The impact of current peri-operative care on outcomes for patients with hip fracture

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Abstract

Background: Fragility hip fractures among the elderly constitute a significant global public health problem. The disease is devastating for both patient and the family, often resulting in reduced mobility (disabling), increased reliance on others, diminished health and quality of life, and sometimes death. Thirty-day and one-year mortality rates are high. Postoperative morbidity and 'delayed discharges' are frequently cited with an average length of hospital stay of 19.5 days.

Aim: This project aimed to assess impact of current perioperative care on patient outcome after hip fracture surgery.

Methods: A systematic review was performed to identify currently available risk stratification tools used in hip fracture patients. The NHFS and SORT scoring tools were evaluated and recalibrated. A mixed methods study to identify public (patients, relatives and healthcare professionals) perceptions on factors delaying discharge was conducted and a cohort follow up study of 341 patients to develop and validate a Hip Fracture postoperative morbidity survey tool (HF-POMS).

Results and conclusion: The NHFS and SORT performed better than other risk stratification tools in the literature; however, they both needed further validation. Five key factors of importance identified by the public affecting LOS were; medical conditions (both prefracture comorbidities and postoperative complications), age and frailty, the recovery process (mobility and rehabilitation) psychological aspects and social factors. A

12- domains validity tool (HF-POMS) was developed with kappa interrater reliability of 0.68. High morbidity presence was seen in the following domains; renal, assisted ambulation, pain and infectious. Presence of any morbidity on postoperative days 8 and 15 was associated with subsequent LOS of 3.08 days (95% CI 0.90 – 5.26, p= 0.005) and 15.81 days (95% CI 13.35 – 18.27, p = 0.001) respectively. The average LOS was 16.9 days. The HF–POMS is a reliable and valid tool for measuring immediate postoperative complications in hip fracture patients. Many patients remained in hospital for non-medical reasons.

Published papers arising from the thesis

Marufu TC, Mannings A, Moppett IK. Risk scoring models for predicting peri-operative morbidity and mortality in people with fragility hip fractures: Qualitative systematic review. Injury 2015;46(12):2325-34. doi: 10.1016/j.injury.2015.10.025. Epub 2015 Oct 21

Marufu, T. C. White, S. M. Griffiths, R. Moonesinghe, S. R. Moppett, I. K. Prediction of 30-day mortality after hip fracture surgery by the Nottingham Hip Fracture Score and the Surgical Outcome Risk Tool. Anaesthesia 2016;71 (5): 515-21

Planned Publications

Towards a 'gold' standard in identification, quantification and measurement of morbidities post-surgery - postoperative morbidity survey (POMS) clinical utility systematic review.

Short-term morbidity factors associated with length of hospital stay (LOS): development and validation of a Hip Fracture postoperative morbidity survey (HF-POMS).

Factors influencing postoperative LOS after fragility hip fracture surgery: public perceptions – a mixed methods study.

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List of Abbreviations

ASA PS	American Society of Anaesthesiologists Physical Status
ASAP	Anaesthesia Sprint Audit of Practice
AUROC	Area-under Receiver Operation Curve
CAS	Cumulative Ambulation Score
CCI	Charlson Comorbidity Index
CI	Confidence Intervals
CT	Computer Tomography
CRD	Centre for Review and Dissemination
CPOMS	Cardiac Postoperative morbidity score
DHS	Dynamic Hip Screw
DVT	Deep vein thrombosis
E-PASS	Evaluation of estimation of physiologic ability and surgical stress
GA	General Anaesthesia
HF – POMS	Hip Fracture Postoperative morbidity survey
H-L	Hosmer Lemeshow
HCP	Healthcare Professionals
HipPEN	Hip Fracture Peri-operative Network
HR	Hazard Ratio
IMHS	Intramedullary Hip Screw
LOS	Length of stay
MDT	Multidisciplinary team
MICE	Multiple imputation by chained equation
MRI	Magnetic Resonance Imaging
NCEPOD	National Confidential Enquiry into Patient Outcome and Death
NICE	National Institute of Clinical Excellence
NHS	National Health Service
NHFD	National Hip Fracture Database
NHFS	Nottingham Hip Fracture Score

NUH	Nottingham University Hospitals
NMS	New Mobility Score
NSAIDS	Nonsteroidal anti-inflammatory drugs
O/E	Observed/Expected ratio
OR	Odds Ratio
O-POSSUM	Orthopaedic Physiological and Operative Severity Score for EnUmeration of Mortality and Morbidity
POMS	Postoperative morbidity survey
POD	Postoperative Day
POSSUM	Physiological and Operative Severity Score for EnUmeration of Mortality and Morbidity
PROMS	Patient Reported Outcome Measures
RDW	Red blood cells Width
RCT	Randomised controlled Trials
ROC	Receiver Operating Curve
RR	Risk Ratio
SIGN	Scottish Intercollegiate Guidelines Network
SORT	Surgical Outcome Risk Tool
STH	Sheffield Teaching Hospital
UHL	University Hospitals of Leicester

CHAPTER 1

Background

1.1 Introduction

Global Context

Fragility hip fractures among the elderly constitute a significant global public health problem. The disease is devastating for both patient and the family, often resulting in reduced mobility (disabling), increased reliance on others, diminished health and quality of life, and sometimes death [1]. It is estimated that the world-wide incidence will surpass 6 million by 2050 [2]. Largely due to the growing in number of the elderly [3], which is greater than the modest reductions in hip fracture incidence [4]. Hip fracture is associated with an increased risk of mortality and morbidity in this population group [5-7] .

Current rates show 30 day mortality range from 1 - 12 % and 1-year mortality range between 12 – 38% [3 8] depending on location and patient characteristics. There is an apparent gender difference; mortality rates are higher in men than in women. Results from a meta-analysis [9] of prospective studies showed a higher relative hazard mortality in men compared to women at 3-months after hip fracture (7.95 (95% CI 6.13 – 10.30 in men and 5.75 (95% CI 4.94 - 6.67) in women). It is estimated that between 24% and 75% will not return to their pre-fracture level of independence [10]. Inevitably there is a rise in the need for and utilisation of, orthopaedic, surgical/medical and rehabilitation hospital beds and other healthcare costs [2] as healthcare systems struggle to meet the demands for services in the face of ever increasing economic constrains.

UK Context

In the UK, hip fracture represents a high volume of common serious injury in older people, with a life risk of approximately 17.5% and 6% for white women and men respectively [11]. Around 76 000 patients sustain a hip fracture every year in the UK [11], and numbers are predicted to rise, in keeping with the global data [12]. More than 20% of the National Health Service (NHS) orthopaedic bed occupancy is due to hip fractures [8]. The total yearly estimated cost is around £1.4 billion (1% of the NHS budget), and this figure doubles when the social care and related dependency costs are taken into consideration [12].

Average length of hospital stay (LOS) in days for a hip fracture patient in an acute orthopaedic ward is 15.8, 19.1 and 12.4 for England, Wales and Northern Ireland respectively. When accounting for super-spells the figures increase to 23.1, 30.2 and 34.9 respectively[11] using over 1 million inpatient days [12]. Hip fracture is a devastating injury representing a huge social, medical and financial burden in the UK.

1.2 Purpose/Scope of the study

It is assumed that optimal approach to address the increasing number of fragility hip fracture is to focus attention on prevention. Advanced age and frailty are recognised risk factors for hip fracture [13]. Bone-mass density and quality are reduced with ageing and complicated by a range of risk factors leading to osteoporosis for people 50 years and above[1] . Other clinical risk factors such as falls and fear of falling, lack of physical

exercise, living in an institution, impaired cognitive function and impaired health have been reported as predictors of long-term risk of hip fracture[14].

