor inhalation technique.

10. *Establish how data can be stored securely and confidentially, and determine who should have access to it*

In the second study, six of the stakeholders questioned how the data collected by EMDs would be stored and who would have access to it. EMD developers need to ensure that the confidential and sensitive information that is recorded by these devices is stored securely and can only be accessed by those with the correct authorisation.

11. *Ensure software for downloading and interpreting data is both intuitive and usable, to reduce time burden on the consultation process*

Nine of the stakeholders in the second study raised concerns about the time that downloading, interpreting and discussing the data could add to their consultations with patients. It is therefore important that EMD developers ensure that dedicated software for handling data is easy and efficient to use, to reduce the impact it has on clinic time as much as possible.

12. *Ensure EMDs are compatible with a range of inhaler types*

Concerns were raised by stakeholders about whether EMDs are only compatible with MDIs, or are available for other inhaler types too. Furthermore, there were recruitment challenges in the first study as some patients had inhaler that were not compatible with the SmartTrack device. EMD developers should look to create devices that are compatible with a range of widely used inhaler types to maximise the amount of potential users who could benefit from them.

13. *Make location monitoring and activity monitoring data visible to the user, to allow them to find their own insights*

In the third study the participants found looking over their own location and activity data an interesting exercise and often drew their own insights it. Some were surprised and pleased with how much walking they did, whilst others felt that the data showed that they needed to get out and exercise more. EMD developers should let users have access to their data – particularly location and activity data, so that they can use it for their own benefit whilst also being aware of what is being recorded about them.

14. Allow users to add contextual information and notes to their data

When comparing the monitoring of location and activity data both manually and with technology, the participants in the third study felt that a benefit of the manual method was that you could add your own notes and comments to supplement the data and provide some background information about a period of time. This could be a useful process for EMD developers to integrate, as it could help keep patients engaged in their care and allow them to report on how they are feeling and any symptoms they are experiencing at a particular time.

6.5 Discussion

Based on a recently published clinical paper that mapped out the asthma care process, this chapter initially set out to develop a 'systems' model of asthma care. This model encompasses the patient, the healthcare provider, health outcomes and procurement processes, and was used in order to frame how EMDs could be introduced to the asthma care system and potentially impact on it. The original model of asthma care produced by Dima et al (2016) was expanded to include aspects of the health belief model (Besch, 1995; Rosenstock, 1966), aspects of the NICE pathway (NICE, 2015), as well as information on purchasing pathways for consumables within the NHS (National Audit Office, 2011). Combining all of these elements together allowed for a more comprehensive view of the factors that could influence the procurement of EMDs, as well as their potential impacts on the behaviours of patients, healthcare providers, and ultimately health outcomes.

Creating the systems model of asthma care (SMAC) provided a useful resource for both considering the potential impacts that EMDs could make on the asthma care process, as well as requirements that need to be met based on the findings of research conducted in this thesis. For these impacts and requirements, each

point is related back to the SMAC, to help understand its place within the care pathway and the way in which it could influence the rest of the system.

Throughout the thesis, the systems perspective used in human factors research has been referred to as a useful framework for considering the surrounding context when making changes to a device, software or procedure and understanding the knock-on effects that this could have (Carayon et al., 2006; Sharples et al., 2012). The SMAC is a useful systems model for specifically thinking about the effects that EMDs could have on asthma care if they were to be commissioned, as well as the importance of meeting certain requirements to ensure that potential impacts are not lost. Using the SMAC allows us to consider the many aspects of the healthcare process that could be affected by the introduction of EMDs. This helps identify a much broader set of requirements than would be found through only following ISO 62366.

The requirements drawn from the three research studies conducted here are related to both the patient and the healthcare provider. For the requirements related to the patient, these mainly focus on improving device features – such as size, appearance and choice of ringtones, which supports previous research (Lang, Martin, Sharples, & Crowe, 2012). Patient requirements were also formed that were related to providing them with sufficient access and control over what data is recorded and who it is shared with. For healthcare providers, the requirements focus more on ensuring the data produced by EMDs does not disrupt the consultation process - through making dedicated software easy to learn and use for downloading and interpreting adherence data. There are also requirements that relate more to both, such as developing EMDs to record inhalation and technique, as well as making sure EMDs are available for multiple inhaler types.

The SMAC allows us to appreciate that if EMD developers only focus on meeting the requirements of the patient, or only the healthcare provider, it is unlikely that they will have their intended impact on asthma care and on health behaviours. By focusing on both, EMD developers can help ensure that the needs of both parties are met, potentially allowing EMDs to have an impact throughout the whole asthma care pathway (Sharples et al., 2012).

6.5.1 Limitations

Whilst the SMAC is a useful framework for visualising the asthma care pathway, it is important to acknowledge its limitations. Whilst the model considers the background of the patient, it doesn't do this as explicitly for the healthcare provider. Furthermore, it does not fully consider the relationship between the healthcare provider and the patient. For example, from literature covered in chapter 2, there is evidence to suggest the relationship between the clinician and the patient can be influenced by whether they are from different ethnic backgrounds (Okelo et al., 2007). Furthermore, adherence has been shown to be influenced by factors such as a clinician having a busy practise, being willing to answer questions, and having a high level of job satisfaction (DiMatteo et al., 1993). So whilst the SMAC provides a useful 'systems' perspective of asthma care, there are still contextual factors that are not included which can have an influence on adherence and health outcomes. Future work could look to integrate additional factors and establish how they could affect the asthma care process, as well as EMDs.

The list of requirements for EMDs produced in this chapter also has limitations that are important to consider. The requirements are drawn from three research studies that were all based in the East Midlands, UK. This means that different findings may have been obtained from a different region where there may be different pressures on the healthcare service and patients may be from different socioeconomic backgrounds and different levels of education. Furthermore, the research related to patients (and non-patients) focuses on adolescents. This was fully justified, as asthma is most prevalent in this age group and adherence is notoriously poor, but there may be needs of other patient groups such as the elderly that have been missed by this research.

6.6 Summary

This chapter has developed a systems model of asthma care (SMAC) that is useful in considering the effects and impacts of new technologies and interventions on the asthma care process, as well as for planning new research. Here, the model has been used to outline the potential impacts of EMDs on asthma care, as well as the requirements of EMDs going forward, based on the research conducted in this thesis.

The model and the requirements could be used by EMD developers as well as health service providers, to inform future design changes and to identify particular concerns and barriers that need addressing for these devices to be

used in everyday asthma care. Furthermore, the model and the requirements could guide future research studies looking to address some of the key issues facing EMDs - such as data governance and determining how to integrate the data produced by these devices into the clinical consultation process.

Chapter 7 Discussion and Conclusions

7.1 Introduction

At the beginning of this thesis it was established that EMDs have potential to be the most accurately available solution for monitoring adherence to inhaler therapy in asthma care. However, the research to date had been largely clinically focused and more concerned with assessing the accuracy and reliability of these devices. Whilst human factors research methods have been used successfully in other aspects of healthcare, there had been no previous work that examined the perceptions of patients and healthcare providers towards EMDs.

A systems approach was adopted in assessing how the attitudes of both patients and healthcare providers may affect and impact the use of EMDs within asthma care. This led to an understanding of the benefits these devices could bring, as well as the barriers and challenges facing the developers of these devices going forward.

Table 7-1 provides a recap of the research questions that were stated in Chapter 1 and highlights how the three research chapters of the thesis contribute to each. This final chapter will discuss how these three research questions have been answered and will also consider the limitations of the studies and how future research should look to build on the work carried out here. This will be followed by an overall conclusion for the research as a whole.

Table 7-1 - A recap of the table showing how the three research chapters contribute to the three research questions

	Chapter 3 – Adolescent attitudes towards the SmartTrack inhaler	**Chapter 4** – Perspectives of stakeholders towards EMDs for everyday asthma care	**Chapter 5** – School workshops on location and activity monitoring
What different perceptions are there towards technologies for monitoring health-related behaviours in asthma care?	Attitudes of adolescents towards various aspects of the device including its appearance and ability to monitor their inhaler use	Investigating what stakeholders and healthcare providers believe the main benefits and barriers of monitoring inhaler use using technology are	Exploring perceptions of healthy adolescents towards technology that can monitor their location and activity levels
What are the requirements of patients and healthcare providers for data-centred health monitoring devices and technologies for asthma care?	Provides the perspective of a sample of adolescents with asthma – a chronic condition where monitoring could provide benefit	Provides the perspective of stakeholders and healthcare providers	Provides the perspective of healthy adolescents (non-patients), who may have differing opinions to adolescent patients with a chronic health condition
What are the challenges and opportunities for health monitoring technologies going forward, as they become more widespread and develop new monitoring capabilities?	Provides insight into current attitudes - which may help indicate how attitudes might form as technology develops	Advantages and disadvantages of monitoring technologies raised by stakeholders can be applied to new monitoring capabilities	Explores the benefits and concerns healthy adolescents believe having their location and activity levels monitored could potentially have

7.2 Reflections on research questions

7.2.1 What different perceptions are there towards technologies for monitoring health related behaviours in asthma care?

Highlights

- *The adolescents with asthma felt that they could use adherence data to show their parents and caregivers that they can manage their inhaler use responsibly and independently*
- *Healthy adolescents could appreciate the usefulness of location and activity tracking technologies, but felt more comfortable with activity monitoring as a way to encourage exercise. Location data was seen as more at risk of hacking and privacy issues*

- *Stakeholders felt monitoring technologies could encourage more regular inhaler use and could inform decision making in consultations. However, they also had concerns including device appearance, cost, and data governance*

Through adopting a systems approach to asthma care, the research conducted in this thesis sought to establish the perceptions of both patients and healthcare providers towards health monitoring technologies. Whilst the technology would primarily be used by the patient, the monitoring data could also be used by stakeholders and healthcare providers to build up an in-depth and accurate picture of a patient's condition or their medication management.

The perceptions of adolescent patients with asthma, as well as healthy adolescents of a similar age and background, were gathered through two studies. The first examined the attitudes of a sample of adolescents with asthma towards an exemplar EMD, whilst the other investigated the perceptions of healthy adolescents towards location and activity monitoring.

From both studies it was clear that the participants could appreciate the usefulness of the data that could be recorded by the monitoring technologies. The patients with asthma recognised how the adherence data recorded by the SmartTrack device could be used to show their parents or their healthcare providers that they have been using their inhaler properly. They also identified the benefit that the technology could provide in helping them to become more independent and manage their own condition responsibly through using the built-in reminder functionality to help them to remember to take their inhaler, rather than rely on their parents. The healthy adolescents could similarly see the advantages of activity monitoring, as it either reassured them that they were exercising enough, or showed them that they needed to become more active.

Although the healthy adolescents demonstrated that they could see how useful location data could be for a variety of scenarios including healthcare, tracking missing people, criminal investigations, business and marketing, they did raise concerns about this intrusive data source. Some commented that they would try to avoid having their location monitored, whilst others felt that location monitoring was bad, yet was likely to occur whether they agreed with it or not. Phrases such as 'hacking', 'stalking' and 'spied on' were frequently used when participants spoke about their concerns over the data potentially falling into the wrong hands. However, this was not a universal opinion, and a proportion of the

participants felt that the location data didn't give away any bad information about them.

In contrast to the patients with asthma where the key issues were related to the appearance of the device, the healthcare providers and stakeholders gave a wide range of opinions on the potential benefits and costs of new health monitoring technologies. Some of these were related to the patient - they felt that that EMDs could help patients remember to take their inhaler on time which could ultimately lead to better asthma control and an improved quality of life. However, they also raised concerns about the device appearance putting patients off and felt that there may be some resistance from patients which could potentially lead to them being less likely to attend clinic visits, particularly if they had not been taking their inhaler regularly.