However, a complete hip fracture risk prevention and reduction discussion is beyond the scope of this project. Rather, with the view that the age of the population is increasing at a greater rate, such that current projections suggest that the number of hip fractures will increase by 25-75% in the next 25 years [12], it is unlikely that efforts to prevent these injuries, on their own, will have a substantial effect in the foreseeable future. Therefore, it is imperative that medical practices are continually refined with the goal of improving patients' outcomes. Provision of optimal clinical treatment and care for the patient who had experienced such a fracture is the focus of this project. Successful implementation of key care priorities for hip fracture patients as outlined in the National Institute for Health and Clinical excellence (NICE 2011) guideline 124 [15] , which include prompt intervention, may prevent development of some complications related to hip fracture. If they (complications) do occur and are identified earlier on, they may be resolved with appropriate and timely clinical management.

1.3 Hip Fracture Peri-operative Care Key Priorities for Implementation

Peri-operative care period refers to pre-, intra-, and post-operative stages of the patient's surgical journey [16]. This begins from the point the patient

is admitted to hospital, and continues when taken to theatres for surgery, post-operative care and discharge. A large number of hip fractures are easily diagnosed on the bases of clinical findings and standard radiographs, although in some cases patients report hip pain with no fracture observed on X-rays [17]. The current clinical NICE guidelines [15] on hip-fracture management outline that if hip fracture is suspected, a magnetic resonance imaging (MRI) scan should be performed despite negative anteroposterior view of the pelvis and lateral hip X-rays. If the MRI is contra indicated or not available for more than 24 hrs, a computer tomography (CT) scan should be considered. The overall primary goal of treatment is for the patients to return to their pre-fracture functional level. For most patients with hip fracture this is best attained with surgery, followed by early mobilisation in an attempt to prevent the complications associated with prolonged recumbence [17].

The key peri-operative care priorities for implementation in hip fracture patients as outlined by the NICE guidelines [15] are as follows:

- Diagnosis (imaging options)
- Timing of surgery
- Analgesia
- Anaesthesia
- Surgical procedures
- Mobilisation strategies
- Multi-disciplinary team

The individual items will further discussed in detail.

1.4 Research Questions:

- Are there robust associations between peri-operative care, perioperative risk measures and outcome in hip fracture in contemporary clinical practice?
- Is it possible to reliably define and collect relevant post-operative morbidity in patients with hip fracture?

Aim: To evaluate and outline the use of measures of perioperative risk and impact of current peri-operative care on outcome in hip fracture patients. This will be achieved in four stages;

i. Systematic Review of risk stratification and risk scoring tools currently used in hip fracture patients to identify patients at low/high risk of mortality and morbidity. From the results, the best evidence tool for use will be recommended as an audit tool for use across healthcare institutes.

ii. Recalibration and comparative analysis of two risk-scoring tools (Nottingham Hip Fracture Score (NHFS) and the Surgical Outcome Risk Scoring Tool (SORT)). This will be done through epidemiological statistical data analysis using data from the National Hip Fracture Database Anaesthesia Sprint Audit of Practice (NHFD, ASAP) and Hip Fracture Peri-operative Network (HipPen).

iii. An exploratory mixed methods multicentre observational clinical study to investigate factors perceived by stakeholders (patients, relatives

and healthcare staff) to influence length of hospital stay (LOS) in hip fracture patients

iv. Development and validation of a Hip fracture Post-Operative Morbidity Survey score tool (HF-POMS) for the identification and quantification of postoperative morbidity after fragility hip fracture surgery.

1.5 Peri-operative care priorities

1.5.1 Hip Fracture Diagnosis

A vast number of proximal hip fractures are readily diagnosed by plain x-ray radiography. Patient history of a fall(s), that led to a painful hip, inability and/difficulty to walk or an externally rotated limb could be surrogate diagnostic markers of a hip fracture [18]. However, a normal x-ray does not necessarily rule out fracture of the hip, which is plausible in approximately 1% of cases.

Advanced imaging is recommended and magnetic resonance imaging (MRI) is currently the most favoured investigation of choice where matters of doubt arise for diagnosis of presumed hip fracture not apparent on initial radiographs [15 18 19]. There is moderate evidence for MRI use compared to other additional imaging options. Five studies [20-24] evaluated the use of MRI to assess for proximal fractures in patients with a clinical history consistent with fracture but negative radiographic films. The studies reported the ability of MRI to successfully identify fractures in the elderly and the cause of hip pain other than hip fracture. Radioisotope bone scan anytime from 12 hours after injury onwards could be

considered. Lee and colleagues [25] assessed the sensitivity of this type of imaging in detecting occult hip fracture. The MRI was found to provide diagnosis earlier than the bone scan, which is more acceptable considering the emergency nature of hip fracture. Considering cost implications, 'limited' MRI, which can be obtained at a lower cost and shorter duration than standard MRI at the same time giving accurate diagnosis is recommended. Where MRI is not available the bone scan can be used. CT scan diagnosis is not highly recommended due to potential radioactive exposure harm [15].

1.5.2 Timing of Surgery

Timing of surgery (time of diagnosis to the time anaesthetic procedure is initiated), is an imperative component of hip fracture care and has been considered to be an early marker of patient progress following injury [15]. Across the globe, current guidelines for hip fracture treatment recommend early surgery[15 26],which has been associated with better functional outcome, shorter hospital stay, shorter duration of pain and lower rates of non-union, mortality and morbidity [27 28]. However, this recommendation has been noted to be one of the major challenges to individual health care systems even within the most technologically advanced systems. The challenge stems from resource requirements. Emergency fragility fracture surgery involves multidisciplinary co-ordination between the accident and emergency departments, acute orthopaedics trauma services, ortho-geriatricians, anaesthetists as well as

the availability of appropriate theatre space with trained staff and relevant equipment [15].

Moreover, in some patients delay to surgery is inevitable. One theoretical advantage, which could sometimes be a legitimate rationale of allowing a delay from admission to surgery is the required time allowance for patient physiological stabilisation and more time for assessment [29] thereby decreasing the risk of perioperative complication [27]. Many elderly patients admitted with hip fracture are significantly frail and present with a concoction of pre-existing co-morbidities some of which might be life threatening [30]. Outlined below are some of the common findings in hip fracture emergency admissions:

- Anaemia
- Anticoagulation
- Hypovolaemia
- Electrolyte imbalance
- Uncontrolled Diabetes
- Uncontrolled heart failure
- Correctable cardiac arrhythmia or ischaemia
- Acute chest infection
- Exacerbation of chronic chest conditions

Early intervention to resolve these problems with the hope of optimising the patient within 24 hours after admission must be a priority. For example, fluid and electrolyte resuscitation should begin immediately after assessment, taking into account the deficits that have already been

accumulated since the time of injury and the ongoing requirements from preoperative fasting. Fluid replacement should therefore be more aggressive than providing simple maintenance requirements [31].

Three most recent systematic reviews [28 29 32] have demonstrated that early surgery is significantly associated with a lower risk of death , relative risk (RR) 0.81 (95% confidence interval [CI] 0.68-0.96, p=0.01) [28], pooled odds ratio (OR) 0.74 (95% CI, 0.67-0.81; p<0.000) [32] , lower rates of postoperative pneumonia RR 0.59 (95% CI 0.37-0.93; p=0.02) and pressure sores RR 0.48 (95% CI, 0.34-0.69; p <0.001) OR 0.48 (95% CI, 0.38-0.60; p<0.000), reduction in hospital stay and complication[28].

The review by Simunovic et al [28] had 16 observational studies that met their inclusion criteria with a total number of 13 478 patients. The other two papers [29 32] had 25 and 35 studies each and a total number of 282 470 and 191 873 patients respectively. There were no randomised controlled studies found in all the three reviews. Based on current evidence, surgery conducted before 24-72 hours is associated with the above outlined postoperative outcomes after hip fracture surgery.

1.5.3 Anaesthesia

Surgery is the main treatment after hip fracture, and the elderly frail population with its multiple comorbidities, is at most risk of developing anaesthesia related complications. Currently in practice two types of anaesthesia available are general and spinal/epidural. Several studies have compared outcome measures; mainly 30 day mortality between

patients receiving general anaesthesia (GA) compared with spinal anaesthesia.

GA refers to the use of various intravenous and or inhalation agents to render the patient unconscious [33]. The patient may breathe spontaneously or require mechanical ventilation following the administration of neuromuscular paralysing drugs. The following potential complications have been observed in GA use:

- adverse reaction to the drugs used
- difficulty in maintaining or establishing airway
- intraoperative hypotension
- aspiration of gastric contents
- post-operative nausea
- respiratory depression
- damage to the teeth and or upper airway

Regional anaesthesia could be epidural or spinal. This method of anaesthesia refers to the injection of a local anaesthetic agent (sometimes in combination with opioid painkillers) into the epidural or subarachnoid space. Spinal anaesthesia is the most commonly used method in hip fracture surgery[33] . Potential complications observed/identified include;

- hypotension
- inadequate regional block
- damage to local structures

- headaches secondary to leakage of cerebral fluid from dura puncture site

Currently, no consensus exist as to which is the best method of anaesthesia for hip fracture surgery and professional guidelines are unable to recommend one method over the other with confidence, such that a wide spectrum of techniques continue to be used by anaesthetists. NICE recommend anaesthetists to offer patients a choice of spinal or general anaesthesia after discussing the risk of patients and benefits, and a consideration of intraoperative nerve block for all patients.

The most recent review by Parker and colleagues on comparison between the two types of anaesthesia consists of twenty-two randomised control trials (RCTs) with 2567 patients undergone hip fracture surgery. Regional anaesthesia showed an association with a mild reduction in deep vein thrombosis (DVT) incidence and lower mortality at one month after operation. No significant differences observed on three months mortality rate. The review concluded that, based on the currently available data, there was insufficient evidence to determine the superiority of one type of anaesthetic over the other [33].

In a more recent study [34] the authors analysed a large dataset of 65 535 patients assessing outcome by mode of anaesthesia after hip fracture surgery. Previously, no large observational study has examined this issue using a national dataset. This data is compiled as part of the national audit by the NHFD [11]. There were no significant differences observed in either cumulative five day (2.8% Vs 2.8%, p=0.99) or 30 day (7.0% Vs

7.5%, p=0.053) mortality between patients receiving GA and patients receiving spinal anaesthesia. Similar results were observed in a retrospective study by Rashid *et al* [35]. The study looked at 194 patients who had dynamic hip screws (DHS) (107 received GA and 87 received regional anaesthesia). No statistical significant differences in all the outcomes; rates of wound infection, length of stay (LOS), post-op ambulation status, intra-op blood loss, post-op complications and mortality between the two groups. Regional anaesthesia was positively correlated with shorter operative duration.

In an American study [36] that reviewed 18 000 patients undergoing surgery for hip fracture across 126 hospitals in New York, they tested the association of regional versus GA with inpatient mortality as a primary outcome and pulmonary and cardiovascular complications as secondary outcomes. Twenty-nine percent of the total patients received regional anaesthesia. Unadjusted rates of mortality and cardiovascular complications did not differ by anaesthesia type. However patients receiving regional anaesthesia experienced lower rates of pulmonary complications 6.8% Vs 8.1%. After adjusting for confounders regional anaesthetic showed an association with lower mortality OR 0.71 (95% CI 0.54-0.93, p=0.014) and pulmonary complications OR 0.75 (95% CI 0.64-0.89, p<0.001) in relation to GA.

Given the current conflicting results among several studies there remains an uncertainty about whether general or spinal anaesthesia is most beneficial during restorative surgery in terms of outcome [34]. There is a

call for anaesthesia research to redirect focus away from mortality and complications only which are and/or might be influenced by other numerous non-anaesthetics factors, and consider outcomes that maybe more directly attributed to type of anaesthesia. Considering that the last systematic review [33] used in the formulation of current NICE guidelines was performed more than 10 years ago, an update review should be considered, with an aim of not just including RCT studies only, but also current observational studies using national datasets.

1.5.4 Analgesia

Low energy trauma hip fractures are inevitably characterised by acute pain, which is one of the key undesirable components of the patient's experience. Effective pain management among elderly patients with hip fractures during the peri-operative period contributes to avoidance of complications and morbidity [37]. After hip injury, pain arises from various sources; surrounding affected muscles, joint capsule, the serrate edges of broken bone, the associated release of local inflammatory markers, non-surgical procedures to diagnose the injury and surgical procedures required for fixation of the femur [38]. Patients with greater post-operative pain are slower to mobilise and have worse hospital outcomes and these factors are also exacerbated by psychological stress and anxiety. Fear of pain is a serious concern to both the patient and their relatives.

Pain levels after hip fracture are high during ambulation and historically adequate pain relief has long been identified as a major priority but not effectively addressed [15]. Adequate and appropriate analgesia should be

administered during diagnostic investigations. One fundamental consideration might be the challenge of inability to effectively assess pain in this patient population due to either cognitive impairment, acute delirium or an underlying expressive dysphasia [37].

Recommended analgesia

Current evidence [15 38] supports the use of nerve blockade for effective relief of acute pain following hip fracture. Nerve blocks consist of the lateral cutaneous of the thigh, femoral nerve, sciatic nerve, 3-in-1 nerve block (femoral, obturator and sciatic nerves), psoas (lumbar plexus, or continuous epidural block) [39]. Nerve blockade also reduces the need for supplementary systematic analgesia and may reduce the risk of delirium. Systematic analgesia includes both narcotic (morphine, fentanyl) and non-narcotics (paracetamol, non-steroidal anti-inflammatory drugs (NSAIDs)). The goal is to provide generic pharmacological analgesia which works on the whole body rather than on a localised area or region. They are the most commonly used drugs for providing pain relief in acute pain situations. However evidence guiding the selection of best drugs to use is scanty needing further research [15].

Within the current hip fracture treatment guidelines [15 19] NSAIDs are not recommended due to their side effects (e.g. upper gastrointestinal bleeding, nephrotoxicity and fluid retention) which are too great in the elderly. Most of these patients might also have comorbidities which could be made worse by this class of drugs. Below is a comparative table of the

effectiveness of current pain intervention and the strength of the evidence [38].

Table 1 Pain management intervention evidence

Pain management intervention in hip fracture	Strength of Evidence
Nerve Blocks	Moderate
Spinal and Epidural Anaesthesia	Low
Skin Traction	Low
Systematic analgesia and multimodal approaches	Insufficient
Rehabilitation, Acupressure, Relaxation Therapy and TENS	Insufficient

1.5.5 Surgical procedures

Hip fractures are broadly classified into two divisions, and the options for corrective surgical treatment are dependent on the type of fracture. This classification is based according to their relationship to the capsular attachment of the hip joint ; extracapsular (fractures below the capsular) and intracapsular (fractures above the capsular) [15]. Approximately 50% of all the fractures are intracapsular and the other half are extracapsular [40].