Other points raised were related to the work of the clinician, with the ability to have an accurate, detailed record of patient medication use recognised as a benefit that could aid discussions as well as decision making. However, there were also concerns about the time and workload this could add to the consultation process, as well as major questions about who would have responsibilities for data handling and interpretation. Another major concern raised was related to cost, with questions over who would fund this device.

Many of the findings from the three studies include in this thesis can be applied to health monitoring technologies more generally. The concerns raised by stakeholders relating to provision of devices and data governance have implications for other technologies in other conditions where similar issues may exist. Furthermore, the views gathered from the healthy adolescents as well as the adolescents with asthma indicate that this age group may be open to using health monitoring technologies, providing the data is useful for them personally and the device appearance is unlikely to negatively impact on their everyday lives.

7.2.2 What are the requirements of patients and healthcare providers for data-centred health monitoring devices and technologies for asthma care?

Highlights

- *Patient requirements include reducing the size of EMDs, adding customisable colours and ringtones, and making data visible and controllable*

- *Healthcare provider requirements include making software for downloading and interpreting data easy and quick to use and establishing who has responsibility for this data*

A key contribution of this thesis is the production of a set of requirements that EMD developers should look to address for these devices to be adopted and used successfully within asthma care. Whilst these requirements relate to EMDs specifically, there are aspects that can be applied to data-centred health monitoring technologies more generally.

For patients, the requirements assimilated from the research mostly focus on the appearance and usability of the monitoring device. The adolescents with asthma recruited into the first study felt that the SmartTrack was too big and attention grabbing which could lead to unwanted questions. This type of feedback has applications for all health monitoring devices, as it suggests that a device which disrupts the user's everyday life through a conspicuous design may influence how likely they are to use it. This may particularly be the case in adolescents, where ensuring conformity with peers is often a priority (Barrett, 1996).

Additional patient requirements formed from the research relate to the ability to customise the device through adding personal ringtones and adding a range of different colour options. Customisation has previously been found to be a requirement for non-data centred medical devices in adolescents (Lang et al., 2014), suggesting that this could be a good way of making monitoring devices more appealing for this age group.

For the data recorded by the devices, the requirements gathered from this research suggest that it is important to make this information visible to the patient, allowing them to have control over whom their data is shared with, as well as to let them use the data for their own benefit. The adolescents with asthma from the first study liked the idea of being able to show their parents or doctor that they have been using their inhaler correctly, whilst the adolescents in the third study liked being able to view their location and activity data to check up on if they're active enough or need to exercise more.

For stakeholders and healthcare providers, the requirements formed from this research have implications for health monitoring devices where data could be used in clinical consultations. Two key issues relate to data governance and how

to successfully integrate and utilise the large quantities of data produced by these devices within short and time-pressured clinic visits with patients. It is yet to be established where responsibility should lie for downloading, interpreting and discussing data with patients. This is discussed further as a challenge for health monitoring technologies in the following section. The developers of data-centred medical devices should work with the health service to establish how this process can be integrated and should also ensure data is stored securely and confidentially. To help in reducing the time burden on consultations, developers should ensure that software for downloading and interpreting data is simple and intuitive to use.

7.2.3 What are the challenges and opportunities for health monitoring technologies going forward, as they become more widespread and develop new monitoring capabilities?

Highlights

- *EMDs need to be compatible with a wide range of inhaler types*
- *EMDs need to be able to record inhalation and technique, not just actuation*
- *Adding data sources such as location and activity raises even more data privacy concerns and potentially increases the time and workload of the clinician even further*
- *For health monitoring technologies more generally, data security is still a grey area which needs to be formally addressed*

This research has helped identify a number of challenges and barriers that may affect EMDs in the near future. Some issues are related to EMDs specifically, whilst others have implications for health monitoring technologies more generally.

A point raised in both the first and second studies was that EMDs currently have limited compatibility with the wide range of inhaler types available and are typically made for traditional MDIs. In order to accommodate for the varying needs of patients, it is important than EMD developers work on making devices compatible with as many of the main types of inhaler as possible, such as turbohalers, accuhalers and breath-actuated inhalers (Asthma UK, 2016b).

An additional point of concern raised by stakeholders was that EMDs currently only record actuation and do not monitor inhalation or technique. Whilst monitoring actuations of an inhaler can still be a useful indication of how often a patient is taking their medication, it gives no information about how well they

have inhaled it. Poor technique is a commonly occurring problem in asthma patients, with robust evidence pointing to a large proportion of patients having inhalation techniques too ineffective to gain proper benefit from their treatment (Crompton et al., 2006; Lavorini et al., 2008). It is important that EMD developers look to incorporate this type of monitoring, to help identify not only when patients are not taking their inhaler on time, but also when they are not inhaling their medication correctly.

Chapter 5 established that location and activity data are two sources of data that would be useful to integrate with data on inhaler use and could offer insight into a patient's individual triggers for their asthma. Whilst this data could help build up an in-depth picture of a patient's condition, there are issues that may need to be addressed with both patients and healthcare providers. The adolescent participants from the third study showed some concern for location monitoring in particular, with levels of comfort with having this information recorded varying from person to person. For healthcare providers, concerns were raised about how to manage and integrate the large quantities of data produced by EMDs into the consultation process. Adding additional data sources would complicate this further and potentially increase the workload and time burden on the healthcare provider. This may therefore be a considerable challenge for EMD developers if new monitoring capabilities are developed.

For health monitoring devices more generally, the research conducted in this thesis has supported the fact that how health data should be stored, handled, and who should have access to it is still a grey area, with recommendations still being established (Martínez-Pérez et al., 2015). The stakeholders in the second study raised questions about how data should be stored securely and confidentially, and the adolescents in the first and third studies raised concerns about data potentially falling into the wrong hands. Data security is widely recognised as a major challenge for healthcare, with potential risks including damage to patient health and safety, leaking of sensitive and confidential information, as well as unauthorised access to devices and software (Lee, 2015). The research in this thesis helps show how data security is a concern for both patients and healthcare providers and reinforces the fact that this is an important and pressing issue to be addressed for health monitoring devices.

7.3 Contributions of the research

As outlined in Chapter 1, this thesis contributes a new understanding of user requirements for EMDs in asthma management. This both informs future development of these devices, and also supplements the literature on human factors methods that have been applied to the healthcare industry.

Clinically, it introduces a new approach to research on EMDs for asthma. Previous studies have been successful in demonstrating the accuracy and reliability of these devices (e.g. Patel et al., 2012) and showing how they can improve adherence (e.g. Chan et al., 2015). This thesis adds a new understanding of the perceptions of patients and healthcare providers towards these devices. Combining the findings of this thesis with previous research helps to build up a comprehensive picture of how EMDs could be effectively introduced into everyday asthma care. The research methods used could also be replicated in future studies to examine the attitudes of prospective users of EMDs further, as well as in other health conditions where similar health monitoring devices may exist.

For human factors research, it provides a new example of where user-focused research methods have been successfully applied in a medical context. It also helps demonstrate the importance of including these methods to elicit user requirements when designing medical devices. The first and third studies provide support for existing research for engaging with teenagers to elicit their attitudes towards health devices and technologies (Lang et al., 2016), whilst the second study gives a new application of the Delphi technique in a healthcare context (Linstone & Turoff, 2002; Meyrick, 2003). This in turn provides evidence for the use of comparative effectiveness research to engage with stakeholders in the clinical domain (Deverka et al., 2013).

For human factors theory, this thesis provides support for the use of a systems perspective when assessing the introduction of a new medical device (Carayon et al., 2014, 2006; Sharples et al., 2012). This approach emphasises the need to consider multiple user groups, as well as the environment and contexts in which the device will be used - rather than evaluating the device in isolation (Sharples et al., 2012). By examining the views of both patients and healthcare providers and finding that both have requirements that are important to meet for EMDs to be used effectively, this thesis supports 'systems' theory and gives evidence for

the importance of considering the wider context when evaluating medical devices.

7.4 Limitations and future research

The research conducted in this thesis has been an important first-step in assessing the needs and requirements of patients and healthcare providers towards EMDs for asthma management. However, further research is necessary to assess the reliability of the findings. A key limitation of all three studies is that they used relatively small, concentrated samples from the East Midlands, UK. This means the opinions of both patients and healthcare providers may be different in other regions of the country, where the quality of the health services may vary, and different financial and organisational pressures may exist.

The research in this thesis could also be considered limited by only using samples related to the NHS health service in England, UK. Asthma occurs worldwide, meaning EMDs could be used in other countries with different health services. Future research could look to assess the attitudes of patients and healthcare providers in other countries. For example, Africa, India and the Eastern Mediterranean recently ranked highest for prevalence of symptoms of severe asthma in children (Asher & Pearce, 2014).

When investigating the attitudes of patients, future research should look to replicate the methods used in the first and third studies such as interviews, questionnaires, workshops and technology trials. Researchers should look to recruit adolescents with asthma from a variety of different socioeconomic backgrounds, education levels and locations. It is also important that future studies inspect the attitudes and perceptions of other patient groups. In the second research study here, the stakeholders felt that elderly patients may struggle with EMDs, offering a potential future direction for user research with another vulnerable age group.

For healthcare providers, the Delphi method used in this thesis offers a highly replicable study design which can be used with stakeholders and healthcare providers in other regions of the country. The priorities and constraints of clinical commissioning groups (CCGs) will vary greatly around the country, meaning different responses and opinions may be received - particularly from less affluent areas where respiratory medicine is a less developed service.

With computer processing chips getting exponentially smaller and more powerful (Kurzweil, 2014), newer EMDs will become increasingly more sophisticated. It is important that research keeps up with this rapid change and continually evaluates new developments against user needs. As additional research occurs, the model used in Chapter 6 could be used as a reference point to firstly target and direct future research efforts and then to understand how new findings and developments may affect and impact on the asthma care pathway as a whole.

7.5 Future work for the development of EMDs

This research has helped to uncover key steps that need to be taken if EMDs are to be used in asthma care. This section outlines this required work in relation to device design, implementation and evaluation.

7.5.1 Device design

Research conducted in this thesis has shown how developers need to work on improving several aspects of device design. Adolescents in the first study felt that the device was too bulky and attention-grabbing – a view supported by feedback received from healthcare providers in the second study.

Healthcare providers also stated that the device should be able to record inhalation, inhaler sharing, and inhaler technique. Considerable developmental work may be necessary in order to successfully capture all of this data, but some examples do already exist where technique and inhalation have been reliably captured by an EMD (D'Arcy et al., 2014; Holmes et al., 2013; Sulaiman et al., 2016).

7.5.2 Implementation

In the second study, concerns were raised by healthcare providers about how the data produced by EMDs could be integrated into the clinical consultation process without creating an overload of information. Importantly however, the healthcare providers did see the benefit this data could bring for more informed decision making and for aiding discussions with a patient.

Researchers should work closely alongside healthcare standards bodies (e.g. NICE) to determine the most appropriate way in which the data produced by EMDs could be used within the current clinical care process. This would mean developing simple, easy to learn software which can quickly provide a clinician with relevant, useful information on a patient.

It is also important to establish who should be responsible for intervening if EMD data indicates that a patient is putting their health at risk. For example, should this be the responsibility of their GP or their respiratory consultant? Furthermore, at what threshold would this responsibility to intervene become active? If a patient is taking a dangerous amount of reliever medication, such as 10, 20, 30 or more puffs in a day, where on this scale would an intervention be necessary? It is important that this is established and also important that the responsible clinician can be appropriately notified if this sort of situation occurs – rather than having to manually check for each of their patients.

The third study of this thesis also pointed to the potential barriers that might exist for introducing location data as an additional monitoring capability of EMDs. For patients, this type of monitoring may be too invasive and some of the students in the study stated they would avoid it at all costs. More work is needed to understand how location monitoring can be integrated in a way that gives the patient control and visibility over the information that is being recorded about them. This will help ensure it benefits their health and does not negatively affect other aspects of their lives.