Intracapsular fractures

Intracapsular fractures are further divided into subcapital, transcervical and bisicervical fractures and could be displaced or undisplaced [19 40]. Due to limited vascular supply at the fracture side and possible tamponade from the capsular, this type of fracture is associated with minimum blood loss at the time of injury. Current evidence and clinical guidelines suggest the best surgical procedure for undisplaced intracapsular

fractures would be internal fixation using either sliding hip screw or multiple screws [15 19 40] and preserving the femoral head[18]. This treatment procedure retains the patient's own tissue and is often a short procedure; however a more prescriptive post-operative management and rehabilitation regime may be required [15] for healing and bone protection. Although undisplaced intracapsular fractures can be treated conservatively for one reason or another, there is on average a 0.3 to 0.5 subsequent potential risk of further displacement [40].

A displaced fracture is the one in which the bone tissue fragments have moved to an unacceptable position in relation to one another for fixation. Under such circumstances, the acceptable recommended surgical procedure is hemiarthroplasty, where only the damaged bone of the proximal femur is replaced or a total hip replacement when both the femoral head and the hip socket are replaced [15]. Hemiarthroplasty could be either cemented or un-cemented. Cemented arthroplasty improves hip function and is associated with lower residual pain post-operatively.

Extracapsular Fractures

These are further divided into inter and sub-trochanteric fractures. Blood loss and pain could be considerably more in this type of fractures. Extracapsular fractures can be managed conservatively with traction coupled with bed rest with a healing time frame of 6 – 8 weeks [18]. Considering the elderly frail patients who experience most of these fractures, such management could be detrimental and more likely to be associated with higher morbidity and mortality precipitating long term

institutional placement. The majority of extracapsular fractures are treated surgically using sliding hip screws. Any untreated disruption to the capsular blood supply of the head of the femur by any kind of fracture, could lead to avascular necrosis of the bone resulting in painful hip and limited function.

1.5.6 Mobilisation and Rehabilitation strategies

After prompt surgical treatment of hip fracture, strategic rehabilitation regimes may potentially go a long way in ensuring maximum recovery and enhancing quality of life among individual patients. Early restoration of mobility as the first step of rehabilitation is a key component of high quality care. Mobilisation is focused on re-establishment of movement abilities between postures, maintenance of upright posture, and walking with increased level of complexity (speed, change of direction, ground clearance, dual and multi-tasking) [15]. Therefore this allows mobility to be measured in several ways; (a) the ability to transfer independently, (b) sit to stand from a chair with arm rest, (c) indoor walking balance [41], with independent considerations on the use of the stairs.

Early mobilisation is a key priority after hip fracture surgery aiming to prevent complications, avoiding prolonged bed confinement, pressure damage, DVT, reduce length of hospitalisation and risk of limb deformity, and re-establishment of people into normal place of residence environment [42 43]. Current NICE guidelines recommend early mobilisation (within 48 hrs of surgery) contrast to late mobilisation (>48 hrs). This is supported by other guidelines such as the Scottish Intercollegiate

Guidelines Network (SIGN) [19] which further outlined that; if the individual patient's overall medication allows mobilisation, multidisciplinary rehabilitation should take effect within 24 hrs post operatively, with weight bearing on the injured leg allowed unless there are concerns about the quality of the fracture repair. The most successful and effective mobilisation strategies (therapeutic procedures implemented by physiotherapists and occupational therapists) were found to be those involving more intensive exercises [42] including increasing number of physiotherapy usual care sessions [15].

1.5.7 Multidisciplinary Team

Specialised co-ordinated interdisciplinary care programs (pathways) are central to the management of the frail elderly hip fracture patients (due to the multifactorial nature of comorbidities – medical, psychological and social) [12 15 40]. Strong evidence supports multidisciplinary patient management from admission until discharge to improve functional outcomes, reduce length of stay, improve management of medical conditions and decreased future need for institutional care, including nursing home care[19] . Multidisciplinary team (MDT) includes various healthcare professionals who meet regularly for discussion and aiming for improvement in the quality and efficiency of care delivered to individual patients [40]. Good multidisciplinary working is characterised by good communication (information sharing – involving accurate documentation in patients' notes in addition to verbal handover), flexible collaboration and collective responsibility for care and outcomes[12].

Two main ortho-geriatric care models exist:

Traditional orthopaedic care – hip fracture patients are admitted to a trauma ward where the orthopaedic surgical team lead both surgical and subsequent rehabilitation care with limited ortho-geriatrician care. Orthopaedic medical team input will be on consultation basis.

The collaborative model (Hip Fracture Programme) – hip fracture trauma patients are admitted to specialised wards under the joint care of both geriatricians and orthopaedic surgeons. This model is more relevant within the current NHS health care system context allowing pre-operative assessment by the ortho-geriatric medical team, who will take the lead in post-operative multidisciplinary care [12 15]. This model facilitates the implementation of the following comprehensive in-patient care activities [15]:

- Ortho-geriatric assessment
- Rapid optimisation of fitness for surgery
- Early identification of individual goals for multidisciplinary rehabilitation to recover mobility and independence, and facilitate return to pre-fracture residence and long-term wellbeing.
- Continued coordinated ortho-geriatric and multidisciplinary review
- Liaison or integration with related services, particularly mental health, falls prevention, bone health, primary care and social services

- Clinical and service governance responsible for all stages of the pathway of care and rehabilitation, including those delivered in the community.

1.6 Conclusion

Good quality peri-operative care in hip fracture patients plays a major role in individual patient and economic healthcare outcomes. Current delivered care as recommended by clinical guidelines has been developed from translational and clinical research. This study will be important and relevant within the current healthcare systems and hip fracture care environments for several reasons. Firstly, the management of hip fracture is heavily influenced by hospital care, therefore identifying and addressing factors that are of concern to the patients and other stakeholders offers reassurance to both the patients and the public on the quality of care delivered. Secondly, development, validation and recalibration of robust national systems and/ or tools for prognostic assessment (NHFS, SORT) and collection of intermediate outcomes following hip fracture – the HF-POMS score tool, which could also be incorporated in the National Hip Fracture Database (NHFD) and CG124 hip fracture NICE guidelines is crucial in our quest for advanced (up to date) medical treatment practice. Thirdly agreed LOS morbidity outcome measures collected using a validated standardised tool allow audits and performance indicators of care across healthcare institutes to be easily comparable with necessary improvement measures and recommendations to improve practice through clinical benchmarks and quality care frameworks

CHAPTER 2

Risk scoring models for predicting peri-operative mortality and morbidity in people with fragility hip fractures: Qualitative systematic review

1.1. Introduction

Predicting and communicating patient prognosis among the frail elderly presenting with traumatic hip fracture in accident and emergency is challenging. Adequate risk stratification and scoring to identify individual patients' risk level is essential [44] and highly recommended nationally across the UK. Risk prediction models utilise available patient data to alert the clinician how these relate to the patient state, either currently (diagnosis) or at some part in future (prognosis) [45]. They seek to quantify an individual's risk of mortality or morbidity based on the severity and other relevant condition, derived from data available at an early stage of hospital stay [44 46]. Risk scoring tools provide increased objectivity in the prediction of death or morbidity, facilitating communication and guiding clinical decision making during the peri-operative period, and enabling informed consent for patients receiving treatment or undergoing hip fracture surgery [46]. The information can lead to treatment optimisation and improved outcomes [47]. Incorporating subjective factors within scoring systems can allow clinicians to apply their experiences and understanding of the situation to an individual patient.