7.5.3 Evaluation

Whilst a selection of clinical studies to date have investigated the impact EMDs have on inhaler use (e.g. Chan et al, 2015), more research is needed to determine the types of patients EMDs could have the most significant effect for. It might be the case that EMDs will be most appropriate for patients with severe asthma and would not have a large enough impact for patients with a milder form of the condition.

This is an important issue to address for procurement and purchasing of these devices. Chapter 6 discussed the routes that could be used for purchasing EMDs and considered who should pay for these devices. If they are to be purchased through the healthcare system, it is important we understand the patients they would be most beneficial for. This would help in ensuring the outgoing costs associated with purchasing the devices is outweighed by the savings they create. These savings could be through less wasted medication, fewer hospital admissions and better asthma control.

7.6 Overall Conclusion

This research has been successful in taking established human factors methods for medical research and applying them to a new area - EMDs for asthma management. It provides a new example of a human factors 'systems' approach and additionally contributes to the clinical literature on these devices for asthma. Through doing so, it provides a new angle of research which is important in ensuring EMDs are used appropriately and effectively.

From this research, it is recommended that developers work on reducing the size of EMDs whilst also incorporating the ability to monitor inhalation and technique. Commissioners need to work with clinical researchers to establish the types of patients EMDs would be most beneficial for to reduce risks of over-purchasing. Additionally, EMD developers, researchers and healthcare standards bodies (e.g. NICE) need to collaborate to determine how the data produced by EMDs can be successfully integrated into the clinical care process to support more informed decision-making and discussions with patients.

Data-centred technologies could dramatically change the way we manage health conditions and could also help inform a much deeper understanding of symptoms, triggers and medical treatment. By undertaking research to engage with multiple patients and healthcare providers, we can help ensure that these technologies create positive change, reduce the burden on the healthcare service, and improve the lives of patients.

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Appendices

Appendix 1 Recruitment Poster

Are You Asthmatic and Aged 13-18?

Could you help us by testing out a Smart Inhaler for a month?

You would…

- Use a Smart Inhaler (it simply clips around your normal inhaler)
- Fill out questionnaires and discuss your experience using it.

Interested?

Please get in touch for more information:

Sam Howard
E-Mail: psxsh3@nottingham.ac.uk

Please Note; Travel expenses will be reimbursed for visits outside of your usual care.

Appendix 2 Participant Information Sheet

Participant Information Sheet - Under 16's
(Final version 1.0: 27/11/13)

Title of Study: Investigating the Attitudes of Asthmatic Adolescents towards the 'Smart Inhaler' – a new Digital Health Monitoring Device

Name of Researcher: Sam Howard

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?

Healthcare is on the brink of a revolution. As mobile phones, tablets and laptops form an ever more important part of our lives, new gadgets and 'apps' are being built to help improve our health. In this study we are looking at a new device called a 'Smart Inhaler' and giving it to a group of adolescents aged 13-18 with asthma.

The Smart Inhaler is a plastic case that clips around a normal everyday inhaler. It has a screen to display messages about when the inhaler was last used and can also play ringtones to remind a patient to use their inhaler. It also records whenever the inhaler is used, so someone with access to this information can see how the inhaler has been used over time.

By allowing a group of adolescents to try this device out for a month we hope to find out more about how they feel about the Smart Inhaler and what it can do. This could help make sure that the Smart Inhaler is an effective device for adolescents (an age where Asthma is common) and could successfully improve their management of the condition.

Why have I been invited?

You are being invited to take part because you have been identified as an individual with asthma, who is at the correct age to qualify as a participant in this study.

Do I 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 your parent/guardian

will have to sign a consent form to consent (give permission) to you taking part and you can sign the form to give your assent (agreement) 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 future care.

If you wish for all data up to the point of your withdrawal to be removed this must be specifically requested, otherwise this will still be used in the results of the study.

What will happen to me if I take part?

You will be given a Smart Inhaler to try out for one month. This will clip around your usual inhaler and you will simply use your inhaler as you would usually.

During the month you will need to meet with the researcher on three occasions (these meetings will be in your usual clinic but are likely to occur outside of your usual clinic visit times). The first of these will be when you are first given the Smart Inhaler, the next will be two weeks later halfway through the study, and then you will meet for a final time at the very end of the study.

At these meetings, you will talk about your experience with the Smart Inhaler with the researcher in an informal interview. For example, when you first get a Smart Inhaler this discussion will focus on your initial feelings towards it. Then, on your second meeting this will focus more on your experience with the Smart Inhaler so far. Discussions will be recorded using a Dictaphone (to record voice only, not video).

Time of Study	Activity
Start – First meeting	- Given Smart Inhaler - Questionnaire - Interview/Discussion
Middle – Second meeting	- Meet with Sam Howard at the clinic again - Connect Smart Inhaler to computer to upload information on your inhaler use to the Smart Inhaler website - Questionnaire - Interview/Discussion
End – Third meeting	- Same as second (middle) visit - At the end, you will return the Smart Inhaler and the study will finish.

Finally, you need a parent or legal guardian to also fill out three questionnaires for you as we are also interested in how they feel about the Smart Inhaler. They do not need to attend the meetings but should fill out their questionnaire as close to your meetings as possible.

At the end of the month, you will return the Smart Inhaler and the study will close.

Expenses and payments

Participants will not be paid to participate in the study but travel costs outside of usual care will be paid for.

What are the possible disadvantages and risks of taking part?

The Smart Inhaler will not affect drug delivery, meaning your treatment will remain exactly the same. This will limit both risks and disadvantages to your everyday life and treatment of your condition.

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 explain how it could help you and others in the future.

What happens when the research study stops?

When the one-month trial period stops, you will return your Smart Inhaler and your treatment will remain exactly the same as it was before and during the trial.

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 NHS Complaints. Details can be obtained from your hospital.

Will my taking part in the study be kept confidential?

All information which is collected about you during the course of the research such as Questionnaire, Interview and Error Diary data will be kept **strictly confidential**, stored in a secure and locked office, on a university computer in a password protected folder. Any information about you that leaves the hospital will have your name and address removed (anonymised) and a unique code will be used so that you cannot be recognised from it.

Although what you say in the interview 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.

Data from the Smart Inhalers will only ever be uploaded to the Smart Inhaler online database. This will **only** be accessible to the researcher and there will never be any personal information attached to this information.

Electronic data will be backed up every 24 hours to both local and remote media in encrypted format.

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 unless specifically requested otherwise.

Involvement of the General Practitioner/Family doctor (GP)

We will inform your GP of your involvement in the study. We will not change your treatment prescribed by your GP or hospital specialist; however in the rare event that your asthma deteriorates we will contact your doctor to inform them so the appropriate management can be taken.

What will happen to the results of the research study?

Results from this study will contribute towards the PhD of the co-investigator Sam Howard and may also be used in peer-review journals or presented at conferences. No participant will be identifiable in the results or any publication of the results. Results will always remain grouped and anonymous.

Who is organising and funding the research?

This research is being organised by the University of Nottingham and is being funded by the Horizon Doctoral Training Centre.

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 Nottingham Research Ethics Committee (REC1).

Further information and contact details

Chief Researcher:
Dr Dominick Shaw
Associate Professor and Honorary Consultant
Faculty of Medicine and Health Sciences
Nottingham City Hospital
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Nottingham
NG5 1PB
Phone: 01158231709
Email: dominic.shaw@nottingham.ac.uk

Co-Investigator:
Mr Sam Howard
Human Factors Research Group
The University of Nottingham
University Park
Nottingham
NG7 2RD
Email: psxsh3@nottingham.ac.uk

Appendix 3 Questionnaire Statements

The statements used in the three questionnaires of the study are provided below, categorised by the theme they fall under. Statements 1-5 were used in questionnaire 1, 6-10 were used in questionnaire 2 and 11-15 were used in questionnaire 3.

Statements for the theme 'Ease of Use':

1. The information on the device's screen is easy to read
2. At first glance, the device looks confusing to use
3. I think adolescents would be able to use this device
4. I understand the purpose of the buttons on the device
5. The device looks too complicated and daunting to use
6. The information on the device's screen is easy to understand
7. The screen on the device would benefit from colour
8. The device tells me if it is not working properly or if there is an error that needs fixing
9. I think the letters and numbers on the device's screen are large enough
10. I could use the device
11. At first glance, the device looks easy to use
12. This device would be usable by someone with learning difficulties
13. I think the letters and numbers on the device's screen are bright enough
14. I think it's easy to learn how to use the device correctly
15. I think the buttons on the device are comfortable and easy to press

Statements for the theme 'Social Acceptance':

1. I would take the device to school
2. I think this device would be appealing for teenagers to use
3. I think the device looks cool
4. I would take the device when out socially e.g. cinema, shopping etc.
5. I think I would feel comfortable using this device out in public
6. I'm comfortable using the device in front of very close friends
7. I'm comfortable using the device in front of other friends/classmates
8. I would take the device to a friend's house
9. When at home I use my device in private (e.g. in my room) rather than in the lounge
10. I think other people think the device looks cool
11. I think other people think the device looks fun to use
12. I think adolescents would be embarrassed to use this device
13. I think adults would be embarrassed to use this device
14. My close/best friends know about my device
15. My other friends/classmates know about my device

Statements for the theme 'Portability and Practicality':

1. The device fits comfortably in my hand
2. The device is too chunky to be held comfortably
3. The device is easy to hold e.g. shape
4. The device is easy to hold e.g. grip
5. I think this device is too big
6. The device fits in my school bag
7. It would be an improvement if the device could fit in a jacket or trouser pocket
8. The device is easy to transport

9. A waterproof case for this device would encourage users to take it out with them more often
10. I think the device would stay intact and not break if it was dropped on the floor
11. I think the device is too heavy for it's size
12. I think this device would benefit from a protective case to carry it around in
13. I need to sit down whilst using the device
14. The device is easy to transport
15. I think the device could easily be broken

Statements for the theme 'Aesthetics':

1. I like the colour of the device
2. I like the shape of the device
3. I think the device looks like it is a quality product
4. I think black is a good colour for medical devices
5. I think the device looks scary
6. The device would benefit from customisable decoration
7. The device would benefit from being more stylish
8. The device looks boring
9. I think the device is well designed
10. I think the device feels like it is a quality product
11. I think the device would look better in a different colour
12. I think the colour of this device is too bright and attention grabbing
13. I think the device looks unfriendly
14. I think the device looks modern
15. I think the colour of this device is too dull (and boring)

Statements for the theme 'Data Monitoring':

1. I feel happy with the device recording when I use my inhaler
2. Being able to track my inhaler use with the device would help me feel in control of my condition
3. I would be interested in seeing the long-term trends of my inhaler use available from this device
4. The device recording when I use my inhaler would make me more likely to use it
5. The device recording when I use my inhaler would make me less likely to use it
6. The device's ability to record my inhaler use makes me feel nervous or anxious
7. I would like the device to be able to link to other technologies; such as computers or mobile phones, so that I could keep track of my routine on a non-medical based piece of equipment
8. I like the device being able to keep track of when I use my inhaler for me
9. I feel like the device is 'watching' me
10. I would like to be able to check my inhaler use when I'm at home
11. I think I could use the device to demonstrate how well I stick to my inhaler treatment schedule
12. I think everyone who has Asthma should use a device like this to keep track of their inhaler use
13. I think adolescents would feel comfortable having this device record their inhaler use
14. If I was given the choice, I would use a device like this that records my inhaler use, in the everyday treatment of my asthma
15. I feel happy with the device recording my inhaler use

Statements for the theme ‘Data Sharing’:

1. I think allowing my doctor to see my inhaler use with this device would benefit my treatment and clinic visits
2. Sharing information from this device on my inhaler use with my parents/guardians would help me show them that I’m responsible with my asthma
3. I would want to control who could and couldn’t see information on my inhaler use
4. I would want the data on my inhaler use to only be accessible to me alone
5. Having information on my inhaler use from this device available to my asthma nurse would benefit my treatment and clinic visits
6. I like the idea of being able to see information on inhaler use for other people at my clinic of a similar age if they were also using this device, to compare with my own
7. I would feel happy sharing information on my inhaler use collected by this device with my parents/guardians
8. I would feel happy sharing information on my inhaler use collected by this device with close friends
9. I would feel happy sharing information on my inhaler use collected by this device with my doctor
10. I would feel happy sharing information on my inhaler use collected by this device with my nurse
11. I would feel happy sharing information on my inhaler use collected by this device with other asthma patients
12. I would want to look at information on my inhaler use collected by this device before deciding whether to share it with others
13. I think having control over who can see your personal information is important
14. I think adolescents with asthma would be happy to share information on their inhaler use
15. I think adults with asthma would be happy to share information on their inhaler use

Statements for the theme ‘Communication & Feedback’:

1. I would like it if I could receive feedback on my inhaler use by text message/BBM
2. I would like it if I could receive feedback on my inhaler use by e-mail
3. I would like it if I could receive feedback on my inhaler use by phone call
4. I would like it if I could receive feedback on my inhaler use when I visit my doctor
5. I would like it if I could receive feedback on my inhaler use through an online website that I could login to with my own username and password
6. I would like it if I could receive feedback on my inhaler use in a graph, showing over time days where I have missed doses and days where I have taken all my doses
7. I would like it if I could receive feedback on my inhaler use on a daily basis
8. I would like it if I could receive feedback on my inhaler use on a weekly basis
9. I would like it if I could receive feedback on my inhaler use on a monthly basis
10. I would like it if I could receive feedback on my inhaler use as a simple percentage of how well I have stuck to my treatment plan over a week, a month etc.
11. I would like it if I could receive feedback on my inhaler use when I’m at home
12. I would like it if I could receive feedback on my inhaler use when I’m at my clinic
13. I would like it if I could receive feedback on my inhaler use when I have been sticking to my treatment plan particularly well
14. I would like it if I could receive feedback on my inhaler use when I have been particularly poor at sticking to my treatment plan, as a reminder
15. I would like it if I could receive feedback on my inhaler use through a Smart Inhaler smartphone app

Appendix 4 Interview Guide

Interview 1	Interview 2	Interview 3
1. So now you've had a chance to look at the Smart Inhaler, I want you to imagine you've been given the job of designing a new version of it. What do you think you would change and improve? - Colour? - Shape? - Size? - Why? 2. What sort of age groups do you think the Smart Inhaler has been designed for? - What about for Adults? The Elderly? - So imagine again they've told you to design a new Smart Inhaler that Elderly people would want to use, what would you change and improve? 3. Would you feel	1. Can you explain the order you've put them in for what you have to do? – Why would your first choice be best in your asthma treatment? – Why would your fourth choice be the worst for your asthma treatment? – What do you think your parents would think is the best? – What do you think your doctor would think is the best? 2. Can you explain the order you've put them in for what you get in return? – Why would your first choice be best in your asthma treatment? – Why would your fourth choice be	1. Now you've come to the end of your month with the Smart Inhaler, how have you found using it? 2. If you were to give me the main advantage of the Smart Inhaler and the main disadvantage of the Smart Inhaler, what would they be? 3. What age groups do you think would benefit from a Smart Inhaler? – Any age groups who wouldn't? – Why? 4. How have your family reacted to your Smart Inhaler? 5. How have your friends reacted to your Smart Inhaler? 6. Do you think you have you ever been made of fun or bullied as a result of your

comfortable taking the Smart Inhaler with you to different places? - Can you tell me a situation when you wouldn't feel comfortable? - School? - A friend's house? - When you're out with friends? - Why? 4. If you had your Smart Inhaler with you when you were out with friends, what do you think they would think of it? - Why? - What would they like about the Smart Inhaler? - What would your friends not like about it? 5. So imagine if you started using the Smart Inhaler all the time for your asthma, what do you think it would be useful for? – Why? 6. What do you think to the Smart Inhaler recording when you use your inhaler? – How would it change how you think about your asthma? 7. So imagine if you've been using the Smart Inhaler with your medication for a month. And the Smart Inhaler has recorded whenever you've used your inhaler, who do you think this information	the worst for your asthma treatment? – What do you think your parents would think is the best? – What do you think your doctor would think is the best? 3. Same again for overall	asthma? – Do you think the Smart Inhaler could influence this at all? 7. Have you felt aware of the Smart Inhaler recording your inhaler use over the month? Has this affected you? – Why?/Why not? 8. If you were to use a Smart Inhaler as part of your everyday treatment for your asthma, whom do you think you'd be willing to share information on your inhaler use with? – Parents? – Doctor? – Nurse? – Other family/friends? – Why would you share it with them? – Why do you think it would be good for them to see? 9. Imagine you'd been using the Smart Inhaler, and your doctor could see how often you were using it and wanted to contact you about it. How would you like him to contact you? - Email? - Text? - Through an app? - Website? - Why have you made this choice? - What reasons would you like him to contact you for? Could be if there's concern, could be if you've stuck to your medication really

would be useful for? - Who would you share this information with? - Doctors? Parents?		well to say well done. What sort of messages would you like? - Would there be someone you'd prefer to contact you about your Smart Inhaler use, rather than your doctor? 10. Any final thoughts?

Appendix 5 Delphi survey one example

Date:
Response Required By:

Dear

My name is Sam Howard, I'm a PhD student from the University of Nottingham and I'm writing to you today to try and improve compliance with asthma treatment.

I'd like to understand what you as a healthcare provider or decision maker believe the key benefits and costs are to introducing new digital devices for inhalers into everyday asthma care.

I wanted to write to you personally to briefly introduce myself and explain my research study, as your participation would prove invaluable to my results.

It is very easy for you to take part. There is a pre-paid return envelope included meaning you can fill in the enclosed forms and return them to me free of charge. The task itself should only take you around 15 minutes to complete.

Please take a look at the enclosed information sheet, where further details on this study are provided.

I would be hugely grateful and appreciative of your time and if you have any questions at all, please do not hesitate to contact me. I thank you in advance for your help.
Yours sincerely,

Sam Howard
PhD Student
University of Nottingham
sam.howard@nottingham.ac.uk
07976260408

For every response received a £3 donation will be made to Asthma Research UK (up to a total donation of £250)

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Nottingham Respiratory Research Unit

Key Information.

"What is the purpose of this research?"

To investigate what key stakeholders in asthma care perceive as the main benefits and costs/barriers to introducing Electronic Monitoring Devices (EMDs) into the treatment of asthma (an explanation of EMDs will be provided).

"What will I have to do?"

This study consists of three short surveys, each being completed approximately a month apart. For the first, you will be required to list a minimum of 6 benefits and 6 costs/barriers that you believe could be associated with the introduction of EMDs in asthma.

The second and third surveys will consist of similar tasks to the first but will also have responses from the prior survey fed into them. This means you will be able to see anonymised responses from other participants previous surveys. No personal information will ever be included, seeing other participant's responses is simply a means of creating interaction and allowing you to potentially adjust or refine your responses based on the responses of others.

Ideally the same people will complete all three surveys, however it is appreciated that your time is very limited and any level of contribution is still valuable to this research.

Your participation in this research would be greatly appreciated. If you are happy to take part, please continue to the consent form on the following page.

Data Protection and Anonymity

Your data will be stored in accordance with the Data Protection Act 1998, namely on a password protected drive in a secure facility for a period of seven years from the date of any publication, under University of Nottingham guidelines. It will only be accessible by those directly involved in the research.

You may withdraw consent from the experiment at any time during or after the task for any reason without penalty by contacting me on the address provided. In this event all data will be erased.

All data will be anonymised before publication. Publishing data will result in information becoming available through the Internet to anyone who wishes to access it.

Consent.

Project Title - **Investigating new electronic monitoring devices for asthma treatment**

Researcher's Name: **Sam Howard,** *PhD Student, University of Nottingham*

Clinical Supervisor: **Dr. Dominick Shaw,** *Associate Professor and Honorary Consultant, Faculty of Medicine & Health Sciences, University of Nottingham*

Academic Supervisors: **Prof. Sarah Sharples,** *Professor of Human Factors, Faculty of Engineering, University of Nottingham* **and Dr. Alexandra Lang,** *Research Fellow, Faculty of Engineering, University of Nottingham.*

- I have read the Participant Information on the previous page. I understand and agree to take part.
- I understand the purpose of the research project and my involvement in it.
- I understand that I may withdraw from the research project at any stage and that this will not affect my status now or in the future.
- I understand that while information gained during the study may be published, I will not be identified and my personal results will remain confidential.
- I understand that data will be stored electronically in password protected files so only the experimenter can access them
- I understand that the details of my address will be kept secure and will not be used for any purpose other than this study, where I will receive three sets of correspondence
- I understand that I may contact the researcher or supervisor if I require further information about the research, and that I may contact the Chair of the Research Committee of the School of Engineering, University of Nottingham, if I wish to make a complaint relating to my involvement in the research.

Please sign below to consent to taking part in this research:

……

Contact details if further information is required:

Sam Howard: Sam.Howard@nottingham.ac.uk
Dominick Shaw: Dominic.shaw@nottingham.ac.uk
Sarah Sharples: Sarah.Sharples@nottingham.ac.uk

EMD Information.

Propeller Sensor

SmartTouch AV

The devices above are both examples of EMDs that can be used in conjunction with a patient's normal inhaler; by either clipping on top of the canister or clipping around the plastic actuator.

The key function of all EMDs is to precisely record the exact date and time whenever the inhaler is used.

This data can then be uploaded to a dedicated website where the patient or anyone with granted access can view detailed information on exactly when that individual has been using their inhaler.

Some EMDs possess additional features, such as audible tones to remind a patient when their next dose is due and GPS location tracking to identify the exact location of each actuated dose, to offer indication of particular asthma triggers.

Specific information on the benefits and costs of EMDs has been avoided in this description as much as possible in order to reduce the likelihood of influencing your responses.

Below are some suggestions for things you may wish to think about when deciding on your main benefits and costs/barriers in the following survey:

- Who could use the data collected by EMDs?
- What could the data collected by EMDs be used for?
- How would this wealth of data affect asthma treatment in its current form?
- Could EMDs have a negative impact on asthma care? If so, how?

Please now continue to the start of the survey on the following page

Pt1. Benefits.

As a stakeholder in asthma care please now list at least six benefits you believe EMDs in asthma could have. This could be benefits for treatment of asthma as a whole, or benefits you see EMDs having in your own personal work, for example if you have direct contact with asthma patients.

For each, please provide a brief explanation for why you have chosen it - this may only need to be a sentence or two.

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If you would like to list more, please use the back of this sheet.

Pt2. Costs/Barriers.

Now please list at least six costs or barriers that you believe there could be for the introduction of EMDs in asthma. Again, this can draw on either your own personal experience or asthma care as a whole.

Like before, please provide a short explanation for each to state why you have chosen it.

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If you would like to list more, please use the back of this sheet.

Thank you.

Your participation in this research is hugely appreciated.

Now please use the return envelope to post your 'Consent', 'Benefits' and 'Costs' sheets back to me.

I will post a photocopy of your consent form back to you with the second survey.

You should receive this in around 1 months time

Additional £3 donations to Asthma UK will be made for all responses received for the second and third surveys! (up to a total donation of £250).

Appendix 6 Grouped Benefits

Benefit	Primary Grouped Benefit
Monitor inhaler technique	Ability to Monitor Inhaler Technique would be beneficial
review of technical barriers in device (technique) and often not appreciated is proper priming	Ability to Monitor Inhaler Technique would be beneficial
checking inhaler technique	Ability to Monitor Inhaler Technique would be beneficial
It would be useful if device measured efficacy of inhalation ie. Technique monitoring	Ability to Monitor Inhaler Technique would be beneficial
provide feedback to patients to improve adherence	Aiding Discussions between Clinician and Patient e.g. visual evidence
clinical: feedback to patients about patterns of use of medication eg drop off in use of preventer therapy followed by increased use of reliever therapy due to loss of asthma control	Aiding Discussions between Clinician and Patient e.g. visual evidence
Use for patient education. See usage and symptoms	Aiding Discussions between Clinician and Patient e.g. visual evidence
Focus on importance and role of preventive treatment in asthma management. Promote dialogue based on true events	Aiding Discussions between Clinician and Patient e.g. visual evidence
If used sensitiviely could aid discussion of concordance	Aiding Discussions between Clinician and Patient e.g. visual evidence
patient education	Aiding Discussions between Clinician and Patient e.g. visual evidence
medication reviews would be better informed	Aiding Discussions between Clinician and Patient e.g. visual evidence
An opportunity for frank discussion about the level of adherence that a patient thinks they could achieve	Aiding Discussions between Clinician and Patient e.g. visual evidence
An opportunity for shared goal setting	Aiding Discussions between Clinician and Patient e.g. visual evidence
Once a mutually agreed level of adherence has been achieved, the opportunity for ongoing monitoring	Aiding Discussions between Clinician and Patient e.g. visual evidence
The computer/downloaded data should be discussed together with the patient/family. We do practise open conversations, but seeing things written down or pictorially presented may be more effective in devising an action plan together.	Aiding Discussions between Clinician and Patient e.g. visual evidence
Graphic data presentation would be essential	Aiding Discussions between Clinician and Patient e.g. visual evidence
Would be good for Drs to see the data at appointments and discuss with patient about their asthma plan	Aiding Discussions between Clinician and Patient e.g. visual evidence
Monitor accurate dosing	An Accurate Record of Adherence for Clinicians/Nurses/GPs for Auditing and Review
Reassure clinicians	An Accurate Record of Adherence for Clinicians/Nurses/GPs for Auditing and Review
Adherence	An Accurate Record of Adherence for Clinicians/Nurses/GPs for Auditing and Review
Accurate dosing	An Accurate Record of Adherence for Clinicians/Nurses/GPs for Auditing and Review
track adherence	An Accurate Record of Adherence for Clinicians/Nurses/GPs for Auditing and Review
clinical : more accurate assessment of adherence to preventer therapy	An Accurate Record of Adherence for Clinicians/Nurses/GPs for Auditing and Review
more reliable than questionnaire-based adherence assessment tools eg morisky	An Accurate Record of Adherence for Clinicians/Nurses/GPs for Auditing and Review
Allows doctors to verify adherence to treatment	An Accurate Record of Adherence for Clinicians/Nurses/GPs for Auditing and Review
Disease Monitoring	An Accurate Record of Adherence for Clinicians/Nurses/GPs for Auditing and Review
more accurate measurement of adherence	An Accurate Record of Adherence for Clinicians/Nurses/GPs for Auditing and Review
Let GP know what the child's adherence is	An Accurate Record of Adherence for Clinicians/Nurses/GPs for Auditing and Review

True assessment of usage.	An Accurate Record of Adherence for Clinicians/Nurses/GPs for Auditing and Review
Provide more accurate information about a therapeutic intervention	An Accurate Record of Adherence for Clinicians/Nurses/GPs for Auditing and Review
Monitoring compliance	An Accurate Record of Adherence for Clinicians/Nurses/GPs for Auditing and Review
GP/nurse can see usage	An Accurate Record of Adherence for Clinicians/Nurses/GPs for Auditing and Review
Practice can audit under or over users	An Accurate Record of Adherence for Clinicians/Nurses/GPs for Auditing and Review
Monitor patient treatment adherence	An Accurate Record of Adherence for Clinicians/Nurses/GPs for Auditing and Review
Monitor treatment objectively without need for diary	An Accurate Record of Adherence for Clinicians/Nurses/GPs for Auditing and Review
staff would see if patients are over/under using	An Accurate Record of Adherence for Clinicians/Nurses/GPs for Auditing and Review
An accurate record of medication adherence	An Accurate Record of Adherence for Clinicians/Nurses/GPs for Auditing and Review
A tool to monitor actual adherence achieved against the goals previously agreed	An Accurate Record of Adherence for Clinicians/Nurses/GPs for Auditing and Review
Ability to audit use	An Accurate Record of Adherence for Clinicians/Nurses/GPs for Auditing and Review
Adherence - How much has been delivered, evidence as to whether they are taking the inhaler	An Accurate Record of Adherence for Clinicians/Nurses/GPs for Auditing and Review
Audit/research - Provide numerical evudence for audit/research purposes	An Accurate Record of Adherence for Clinicians/Nurses/GPs for Auditing and Review
Dr/Asthma Nurse benefit: For review can see they are taking medication	An Accurate Record of Adherence for Clinicians/Nurses/GPs for Auditing and Review
Useful to assess how often SABA is used	An Accurate Record of Adherence for Clinicians/Nurses/GPs for Auditing and Review
Drs and nurses can if patients have taken the dose of medication	An Accurate Record of Adherence for Clinicians/Nurses/GPs for Auditing and Review
Monitor when inhaler has been used	An Accurate Record of Adherence for Clinicians/Nurses/GPs for Auditing and Review
Monitor how often inhaler has been used	An Accurate Record of Adherence for Clinicians/Nurses/GPs for Auditing and Review
Can be used to monitor inhaler usage	An Accurate Record of Adherence for Clinicians/Nurses/GPs for Auditing and Review
Improve assessment of compliance - rather than rely on patient telling clinician	An Accurate Record of Adherence for Clinicians/Nurses/GPs for Auditing and Review
Improved quality of life of patients	Better Asthma Control and Improved Quality of Life
improves asthma control - by improving adherence. And improving asthma control may reduce the incidences of exacerbation	Better Asthma Control and Improved Quality of Life
Improved care, because of increased adherence	Better Asthma Control and Improved Quality of Life
reduce symptoms	Better Asthma Control and Improved Quality of Life
Perhaps better Asthma Control	Better Asthma Control and Improved Quality of Life
May help improve asthma control, as long as patient and health professional are honest about it being used	Better Asthma Control and Improved Quality of Life
Inform appropriate choice of device that is accepted for use	Can be used to identify inhaler types that are less likely to be used - find more widely accepted and used inhaler types
Nationwide benefit: Can identify devices which are less likely to be used and weed them out + which ones easier and more likely to be used	Can be used to identify inhaler types that are less likely to be used - find more widely accepted and used inhaler types
Assessing which type of inhalers are less likely to be used by patients - ie the inhaler device type	Can be used to identify inhaler types that are less likely to be used - find more widely accepted and used inhaler types
"Cool"	Cool' Technology may Appeal to Patients
The device may appeal to patients who like the new technology and gadget feel	Cool' Technology may Appeal to Patients
Monitor actuations in inhaler ie. never run out	Could be good for alerting when inhaler is about to run out

Alert - bleep or an alarm when the inhaler is half empty ie. 20 actuations left	Could be good for alerting when inhaler is about to run out
Be good if alarms/signals if drug has expired	Could be good for alerting when inhaler is about to run out
Can be used in conjunction with other types of monitoring, for example electronic ?, peak flows	Could be used with other monitoring techniques e.g. peak flow
fantastic data for "real world" research	Data for Research
to assist in research eg data re adherence; patterns of increased use of relievers and preventers	Data for Research
real-world adherence data for research; real-life monitoring	Data for Research
Collective information -- when linked to disease co-morbidities. e.g. Dose of salbutatmol used in patients with asthma and rhinitis vs patients with just asthma.	Data for Research
information for research	Data for Research
Help to actually correlate benefit to real world usage of inhalers not trials.	Data for Research
Data for research could be available for studies	Data for Research
Within asthma research to validate study results by showing compliance with a particular treatment	Data for Research
Track patterns of use and can be used to help the patient improve adherence - for example adherence decreases in school holidays when there is less of a routine	For Identifying Patterns of Inhaler Use e.g. days, times, school, holidays etc.
patterns of use in time and location might be useful	For Identifying Patterns of Inhaler Use e.g. days, times, school, holidays etc.
Date - to highlight if the drug is taken every day	For Identifying Patterns of Inhaler Use e.g. days, times, school, holidays etc.
Time - Evidence of the time taken, ie. Is it as prescribed	For Identifying Patterns of Inhaler Use e.g. days, times, school, holidays etc.
Knowing the time when inhalers have been omitted may help with strategies to combat this	For Identifying Patterns of Inhaler Use e.g. days, times, school, holidays etc.
When used with salbutamol MDI, the data would be useful to show underuse and overuse of the salbutamol, in relation to an exacerbation of asthma. The frequency it is used at school.	For Identifying Patterns of Inhaler Use e.g. days, times, school, holidays etc.
If used correctly it may give useful information on timing of usage	For Identifying Patterns of Inhaler Use e.g. days, times, school, holidays etc.
Can check times meds taken and compliance of patient	For Identifying Patterns of Inhaler Use e.g. days, times, school, holidays etc.
Monitor times of worsening asthma ie. Day/night symptoms.	For Identifying Patterns of Inhaler Use e.g. days, times, school, holidays etc.
Identify occupational asthma	For Identifying Patterns of Inhaler Use e.g. days, times, school, holidays etc.
Being able to demonstrate patterns of use. This is particularly important for patients who forget to use their inhalers or are unsure of the frequency of use for 'as required' inhalers.	For Identifying Patterns of Inhaler Use e.g. days, times, school, holidays etc.
Beneficial to match 'as required' inhalers with specific environmental/lifestyle triggers more accurately than relying on memory	For Identifying Patterns of Inhaler Use e.g. days, times, school, holidays etc.
GPS to track potential environmental triggers is helpful	GPS could be beneficial in identifying triggers
GPS monitoring to identify triggers could help but may not be accurate if trigger is mobile	GPS could be beneficial in identifying triggers
If had GPS tracker may help to identify triggers	GPS could be beneficial in identifying triggers
Would show if inhaler doses are being wasted - inhaler pressed several times without being taken. 'Dumping' of doses'.	Helpful for identifying dose dumping
identify patients at risk for poor adherence	Identifying 'at risk' Patients with Low Adherence
Pts may use inhalers more and then have better control of asthma	Improve Compliance
compliance of patients	Improve Compliance
Patient Compliance	Improve Compliance