There are two classifications of risk stratification tools, risk scores and risk prediction models. Multivariable analysis of risk factors for a specific outcome, are used to develop such tools; with various methodologies available to measure their performance [48]. Risk scores assign a weighting to factors identified as independent predictors of an outcome, with the weighting for each factor often determined by the value of the regression

coefficient in the multivariable analysis, or by consensus/clinical experience. Hence the sum of the weightings in the risk score then reflects increasing risk [44]. The American Society of Anaesthesiologists' Score (ASA) and Charlson Comorbidity Index (CCI) are examples of risk scores [49 50]. By contrast, risk prediction models estimate an individual probability of risk for a patient by entering the patient's data into the multivariable risk prediction model – the Nottingham Hip Fracture score and Surgical Outcome Risk Tool are examples of risk prediction tools [51 52]. In order to quantify how close risk stratification tools predictions are to the outcome, customary statistical approaches which include the use of measures such as explained variation (for example R^2 statistics) and the Brier Score [48] are used. The Hosmer-Lemeshow 'goodness-of-fit' is also used to quantify performance in terms of calibration (how close to x of 100 patients with a risk prediction of x% has the outcome?)[53]. Alternatively, discrimination is an option (how well a model or score correctly identifies a particular outcome). Sensitivity, specificity, and the area under the receiver operating characteristic curve (AUROC) (or concordance statistic, *c*) are commonly used to quantify discrimination [54 55].

2.2.1 Usefulness of risk scoring models

Risk scoring models are advantageous in that they are usually cost neutral or cheap to perform, and can be performed at any time of the day or night [56]. Moreover, by adjusting for risk, an accurate risk-scoring tool enables meaningful comparison of hip fracture outcomes between

hospitals for service evaluation or clinical audit. The ideal risk prediction tool would be one that is simple, reproducible, accurate, objective and available to all patients [44 56]. Within the current economic environment many hospitals lack adequate resources to perform expensive tests, so ideally it should be, inexpensive, quick and easy to perform or use, to increase participation of both patients and medical professionals [46 56]

2.2.2 Rationale for the study

There is a wide range of scoring tools currently available and there is uncertainty as to the most suitable for use in hip fracture. Literature shows that some tools are more commonly used than others. This might be ascribed to lack of clarity of the precision of available tools, sometimes resulting in unnecessary efforts to make minor refinements to existing methods, or develop novel methods with the aim of achieving greater predictive accuracy [44]. The four most commonly used tools in hip fracture include the American Society of Anaesthesiologists (ASA) score, Charlson Comorbidity Index (CCI), Nottingham Hip Fracture Score (NHFS), and the Physiological and Operative Severity Score for EnUmeration of Mortality and Morbidity (POSSUM), all summarised in Appendix 1. The ASA, CCI and NHFS are pre-operative risk scoring tools using data available on admission while POSSUM is a physiological score of severity of illness, which includes both pre-operative and intra-operative variables. These tools and others have been developed and validated in different surgical patient populations, procedures and outcomes [7] except the NHFS which has been validated in hip fracture patients only. They differ in their

discriminant ability, and reliability impacting their predictive accuracy, comparability and applicability [57].

Clinical experience informs us that choice of risk scoring system is sometimes dependent on the healthcare institution or individual clinician and some models are patient group specific [58]. The aim of this review is to critically assess and evaluate the quality of risk stratification tools used in hip fracture patients. Quality assessment will be based on validation (the degree of validation of published systems) for use in this patient population group and prognostic variables in each tool. The most commonly used tools and rationale for their popularity, their strengths and weakness (the components and likely clinical utility of published systems) will also be outlined to aid current research in terms of which are the best tools to be used. Outcome variables used by individual risk scores will be explored to quantify their importance due to the variation and inconsistency on outcome definitions in different studies.

2.2.3 Aims and Objectives

Aim

To conduct a systematic review of published literature on validity of tools used to predict post-operative mortality and morbidity in hip fracture patients.

Objectives:

a) To identify all relevant studies that assess post-operative morbidity and mortality scoring tools in hip fracture patients

b) To identify tools currently used to collect peri-operative morbidity for patients with hip fracture

c) To identify tools currently used to predict mortality and morbidity in hip fracture patients

d) To assess the reliability and validity of currently used tools

2.3 Methods

2.3.1 Criteria for considering studies for this review

Types of Studies

The review considered all relevant published studies focusing on development, validation and use of risk stratification tools in patients with fragility hip fracture. All included studies were of cohort design. Studies were considered using the recommended standard guidelines for reporting systematic reviews of observational studies (Centre for Reviews and Dissemination (CRD)) [59]. All relevant studies worldwide in any language published to 30th April 2015, inclusively, were included in the review. Case reports and opinion pieces were excluded.

Population

Patients with a hip fracture admitted to hospital as an emergency.

Intervention or treatment

Risk score tool performance for prediction of mortality, morbidity or functional outcomes of individual patients or a group of patients with hip fractures. For the purpose of this study, a risk scoring tool/model was defined as a system used to predict or adjust for either mortality or

morbidity during the peri-operative period, and which has at least two different risk factors [44].

2.3.2 Outcome measures

a) Predictive accuracy and reliability of each risk tool to differentiate patients who are at high risk and those at low risk.

b) Simplicity and easy of use – how easily the tool can be applied at the patient bedside.

c) Validity of the risk stratification tool – how widely the tool has been applied and used and the subjective nature of prognostic variables.

2.3.3 Search methods for identification of studies

A range of online database search strategies were used to identify relevant studies. The following eight databases were searched through University of Nottingham using EBSCO and Ovid platforms and other healthcare databases.

MEDLINE using OVID platform (1948 to30th April 2015)

EMBASE using OVID platform (1980 to 30th April 2015)

AHMED using OVID platform (1980 to 30th April 2015)

CINHAL using EBSCO platform (1980 to 30th April 2015)

Web of Science (1899 to 30th April 2015)

Cochrane Database via Cochrane Library

DARE database using the Cochrane Library

Clinical Trials.gov

Search terms were initially developed by Takawira Marufu (TM) and confirmed through discussions and initial trial searches. The search terms encompassed similar terms to those used in a recent qualitative systematic review on Risk Stratification tools for predicting morbidity and mortality in adult patients undergoing major surgery [44]. See Appendix 2 Search Strategy of final search terms used. One reviewer (TM) executed the search strategy. All search outcomes are discussed in detail in the results section.

Hand searching of reference lists

Further articles of potential relevance were checked manually by searching the reference list in studies identified for inclusion during electronic record search. Manual searching of reference list for eligible articles was limited only to first generation full text as this is more likely to provide relevant studies [60]. This review was based on published studies only. The key concern with unreported research studies is that the results of such studies could be viewed as less likely to be reliable since they have not been through a peer review process. The rigorous process of peer review has been highlighted as an imperative means of quality assessment [61].

Citation tracking

The Web of Science (Science Citation Index) was tracked regularly checking for relevant updates, monitoring and identifying new published studies.