Effective use of treatment	Improve Compliance
Increased adherence. Poor adherence is common in asthma	Improve Compliance
encourage adherance	Improve Compliance
More likely to comply	Improve Compliance
Compliance Enhanced	Improve Compliance
Measuring compliance and concordance in asthma care to increase control	Improve Compliance
emphasises concordance is important	Increase Patient Involvement and Motivation
Patient empowerment, through knowledge of their inhaler useage	Increase Patient Involvement and Motivation
Increase motivation to use inhalers adequately	Increase Patient Involvement and Motivation
The patients can individualise the EMD by selecting their own tune and time of the alarm, which by involving the patient in choice may increase adherence to medication	Increase Patient Involvement and Motivation
Uploadable results may improve patients involvement and interest in their treatment	Increase Patient Involvement and Motivation
Sense of being monitored by the clinical team, increased confidence in the care provided	Increasing Patient Confidence in their Care
patient accountability	Independence, Accountability and Self Management
I comment here on EMDs with broader capability than as adherence tools. i.e. as monitors for lung function, symptom diaries etc. They have the potential to improve self-management. This is the most important impact anything can have on outcomes as particularly with a condition such as asthma, where outcomes are so dependent on patient self-management, this would be important.	Independence, Accountability and Self Management
part of self mamanegement paln	Independence, Accountability and Self Management
If EMD is used in teenagers - helps promote independence instead of relying on parents. Gives them some responsibility, preparing them for adulthood.	Independence, Accountability and Self Management
Develop technology for bio-feedback - long term	Long term - could be used to develop bio feedback
objective data for clinicians to make decisions, not report	More Informed Decision Making for Clinicians
could partially automate decision-making/alerts	More Informed Decision Making for Clinicians
inform clinical management	More Informed Decision Making for Clinicians
Manage risk	More Informed Decision Making for Clinicians
Changes in medication recommended could be based on accurate report of current medication regimen administered	More Informed Decision Making for Clinicians
More direct/accurate decision sharing with patient	More Informed Decision Making for Clinicians
Let parent know what their child's adherence is	Parents can check on their child's inhaler use
Parents could check children/YP have taken medication and then remind if not	Parents can check on their child's inhaler use
Useful for parents monitoring the use of inhalers with older children who are no longer directly supervised when taking their inhaler	Parents can check on their child's inhaler use
Could allow patients and family to be sure the dose was correctly inhaled.	Patient can see their inhaler use from home and know if they are underusing/overusing
Could advise patients of not being well controlled	Patient can see their inhaler use from home and know if they are underusing/overusing
Let child know what their adherence is	Patient can see their inhaler use from home and know if they are underusing/overusing
Prevent inadvertent overdosing if using more than recommended dose	Patient can see their inhaler use from home and know if they are underusing/overusing
patients would see if they were over/under using	Patient can see their inhaler use from home and know if they are underusing/overusing

Patients could access data in comfort of their own home.	Patient can see their inhaler use from home and know if they are underusing/overusing
Helpful if it indicated overuse to patient. Main benefit will be in patient empowerment.	Patient can see their inhaler use from home and know if they are underusing/overusing
Patients can see that they have taken their inhaler	Patient can see their inhaler use from home and know if they are underusing/overusing
patients know that clinicians "believe" them re concordance	Patient has proof of their adherence to share with their Clinician - Increasing Trust
Act as patient reassurance	Patient has proof of their adherence to share with their Clinician - Increasing Trust
Increase trust	Patient has proof of their adherence to share with their Clinician - Increasing Trust
patients would be able to share data with their clinician	Patient has proof of their adherence to share with their Clinician - Increasing Trust
Patient benefit: "proof" at asthma review they have been compliant.	Patient has proof of their adherence to share with their Clinician - Increasing Trust
Patient benefit: May encourage asthma review as have "done well" and will receive praise.	Patient has proof of their adherence to share with their Clinician - Increasing Trust
Positive observation effect: people won't know when they are being watched so are more likely to behave	Patient's Awareness of Monitoring by their Clinician may Improve their Compliance
Motivation to patient as they will know that their usage can be monitored	Patient's Awareness of Monitoring by their Clinician may Improve their Compliance
May make patient take more regularly knowing that they are being checked, therefore reducing symptoms	Patient's Awareness of Monitoring by their Clinician may Improve their Compliance
Promote competition	Promote Competition
Reduced exacerbations Poor adherence is the most common cause of an asthma attack	Reduced Exacerbations
reduce exacerbations	Reduced Exacerbations
decreased cost	Reducing Costs through less wasted medication and less time in hospital
able to prevent/reduce drug wastage hence cost - some patients tend to 'lie' that they have lost their inhalers (when in fact they still have it) so that the pharmacy will make a refill for the patient earlier than it should be. as a result, the patient will have two of the inhalers at that time - a loss for the pharmacy	Reducing Costs through less wasted medication and less time in hospital
reduce HCU	Reducing Costs through less wasted medication and less time in hospital
Safe wastage of prescriptions not used properly	Reducing Costs through less wasted medication and less time in hospital
Reduce cost	Reducing Costs through less wasted medication and less time in hospital
Reduced losses of MDI devices	Reducing Costs through less wasted medication and less time in hospital
Financial - If patient compliant, less time in hospital	Reducing Costs through less wasted medication and less time in hospital
Cost of medication may be reduced, as if the data shows the inhalers aren't being used, it would stop further extra drugs being prescribed to increase control, such as omalizumab	Reducing Costs through less wasted medication and less time in hospital
If asthma control is improved, leads to cost improvements	Reducing Costs through less wasted medication and less time in hospital
Ensuring better adherence to inhaler treatment will have a positive effect on wider health economics e.g. - more patients being well managed.	Reducing Costs through less wasted medication and less time in hospital
Relationship of actual dose to outcomes	Relating Inhaler Use to Health Outcomes and Asthma Control
Relationship of actual dose to adverse effects	Relating Inhaler Use to Health Outcomes and Asthma Control
save time in deciding what factors are related to the patient's current asthma control level - adherence is not something easy to assess without hard evidence	Relating Inhaler Use to Health Outcomes and Asthma Control
Ascertain how adherent a patient is ie. Is their asthma control poor simply because they are not taking ICS or do they need a step up in treatment	Relating Inhaler Use to Health Outcomes and Asthma Control
Relate control to a known amount of medication	Relating Inhaler Use to Health Outcomes and

	Asthma Control
Helpful in establishing if poor control in individual patient is due to poor concordance	Relating Inhaler Use to Health Outcomes and Asthma Control
An explanation of therapeutic failure	Relating Inhaler Use to Health Outcomes and Asthma Control
The data could be used to establish if their asthma control is poor due to reduced adherence to medication or their medication requires escalation to improve control	Relating Inhaler Use to Health Outcomes and Asthma Control
Useful when you're not sure patient is taking medication before stepping up	Relating Inhaler Use to Health Outcomes and Asthma Control
To monitor patients medication use to prevent inappropriate increases in medication when patient is 'poorly controlled' but actually is non compliant	Relating Inhaler Use to Health Outcomes and Asthma Control
Encourage compliance through reminders	Reminding the Patient to Use Their Inhaler
reminders of dosing for patients	Reminding the Patient to Use Their Inhaler
a bonus for patients who are blind and/or memory problems - reminder for them on dosing time	Reminding the Patient to Use Their Inhaler
Allows patients to not forgive controller medications	Reminding the Patient to Use Their Inhaler
Reminders	Reminding the Patient to Use Their Inhaler
reminder is helpful , may improve adherence	Reminding the Patient to Use Their Inhaler
Help the patient to remember to take their ICS i.e. if there is an alarm or a log to let them know if it has been taken that day	Reminding the Patient to Use Their Inhaler
Reminder to take meds	Reminding the Patient to Use Their Inhaler
patients would be reminded to use their preventer	Reminding the Patient to Use Their Inhaler
Reminder for Patient	Reminding the Patient to Use Their Inhaler
The EMD would be useful in patients who forget to take their inhaler, and acts as a reminder, and gets them into a habit of taking their inhaler regularly	Reminding the Patient to Use Their Inhaler
The alarm on the EMD is heard by other members of the family who can prompt the patient to take their inhaler	Reminding the Patient to Use Their Inhaler
Some children would love the fact that devices are being used to remind them to take inhalers as prescribed	Reminding the Patient to Use Their Inhaler
Potential to help patient remember dosing	Reminding the Patient to Use Their Inhaler
Patient benefit: reminder - esp for stable patients who 'forget'	Reminding the Patient to Use Their Inhaler
Patient benefit: positive action alarm goes, meds taken, patient does not feel guilty about forgetting	Reminding the Patient to Use Their Inhaler
Alarm - excellent for people who forget	Reminding the Patient to Use Their Inhaler
Reminder to take inhaler	Reminding the Patient to Use Their Inhaler
Audible tone to remind patient to improve compliance	Reminding the Patient to Use Their Inhaler
Ensuring patients remember to take their inhaler. This is essential to maintenance of their asthma management	Reminding the Patient to Use Their Inhaler
Audible bleep. This is a good way to remind patients.	Reminding the Patient to Use Their Inhaler
Useful information in emergency situations - if a patient arrives at clinic/ED in distress, the information provides the clinician with valuable data.	Useful data for emergency situations
Useful to monitor concordance of different groups of patients on different treatment regimens	Useful to Monitor Adherence of Different Groups of Patients on Different Treatments

Appendix 7 Grouped Costs/Barriers

Cost	Primary Grouped Cost
what if it doesnt work? tech always goes on the fritz and who fixes it?	Accuracy, Reliability and Technical Issues
Clinician concern over use of device ie batteries etc.	Accuracy, Reliability and Technical Issues
Technical problems - unless the device is ?durable the data they provide will be limited	Accuracy, Reliability and Technical Issues
reliability	Accuracy, Reliability and Technical Issues
Info may not be accurate if device doesn't send data	Accuracy, Reliability and Technical Issues
Data collected may be unsuitable if incorrect - ie if device not picking up all information required	Accuracy, Reliability and Technical Issues
How robust are they? They need to be up to being thrown around and chucked in bags or drawers & left in wet steamy bathrooms!	Accuracy, Reliability and Technical Issues
How long does this device last? Does it need replacing or is it used as an initial tool to instill good habits?	Accuracy, Reliability and Technical Issues
EMD is a clip-on and can be taken out anytime, can its generated data be trusted all the time?	Accuracy, Reliability and Technical Issues
EMD is similar to MPR (another adherence assessment tool), except MPR cant tell the exact time the dose is taken and it is free. Not many clinicians will agree to ask their patients to buy an EMD. Even NHS may not agree to subsidize this equipment	Are there better alternatives e.g. Telehealth or Medication Posession Ratio (MPR)?
Nottinghamshire are using FLO - telehealth reminders - is this any better?	Are there better alternatives e.g. Telehealth or Medication Posession Ratio (MPR)?
save the planet! use fewer batteries and less plastic!	Bad for the Environment - Plastic and Batteries
Patients may find it a bit bulky to carry with them	Bulkiness and Appearance may put Patients off
Large design	Bulkiness and Appearance may put Patients off
Looks more bulky - patients may not want to carry this around with them	Bulkiness and Appearance may put Patients off
maybe unattractive to patient eg because if its extra bulk	Bulkiness and Appearance may put Patients off
Bulky devices	Bulkiness and Appearance may put Patients off
Patient may find bulky	Bulkiness and Appearance may put Patients off
Portability - Carrying inhaler around less practicle ie. EMDs are bigger	Bulkiness and Appearance may put Patients off
makes device more bulky	Bulkiness and Appearance may put Patients off
Ugly devices	Bulkiness and Appearance may put Patients off
bulkiness - may be difficult for some patients to actuate	Bulkiness and Appearance may put Patients off
They were not popular with patients, many liked the idea but found the reality of the device too bulky and cumbersome	Bulkiness and Appearance may put Patients off
bulkiness	Bulkiness and Appearance may put Patients off
The inhaler is more bulky and heavy with the monitor	Bulkiness and Appearance may put Patients off
bulky	Bulkiness and Appearance may put Patients off
EMD may make the whole inhaler bulky - not user friendly and may discourage patients to clip it onto their inhaler	Bulkiness and Appearance may put Patients off
size	Bulkiness and Appearance may put Patients off
May further stigmatise patient - not seen to be "cool"	Bulkiness and Appearance may put Patients