2.3.4 Data Collection and analysis

Selection of studies

All identified studies, literature or other documents were screened for eligibility using the three-staged sieving approach: reviewing the title, abstract and full text. As an initial step, TM independently screened titles of all relevant studies against eligibility criteria discarding all that were irrelevant. TM and a co-invstigator (Alexa Mannings (AM)) independently identified potential studies for inclusion at abstract stage. Full text papers were retrieved for those studies were a decision of eligibility could not be made from title and abstract alone. Differences of opinion were resolved through discussion and the involvement of a third reviewer (Iain Moppett (IM)) and consensus reached. The final study selection was agreed among TM, AM and IM. Details of full text studies which did not meet eligible criteria are specified in table of characteristics of excluded studies.

2.3.5 Data Extraction and management

The data extraction form with specific eligibility criteria and outcome sections was designed by TM and finalised with agreement from AM and IM. The form was piloted on several studies and required changes were made in agreement. Data extraction was performed independently by TM and AM using standardised forms. We extracted data for each study against the following four facets of validity and reliability:

1. Development of items: development and validation samples in same or different cohorts; random selection of samples
2. Process for validation: single centre; multicentre; international

3. Metrics of discrimination: AUROC/ *c*-statistics
4. Metrics of calibration: Hosmer-Lemeshow or Pearson chi-square statistics

The following aspects were documented on data extraction form:

a. General information

Date of data extraction, reviewer, first author name, full study title and year of publication.

b. Study Details

Risk score tool being assessed, study design, setting, country were the study was conducted, inclusion and exclusion criteria, sample size, comparability between samples/groups on demographic or other characteristics.

c. Participants

Total number of participants, number of those lost to follow up and number of those included in the final analysis.

d. Analysis

Identification of analysis used in the development or validation of the risk score/model being assessed or in use using measures of discrimination and where appropriate calibration.

e. Outcome

Calibration or discrimination values showing the predictive capability of the risk scoring tool, outcome measures and end points, clinical outcome data (mortality and morbidity).

2.3.6 Assessment of risk of bias in included studies

Individual studies were assessed for methodological quality and risk of bias at both the study and outcome level. Altman's [62] framework for assessing the internal validity of studies was used (Appendix 3). Assessment criteria include specification of both inclusion and exclusion criteria, sample selection and size, timing of data collection (prospective or retrospective), demographic and comorbidity factors identified, confounders adjusted for, prognostic variables, number of variables and how they were defined, outcomes and outcome end points. The study was considered to have selection bias if participants selected were confined to one particular group, for example if sample selection was restricted to those of specific ethnicity or sex.

2.3.7 Data analysis and synthesis

Calibration and discrimination are the two main performance measures used to evaluate individual risk scoring tools. Discrimination (do patients with the outcome have higher risk predictions than those without?) [45], was reported using either the AUROC or the concordance statistic (*c*-statistic). The use of the AUROC as the main outcome measure was deemed imperative as a uniform outcome measure to provide clarity to the readers. A better discrimination model will show less overlap between those with, and those without the outcome, therefore an AUROC of less than 0.7 was considered to show poor performance, 0.7-0.8, 0.81-0.90 regarded as good and moderate respectively and greater than 0.9 to indicate high performance [44]. As AUROC was not consistently reported,

the observed compared to expected outcome ratio (observed/expected (O/E)), Spearman's rank correlation and chi-squared test were also used to evaluate risk scoring tool performance.

Calibration refers to the agreement between observed outcomes and predictions, that is, how well the prognostic estimation of a model matches the probability of the outcome of interest across the full range of outcomes in the sample under investigation [53]. Hosmer-Lemeshow or Pearson chi-square statistics were used to evaluate calibration. $P<0.05$ reflected that there was no statistically significant evidence of a goodness of fit to the model.

2.4 Results

Overview

The initial online database search produced 15,602 articles. After removal of duplicates 12,894 study titles were screened, 680 were eligible for abstract screening. A large number of studies considered at the abstract stage, looked at risk and predicting factors for hip fracture rather than outcome and therefore were not eligible. Twelve studies were conference abstract presentations with no full-published papers therefore were excluded leaving 44 studies for full text analysis. Out of the 44 full text studies sought 30 [30 51 58 63-89] met the inclusion criteria with results presented with sufficient statistical consideration for evaluating the performance of each risk score (Table 2 Characteristics of included studies).

Eighteen studies [51 58 63-69 71-75 78 82 88 89] presented the results in AUROC, three [70 77 79] as a ratio of observed/expected (O/E) outcome, one [83] r^2, four[30 80 81 87] Spearman's rank and Pearson's correlation, two studies [84 85] percentages only and one study [87] used both chi-squared test and percentage. Flow chart of the review is detailed in Figure 1 Study identifcation process.

Fourteen full text studies [90-104] did not meet the inclusion criteria (Table 3 Characteristics of excluded studies). Seven studies [90-96 102] presented results in odds ratio (OR), risk ratio (RR) or hazards ratio (HR) showing the association between the risk scoring model and the outcome, and three studies [97-99] presented results in other forms but were not robust enough to evaluate or quantify performance of the risk scoring systems. One study [100] provided AUROC graphs with no statistical figures. A study by Wang et al [101] included elective surgery patients in the study and therefore it was excluded. One study [104] was published in Chinese in which the authors were unable to obtain an English translation, the study author was contacted via email but there was no response.

2.4.1 Types of studies

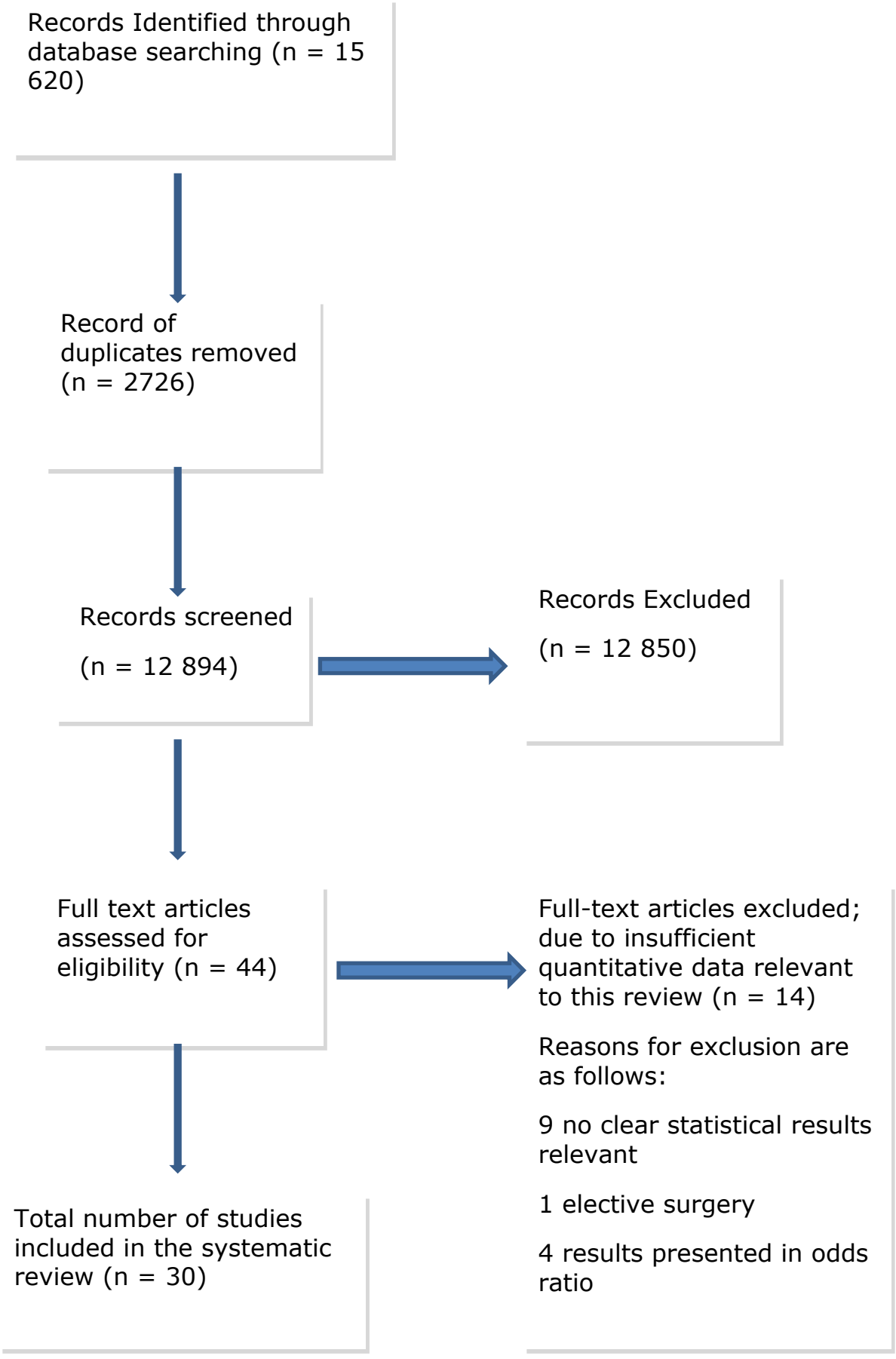
All studies included in this review were cohort studies, nineteen prospective [51 58 63 65 68 70 71 73-77 80-84 87 88] and eleven retrospective [30 64 66 67 69 72 78 79 85 86 89]. All studies were conducted in developed countries, nine in the UK [51 68 73 77 78 82-85 89], five in the Netherlands [58 63 67 71 75] two in the USA[64 69] four in Japan [30 79 81 101], two from Italy [70 76], Sweden [74 88], Israel [78 86] and one from each of the following countries, Spain [65], Canada [72],