	off
Does it need servicing	Cleaning and Maintenance of Device
maintenance	Cleaning and Maintenance of Device
Cleaning - sterilisation process? Effect how EMD works	Cleaning and Maintenance of Device
Pharma may not want to see a system being used which highlights widespread non adherence	Concerns about role of Pharma Companies
whose benefit is this for? drug companies/	Concerns about role of Pharma Companies
I bet this is PHARMA sponsored	Concerns about role of Pharma Companies
Uncertain if available on all inhalers might limit inhaler selection	Concerns if only Compatible with MDI Devices
not available for all medications	Concerns if only Compatible with MDI Devices
EMD is suitable for MDI only, if I'm not wrong. How could it accommodate other types of inhalers? This will be a limitation in the real-world database	Concerns if only Compatible with MDI Devices
May only be able to be used with certain inhaler devices	Concerns if only Compatible with MDI Devices
Only suits MDI devices	Concerns if only Compatible with MDI Devices
Partial data collection as only relevant to MDI	Concerns if only Compatible with MDI Devices
possibly not suitable for all inhalers?	Concerns if only Compatible with MDI Devices
Expense in time outset/setup and tech changes	Concerns over Time and Workload this would add to Consultation Process
Time	Concerns over Time and Workload this would add to Consultation Process
Inclusion in consultation should be easily done - integrated and minimal effort	Concerns over Time and Workload this would add to Consultation Process
The time to download and examine the data collected from the EMDs in clinic may be limited.	Concerns over Time and Workload this would add to Consultation Process
There isn't time in primary care for GP to review data.	Concerns over Time and Workload this would add to Consultation Process
lack of time for shared decisions in consultation	Concerns over Time and Workload this would add to Consultation Process
Doctor´s don´t have enough time to follow up adherence	Concerns over Time and Workload this would add to Consultation Process
Who pays for the increased work in the consultation	Concerns over Time and Workload this would add to Consultation Process
another aspect of asthma care that the doctor has to spend time explaining to the patient	Concerns over Time and Workload this would add to Consultation Process
Would the EMD be single patient use or reused for other patients? - Cost may be an issue	Cost of Devices
Cost!!	Cost of Devices
Cost. Would need to understand full cost vs benefit analysis.	Cost of Devices
EMD itself could be costly, i don't think all patients can afford it. if one patient has 2 inhalers, does that mean he has to buy 2 EMDs?	Cost of Devices
Cost is likely to be a barrier. Quantity and frequency of prescription requests is usually a useful indicator of usage.	Cost of Devices
who pays?	Cost of Devices
Chesterfield CCG has to save 10m - not a hope in persuading them to spend more than if it means long term savings	Cost of Devices
Who funds the device?	Cost of Devices
How expensive is the device	Cost of Devices
Suitable access to download - costs	Cost of Devices
Who pays for the monitoring system?	Cost of Devices
higher financial burden to health care system if more costly device	Cost of Devices

I don't know how much EMDs cost so cannot comment	Cost of Devices
The cost of each EMD may be expensive, may be limited to the more severe asthmatics having them.	Cost of Devices
costs (although these may be reasonable)	Cost of Devices
Lack of evidence vs cost data initially	Cost of Devices
Cost of unit	Cost of Devices
Cost - possibly more expensive to attach the device	Cost of Devices
cost	Cost of Devices
higher financial burden to patient if more costly device	Cost of Devices
Cost	Cost of Devices
increased inhaler costs	Cost of Devices
How much do they cost? Is this cost incurred by the department, GP practise or patient?	Cost of Devices
I would expect the devices to be included in the cost of combined inhalers. The cost is enough as it is.	Cost of Devices
inhalers are already expensive	Cost of Devices
Cost of the device and selecting patients - how could this be managed? Who would pay the costs?	Cost of Devices
Expense	Cost of Devices
What is the cost of this device added to the inhalers themselves?	Cost of Devices
Actual cost of devise	Cost of Devices
cost	Cost of Devices
Cost - More expensive	Cost of Devices
Likely to be more expensive (with additional equipment for download/interpretation)	Cost of Devices
an expensive high tech solution	Cost of Devices
More expense for practice	Cost of Devices
Cost- depends on how much	Cost of Devices
Practicalities - Not compatable with all spacers/breath activated devices	Could interfere with technique or not be compatible with spacer
Is the system compatable with a spacer?	Could interfere with technique or not be compatible with spacer
interference with technique	Could interfere with technique or not be compatible with spacer
data tsunami - who will have time to review all this stuff?	Data Overload
too much data may overwhelm providers and patients	Data Overload
Information overload. The prospect of going through ? Of data does not fill me with enthusiasm	Data Overload
Ease of Use. Would they be suitable for all patients?	Ease of Use - Another thing patients have to learn
Added complexity to inhaler confuse people.	Ease of Use - Another thing patients have to learn
This may be another device the patient has to get to grips with along with the various types of inhaler they may be using	Ease of Use - Another thing patients have to learn
may reduce concordance in elderly	Elderly Patients may struggle with the technology or have a negative attitude towards it
There are older patients with asthma that won´t like technology or the will feel they are spied	Elderly Patients may struggle with the technology or have a negative attitude towards it
Are they accessible to the older generation who may	Elderly Patients may struggle with the

not be quite so ok with using technology	technology or have a negative attitude towards it
The child may have two addresses if parents are separated, and may not carry the device between houses. The cost implication of having 2 EMDs.	EMD may be required for more than one inhaler per patient
Expensive if needs more than 1, if patient has several inhalers	EMD may be required for more than one inhaler per patient
EMD's are specific to be used with certain types of inhaler devices and if medication is changed from a seretide MDI to a symbicort Turbohaler, another EMD (If available) would be required.	EMD may be required for more than one inhaler per patient
Devices need to be easy for the patient to fit so that they can easily be switched over when they change device	EMD may be required for more than one inhaler per patient
If they use more than one inhaler, cost implications if need more than 1 EMD	EMD may be required for more than one inhaler per patient
Has the data they collect been validated? Personal use with an older generation of these devices (on a research study) has been poor. Ranged from recording puffs for patients who had never used them to recording nothing at all when we knew they were definitely used.	Evidence of Effectiveness Required
What evidence is there to support devices	Evidence of Effectiveness Required
Pilot study data for effectiveness required	Evidence of Effectiveness Required
The EMD may have a limited effect as a reminder. How long has the EMD have a sustainable effect as a reminder.	Evidence of Effectiveness Required
Duration of Data Storage	How is data stored and who has access?
data storage	How is data stored and who has access?
FOI access to insurance agencies	How is data stored and who has access?
Access to data. How would clinicians access the data. Would this be secure?	How is data stored and who has access?
Concern about who has access to data	How is data stored and who has access?
How secure is the the data in terms of confidentiality? Who would it be shared with?	How is data stored and who has access?
GPS location - ?? Need for this - does this comply with caldicott rules?! Can see the police might want info!	How is data stored and who has access?
Many who get this device may do so as there are adherence concerns and therefore will show (inevitably) that adherence is poor	Many who get this device may do so as there are adherence concerns and therefore will show (inevitably) that adherence is poor
The idea of 'monitoring' by health care providers. Most asthma patients do not take their medication regularly because they are do not believe they need to, a reminder system will not assist here and certainly using the EMD as a monitoring tool by the HCP would fail. Patients tell HCP what they want them to know, they fail to disclose in a conscious way. If the EMDs are perceived as monitoring tools, this will fail.	May make no difference to already unengaged patients
This would not be an effective tool for all children/families, as some people do not always fully appreciate that effective healthcare is only really achieved by an open, honest, relationship and working together. Patients/families should not just do what they are told, but agree that this is best action to take.	May make no difference to already unengaged patients
Asthmatics are notorious for not attending reviews or taking their asthma seriously - this may not make any difference to an already unengaged patient	May make no difference to already unengaged patients
Patients may feel their clinician is checking up on them and may be put off coming for review	May put patients off coming to clinic particularly if they have failed
may reduce attendance	May put patients off coming to clinic particularly if they have failed
Patients may not attend asthma review if they have "failed"	May put patients off coming to clinic particularly if they have failed

EMD (without additional feature like the beep or GPS) seems to offer benefits more to researchers rather than patients themselves, it will lose its worthiness in the patients' eyes	More Benefits for Researchers than Patients, meaning Patients may fail to see worth
Non adopters - selection bias	Non-Adopters leads to Selection Biases
Over-reliance on data. Need to build a picture of usage from observation/discussion and data.	Over-reliance on data - also need to determine reasons for nonadherence
Whilst they provide some information on adherence they do not determine reasons for poor adherence	Over-reliance on data - also need to determine reasons for nonadherence
will this replace genuine patient empowerment	Paternalistic Approach
Paternalistic Approach to Medicine	Paternalistic Approach
Restriction of Patients Autonomy	Paternalistic Approach
The patient may forget to bring the EMD with them.	Patient may forget to bring device with them to clinic
Not bringing it with them to consultation	Patient may forget to bring device with them to clinic
Big brother watching	Patient may not like being 'watched'
perception of 'Big Brother' watching you	Patient may not like being 'watched'
Big brother concerns	Patient may not like being 'watched'
patient feels being monitored	Patient may not like being 'watched'
people highly resistant to being watched	Patient may not like being 'watched'
Patient might not like being monitored.	Patient may not like being 'watched'
Patient may feel spied on/distrust of doctor	Patient may not like being 'watched'
Intrusion may not be well received. "Big Brother"	Patient may not like being 'watched'
May find intrusive if they feel someone is looking at results	Patient may not like being 'watched'
patients may feel that they are being "watched over" too much	Patient may not like being 'watched'
May be afraid to use inhaler incase someone else thinks they are over using inhaler	Patient may not like being 'watched'
may upset patient to be watched so closely	Patient may not like being 'watched'
Feeling of mistrust between patient and medical team	Patient may not like being 'watched'
Will patients use them?	Patient Resistance or Refusal
Pts refusing to use	Patient Resistance or Refusal
Patient concern over use of device	Patient Resistance or Refusal
patient discomfort	Patient Resistance or Refusal
Patient not using it	Patient Resistance or Refusal
patient resistance	Patient Resistance or Refusal
Nuisance of reminders	Patients may find the reminders a nuisance
More expensive if lost	Patients may lose or break EMD - Expensive to replace
Losing it/expensive to keep replacing	Patients may lose or break EMD - Expensive to replace
Losing it	Patients may lose or break EMD - Expensive to replace
insurance	Patients may lose or break EMD - Expensive to replace
Breakages / Loss replacement	Patients may lose or break EMD - Expensive to replace
Who pays if the device is lost	Patients may lose or break EMD - Expensive to replace
May start to overrely on it and not manage asthma as effectively	Patients may overrely on the device
Careful communication will be required to discuss EMD data with patient/family to avoid conflict	Potential Conflicts

May cause increased conflict in families, especially with YP, regarding non compliance	Potential Conflicts
The patient may not wish to acknowledge non-adherence e.g. because of fear of loss of benefits	Potential Conflicts
May unintentionally irritate patients and increase guilt and non compliance to both taking meds and attending clinic	Potential Conflicts
Potential conflict	Potential Conflicts
Some devices record an actuation rather than the dose actually being taken. Therefore somebody may appear adherent even if they are not.	Records Actuation but not Inhalation, Technique, or identify if Canister is Empty or inhaler is shared
No data about inhaler technique	Records Actuation but not Inhalation, Technique, or identify if Canister is Empty or inhaler is shared
Dose may be actuated but not administered, will not give information regarding technique/administration	Records Actuation but not Inhalation, Technique, or identify if Canister is Empty or inhaler is shared
EMD may not reflect truth of actual drug delivery "Being fooled"	Records Actuation but not Inhalation, Technique, or identify if Canister is Empty or inhaler is shared
Some data may not be reliable. The inhaler has been actuated but did the patient breath in?	Records Actuation but not Inhalation, Technique, or identify if Canister is Empty or inhaler is shared
Accuracy - has the patient actually used the inhaler.	Records Actuation but not Inhalation, Technique, or identify if Canister is Empty or inhaler is shared
Do they measure the dose in each canister - may be unaware of empty canisters.	Records Actuation but not Inhalation, Technique, or identify if Canister is Empty or inhaler is shared
I would want assurance that the device was not open to abuse e.g. removable in order to conceal overuse or inhaler sharing, or pressing device and not inhaling	Records Actuation but not Inhalation, Technique, or identify if Canister is Empty or inhaler is shared
May just click inhaler to stop it rather than use it - yes we do have patients who would do this!	Records Actuation but not Inhalation, Technique, or identify if Canister is Empty or inhaler is shared
Still not sure as to whether they have taken it correctly!	Records Actuation but not Inhalation, Technique, or identify if Canister is Empty or inhaler is shared
Patients who use inhalers incorrectly may continue to use this device incorrectly	Records Actuation but not Inhalation, Technique, or identify if Canister is Empty or inhaler is shared
cannot tell if drug has been shared	Records Actuation but not Inhalation, Technique, or identify if Canister is Empty or inhaler is shared
Some patients only want treatment for symptoms	Some patients only want treatment for symptoms
Some patients will only be adherent when they know they are being monitored	Some patients will only be adherent when they know they are being monitored
Training the staff initially how to use the device, and then showing the parents and child takes time.	Training clinicians and staff on how to use device, how to teach patients and how to interpret results
Clinicians will require training on the use and interpreting of the results	Training clinicians and staff on how to use device, how to teach patients and how to interpret results
Training required on obtaining the data from both patient and nurses/drs	Training clinicians and staff on how to use device, how to teach patients and how to interpret results
Time taken to download and interpret data - whose responsibility would this be?	Whose responsbility is downloading, processing and interpreting the data and discussing with patients?
Who will evaluate the data? Cost of analysis	Whose responsbility is downloading, processing and interpreting the data and discussing with patients?
Some clinicians may not appreciate that the time taken to discuss results together is actually saving time In the future. Who is best professional to discuss data with patient/family? GP, nurse, specialist doctor or other?	Whose responsbility is downloading, processing and interpreting the data and discussing with patients?