and Denmark [87] . Sixteen studies were tool development or validation studies [30 51 58 67 70-72 75 77 79 81 83-85 88 89], eight evaluation studies [63-65 68 73 80 82 87] and six were comparative studies [45 67 69 74 76 86]. Twelve studies evaluated one or more risk scoring systems [51 65 67 69 70 74-76 79 86 87 89].

2.4.2 Quality Assessment

A high proportion of the included studies were single centre, twenty in total [51 58 63 65-70 73 75-78 80 83 84 86-88], eight studies [30 71 72 74 79 81 82 85] were multicentre with a maximum of nine centres in one study [81]. Only two studies [64 89] was based on administrative data. Twenty-three studies [30 51 58 63-73 78 82-89] clearly outlined both the inclusion and exclusion criteria, while the rest of the studies detailed only one or neither of the criteria. Prognostic variables were available for all of the studies with outcome measurements of mortality only in thirteen studies [51 64 66-69 72 74 78 82-84 88]; both mortality and morbidity were present in ten studies [30 63 65 75-77 79-81 87]; morbidity only in three studies [58 71 86]; and finally, seven studies [65 70 71 75 80 81 86] had mobility also as a measured outcome. Nineteen studies [51 58 63-65 68-72 74-77 79-82 86 87] clearly assessed and reported patients' baseline characteristics including demographic, comorbidities, physical and physiological status data. Selection bias was not observed in the included studies. Heterogeneity among included studies was observed in statistical analysis, variation in outcome definition and measurements, and in the number of models assessed by individual articles. Twenty-one studies were considered of high quality [30 51 64 66-69 71 73-82 86 87] and the eight studies moderate quality [58 63 70 72 84 85 88 89].

Figure 1 Study identifcation process



2.4.3 Types of Risk scoring systems and Models

A total of 24 risk stratification tools (Appendix 4 identified risk stratification tools) were either validated or evaluated, with some studies comparing the predictive accuracy. Two studies [70 72] developed and validated two new hip fracture specific risk adjustment tools. The new predictive risk score by Bellelli et al [70] categorised patients as high, moderate or low risk and this was compared to other risk scores.

Ten of the twenty-four risk scoring tools were considered in two or more studies (Table 4). The orthopaedic Physiological and Operative Score for the enUmeration of Mortality and Morbidity (O-POSSUM, [67 73 75-79]), Estimation of Physiology Ability and Surgical Stress (E-PASS, [30 67 79-81]) and Nottingham Hip Fracture score (NHFS, [51 67 82-85 89]) were the most commonly reported, in five, seven and seven studies each with a total sample number of 5975, 4058, and 26 889 patients, respectively. The Charlson Comorbidity Index with the highest sample size was also reported in five studies (CCI, [64-67 69], N=6 230 456) and the American Society of Anaesthesiologist's Physiological Score (ASA, [51 65 74 75], N=7415) was considered in four studies. The other five tools, Risk model for Delirium (RD), the Physiological and Operative Score for the enUmeration of Mortality and Morbidity (POSSUM), the Portsmouth Physiological and Operative Score for the enUmeration of Mortality, Morbidity (P-POSSUM), Barthel Index and Mini-Mental Score Examination (MMSE) were reported in two studies each. The rest of the risk models were reported in one study each.

2.4.4 Outcomes

The three main outcomes identified in this review were mortality, morbidity and mobility (Table 5 Outcomes). All risk outcome prediction measurements were presented in one of the following; AUROC, O/E, Spearman's correlation or chi-squared. Nearly all studies (26) reported mortality as the main outcome of which 24 studies also presented mortality rates. Sixteen studies reported morbidity with thirteen giving morbidity rates. One study [71] reported mobility at discharge only as the main outcome.

The outcome measurement end point ranged from in hospital mortality or length of hospital stay to more than one year time period. In hospital and 30 day mortality rates were similar; in hospital mortality ranged from 1.6% [30] to 9.7% [65], 30 day mortality 6.6% [82] to 10.9% [77] in comparison to 1 year mortality rates 26% [69] to 30.8% [72]. Morbidity widely varied from 17.0% [81] to 49.6% [65].

2.4.5 Discrimination

AUROC was presented in fourteen studies and ranged from 0.50 to 0.87. Twelve studies reported AUROC values for scoring systems of >0.7. None of the studies reported AUROC values >0.90.

2.4.6 Calibration

Nine studies reported calibration. Seven calculated calibration using Hosmer-Lemeshow (H-L) test with p values ranging from 0.00015 [73] to 0.79 [51]. Two [71 75] studies reported whether the model was of 'good fit' or

'poor fit' without further statistical presentation. Calibration values for one study [79] were not presented in the original paper, but were given by the authors in a subsequent letter [105].

2.4.7 Validation

Three forms of validation were observed across included studies; a) internal – validation in split sample of the same study population as tool derivation cohort, b)external- validation in new cohort unrelated to tool derivation study at a different institute and c) temporal - validation in new cohort from derivation study but same institution(s). Internal validation was observed in six studies while seventeen studies were externally validated. Only two studies were considered to have temporal validation. Table 6 summarise data for commonly used tools and shows how widely each risk stratification tool has been validated and the original tool development cohort.

2.5 Frequently used risk predicting models observed in this review

2.5.1 Preoperative scores

There are three clinical scoring systems that use readily available preoperative data that were evaluated or validated in multiple studies, ASA [51 65 74 75], CCI [64-67 69] and NHFS [51 67 82-85 89].