Who is responsibe for over use	Whose responsbility is downloading, processing and interpreting the data and discussing with patients?
Who is responsible for under use	Whose responsbility is downloading, processing and interpreting the data and discussing with patients?
Who cares if the patient does not take their treatment	Whose responsbility is downloading, processing and interpreting the data and discussing with patients?
Who will do the printing downloading,IT support	Whose responsbility is downloading, processing and interpreting the data and discussing with patients?
does not address intentional non-adherence	Will not address intentional non-adherence

Appendix 8 Letter to parents

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CENTRE FOR DOCTORAL TRAINING

The University of Nottingham
UNITED KINGDOM · CHINA · MALAYSIA

18/11/2015

Dear Parent(s)/Guardian(s),

My name is Sam Howard, I am a PhD student at the University of Nottingham, carrying out some research with students at The Long Eaton School Sixth Form.

Both the Head of Sixth Form, Mr Caton, as well as the Head Teacher, Mr. Calvert, have given their approval for this work to go ahead and believe it could offer a beneficial insight for students into University research.

I will be running two workshops with students over the coming weeks and will also be offering students the opportunity to try out some new technology. The study is looking to investigate the attitudes of teenagers towards monitoring of location and activity data.

You are receiving this letter because your child has decided to take part in this research. If you would like to learn more about the study, please feel free to read the information sheet that they have been given.

You can also learn more about my research and that of my fellow PhD students by visiting www.horizon.ac.uk/About-the-CDT or by visiting my personal webpage http://www.nottingham.ac.uk/~psxsh3/

If you have any questions at all, I would be glad to answer them for you. You can get in touch with me at the e-mail address or mobile number provided below.

Yours Sincerely,

Sam Howard
PhD Researcher
Horizon Centre for Doctoral Training
University of Nottingham
Tel: 07976260408
E-mail: sam.howard@nottingham.ac.uk

Appendix 9 Participant information sheet - school workshops

Participant Information Sheet
Location and Activity Data Workshops

Name of Researchers: Sam Howard (PhD Student) and Sarah Sharples, Dominick Shaw and Alex Lang (Supervisors).

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.

What is the purpose of the study?

Our smartphones and electronic devices record a vast amount of information about who we are, the things we do, the places we visit and our everyday habits. The amount of data being generated is hard to comprehend.

For every minute of every day there are…

4,000,000 searches on Google

2,460,000 pieces of content shared on facebook

347,000 photos sent on WhatsApp

The types of data we record is growing too. With technology becoming ever-smaller and more efficient, there has been a huge rise in the number of 'wearable' devices people use to capture information about themselves on an everyday basis. Fitbit, Jawbone and Nike are just some of a host of different companies offering devices that can monitor your step count, calories burned and distance travelled so you can monitor this yourself or share it and compete with friends and family.

Our phones are also capable of recording highly accurate information on the places we've visited. Many phones now do this automatically whenever you take a photo and many apps ask for your location whenever they are opened.

Data on your location and your daily activity has a variety of potential uses. But how aware are we of what this information looks like and what it could potentially say about us? What could be the benefits and what could be the consequences of sharing it? How much control should we have over it?

Through two workshops and a trial of some monitoring technology, this study is looking to investigate the attitudes of teenagers towards this type of data.

Do I 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. Once the research starts, you are still free to withdraw at any time and without giving a reason.

What will happen to me if I take part?

You will take part in two workshops with fellow students from your school where you will participate in a series of discussions and tasks that will focus on the topic of monitoring location and activity data. The workshops will be very open and you'll be encouraged to freely talk about your opinions.

Between the two workshops, you will be offered the chance to try out some technology that can monitor your location and activity. You'll get to use this technology for five days and for another five days you'll be asked to manually record your location and activity data in a paper-based diary.

Your data will be kept confidential and will not be shared with your classmates, teachers or parents. During the second workshop you will receive a print-out of your location and activity data for you to look through, but this will be given to you alone and does not need to be shared with anyone.

To help document the research, photos may be taken during the workshops. If you would prefer to not be photographed, you will be given the option to step out of any photos before they are taken. Parts of the workshop will also be audibly recorded, so that the researcher can listen back to the topics discussed and report on the findings.

What happens when the research study stops?

The research study will end when you have completed an online questionnaire after the second workshop. After completing this questionnaire, you will receive a certificate of participation. There will be a follow-up presentation arranged with the school for the researcher to come and talk about the findings of the study at a later date.

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.

All information which is collected about you during the course of the research such as your location and activity data will be kept **strictly confidential**, stored in a secure and locked office, on a university

computer in a password protected folder. Any information about you that leaves this office will have your name removed (anonymised) and a unique code will be used so that you cannot be recognised from it. Location data recorded in this study will only be used by the researcher and **will not** be shared with others, such as Teachers or Parents.

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.

Who is organising and funding the research?

This research is being organised by the University of Nottingham and is being funded by the Horizon Doctoral Training Centre.

Further information and contact details

Mr Sam Howard
Human Factors Research Group
The University of Nottingham
University Park
Nottingham
NG7 2RD
sam.howard@nottingham.ac.uk

Location and Activity Workshops

Worksheet

9th December 2015

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1. Data Reports

Please take a look through your own personal data report, looking at both the location data and the step count data recorded by the Fitbit. Then answer the following questions….

6) **Please describe your initial reaction after looking through your location data. Is it as you expected? Has anything about it surprised you?**

7) **Now please do the same for your initial reaction to your activity (step count) data…**

8) **Please describe how aware you felt of being monitored during the trial. Did this affect or change your behaviour at all? Give examples if possible.**

9) **Have your attitudes towards location monitoring changed after viewing this data? If so, how?**

10) **Have your attitudes towards activity monitoring changed after viewing this data? If so, how?**

2. Participant X

Each of you has been given an additional data report for 'Participant X'. You have also been given a sheet giving a short description of 3 students. Please have a read of the bios for each of these students, and then look through the Participant X data report, before answering the questions below.

Which student do you think the data belongs to?

Please explain what it was in the data that made you decide that it belonged to the student you chose above:

Now look back over your own personal data report… how much does it say about you? Would you have concerns if someone was to look through your own location and activity data?

3. Tech vs. Diary

During this research you have spent a week having your location and activity data monitored automatically through technology, and another week manually recording this information in a paper diary. The following questions will ask for your thoughts on these two separate methods…

Imagine you suffer from severe asthma and your Doctor would like to monitor the places you visit and the places you use your inhaler to investigate what might be causing your attacks (e.g. pollen, pollution), and your exercise/activity levels to see how these could also affect your health…

Explain the potential benefits of recording this data manually in a diary:

Explain the potential costs/negatives of recording this data manually in a diary:

Now explain the potential benefits of having this data recorded automatically using technology:

Finally, explain the potential costs/negatives of recording this data automatically using technology:

4. Location & Activity Data

5 most important benefits of Location tracking…

1.
2.
3.
4.
5.

5 most important costs/negatives of Location tracking…

1.
2.
3.
4.
5.

5 most important benefits of Activity tracking…

1.
2.
3.
4.
5.

5 most important costs/negatives of Activity tracking…

1.
2.
3.
4.
5.

Appendix 11 Participant X Data Report

Location and Activity Data File

Participant X

25/11/15 – 29/11/15

Total Steps

40,625

Best Day Step Count

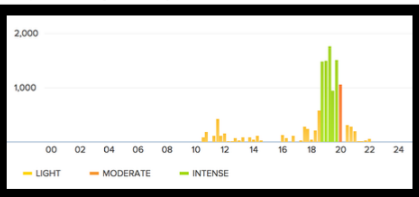
12,586

Wednesday 25th November

Participant X

Location – Overall Journey and Points of Interest

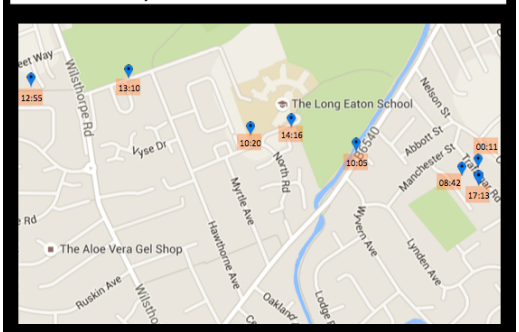
Activity – Step Count Throughout the Day



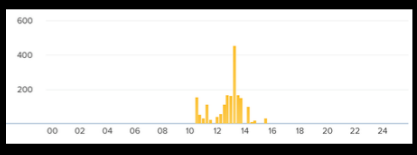
Thursday 26th November

Participant X

Location – Overall Journey and Points of Interest



Activity – Step Count Throughout the Day

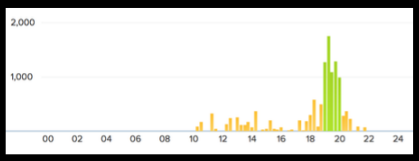


Friday 27th November

Participant X

Location – Overall Journey and Points of Interest

Activity – Step Count Throughout the Day

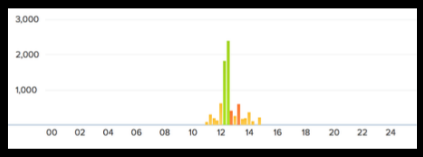


Saturday 28th November

Participant X

Location – Overall Journey and Points of Interest

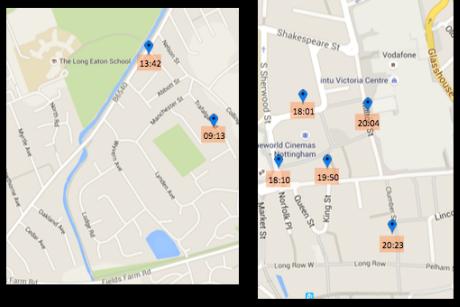
Activity – Step Count Throughout the Day



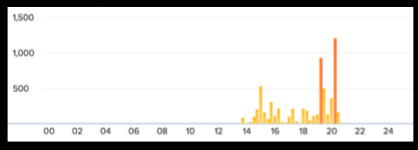
Sunday 29th November

Participant X

Location – Overall Journey and Points of Interest



Activity – Step Count Throughout the Day



Produced by Sam Howard, University of Nottingham for students at Long Eaton School. For questions, contact sam.howard@nottingham.ac.uk

Appendix 12 Example 'Future Me' responses