American Society of Anaethesiologists Physical Score (ASA)

The ASA is widely used as a surrogate for operative risk and was originally devised to grade the patients in accordance to their fitness

status [57]. The four studies which considered ASA presented their results in AUROC which found it to be of poor to a moderate discriminant accuracy (AUROC varying from 0.60 - 0.76).

Charlson Comorbidity Index (CCI)

The CCI is a medical risk prediction tool adapted for surgical risk stratification. One of the studies ([64], which used administrative data) used three adapted Charlson scores (CCI-ICD-9 adapted, CCI-age adjusted and CCI-updated 2011) the other study [69] also used the ICD-9 adapted while [65-67] used the original Charlson score. All the studies reported moderate AUROC for CCI for 1 year mortality (0.7-0.77) but poor prediction with regards to 90 day mortality (0.59).

Nottingham Hip Fracture Score (NHFS)

The NHFS is a combination of seven independent predictors of mortality that have been incorporated into a predictive score specifically designed for hip fracture. It has been included in four studies, only the original validation study presented AUROC 0.72 [51] showing this score to be a moderately discriminate tool. Calibration is adequate: the original single centre tool development showed H-L p=0.79 [51] and multicentre validation (using an updated regression equation) reported p>0.1 [82] showing adequate 'goodness-of-fit' on model performance. One study [83] showed that increasing NHFS was negatively correlated with eventual return-to-home r^2=0.949. The fourth study [84] presented results in percentages showing survival rates. The 30 day and one year survival rates were 96.5% vs 86.3% (p<0.001) and 84.1% vs 54.5% (p<0.001) in higher vs

low group, support by [89] which showed a 30 day mortality of 10.4% compared to 1.6% for patients with NHFS ≥ 5 and those with NHFS <5 respectively.

2.5.2 Physiological scores (models incorporating pre- and Intra-operative scores)

The POSSUM score [65] has been devised to predict mortality and morbidity in surgical patients using physiological and surgical factors. Predictive values range from 0.63 – 0.67 for mortality and ambulation suggesting a poor fit [65]. This system devised with 18 variables, 12 preoperative and 6 postoperative has also been presented in modified version for orthopaedic use (O-POSSUM,[67 73 75-78]). After finding the original equation over predicts the mortality rate Whiteley et al [106] proposed Portsmouth modification (P-POSSUM,[76 79]). O-POSSUM AUROC values for both mortality and morbidity was 0.83 [75] showing high discriminant accuracy, but the observed and expected ratio ranged from 0.12 – 1.19. The P-POSSUM observed and expected ratio values were considerably different with 0.15 [79] and 2.17 [76] for in hospital mortality.

Estimation of Physiology Ability and Surgical Stress (E-PASS) is a nine item tool originally designed and validated in general surgical patients. Similarly to POSSUM it assess physiological (Physiological Risk Score: PRS) and surgical (Surgical Stress Score: SSS) items to produce a comprehensive risk score (CRS). The five studies on E-PASS [30 67 79-81] reported their results in O/E and spearman rank correlation; AUROC is reported in only one study [67] 0.72. The O/E values ranged from 0.55-1.59

[79]. All studies observed a significant positive correlation between both PRS and CRS to measured outcomes (mortality and morbidity) but there was no significant correlation observed between the surgical stress score (SSS) and outcomes. One study [81] also reported that PRS and CRS were independent predictors of walking ability at hospital discharge and one year after hip fracture surgery. In one study [80] the cost of hospitalisation was reported to be associated with SSS and CRS while in [30] all the sub-scores (PRS, SSS, CRS) were found to be positively correlated with the outcome.

2.5.3 Other risk sores

Two models for cognitive state assessment, Risk Model for Delirium (RD) and Mini Mental State Examination (MMSE) and one functional evaluation model, Barthel Index were evaluated or validated in two studies each. AUROC values for both cognitive function models ranged from 0.72-0.77 [58 63 70]. The Barthel Index showed predictive measurements varying from 0.67-0.87 [65 70] for 30 days and 90 days after surgery.

2.6 Discussion

This study provides a comprehensive review of the current evidence on a variety of risk stratification tools used in hip fracture patients. Of the 24 scoring systems identified, only five had been evaluated in more than two studies, and only three outside their original centre. Of these five ASA does not perform well, despite its simplicity [51 74] , it does not appear to be robust enough in this population. Each of the other four tools has

arguments for and against its clinical utility; e.g. tool availability and the objectivity of its parameters. Some tools may be perceived as complex and less likely to be part of the daily routine use.

2.6.1 Simplicity and Availability

NHFS and CCI use readily available pre-operative data. They both have reasonable, though not excellent discriminant characteristics for early morbidity and have been validated externally from their original cohort. The CCI uses well-defined comorbidities. Its weights are based on severity and assigns each individual an overall risk score presenting the sum of their comorbidity weights [69]. These data are widely collected as routine, particularly in the US. Conversely, for units that do not collect these data as routine, it may be a relatively burdensome addition. Given that patients' pre-operative medical history is a predictor of adverse postoperative outcomes, it would be logical to expect the CCI to be indicative of the prognosis although it appears to be less used in this patient population. It is a moderately discriminant tool for in hospital morbidity and one year mortality; there does not appear to be much to choose between the CCI variants with regards to discrimination. However, calibration is not well described and this limits its ability as an audit tool. Functional ability and confusion (as opposed to dementia) which are known predictors of outcome following hip fracture are not included.
The Nottingham Hip Fracture Score is a hip fracture specific score, which has been validated for early hospital discharge [83], 30 day mortality [51 67] and one year mortality [84]. Its discriminant ability is similar (moderate) to

other scores and it has reasonable calibration. All the required data items are routinely collected. It uses the Abbreviated Mental Test Score (AMTS) as its assessment for cognitive impairment which may not be so widely used in countries outside the UK. There are currently no data on regarding the interchangeability of screening tests for cognitive impairment, such as MMSE, clock drawing, in this context.

2.6.2 Post-operative Scores

E-PASS and O-POSSUM

E-PASS and O-POSSUM are comparable in their applicability and limitations The O-POSSUM is the orthopaedic version of the original POSSUM model. Both models use weighted pre- and intra-operative data; hence they cannot be used for preoperative risk prediction. They are also perhaps more complex to score with several variables; the O-POSSUM has eighteen variables. Additionally, the use of intra-operative variables such as blood loss which could be linked to surgical performance, may lead to inappropriate adjustments for poor surgical performance, thus jeopardising the tools' validity as a risk adjustment model for comparative audit of surgeons or hospitals [44].

E-PASS was reported as a good predictor of morbidity, mortality and cost of hospitalisation [30 67 79-81]. The O-POSSUM model has also been shown to have accuracy in predicting both morbidity and mortality. Unlike the O-POSSUM that has been validated internationally, the E-PASS has been developed and validated in one country.

2.6.3 Reported Outcomes

Mortality

Outcomes in the included studies were biased towards mortality (twenty-two studies reported mortality as the main outcome). Mortality rates at fixed time periods were more easily comparable between studies. When considered as a quality metric, this outcome exhibits several advantages. It is a dichotomous variable that is objective, clinically important and not subject to inter-observer variability [7]. Unfortunately, it also has some limitations as an outcome measure. It has a well-recognised dependence on the time frame of measurement; that is hospital discharge/ in hospital mortality, 30 day, 90 day 1 year or more. In-hospital patient mortality has the advantage that data may be easier to collect with minimal loss to follow up. Nevertheless this could be influenced by other factors such as hospital discharge criteria which may differ between individual hospitals and hospital mortality might not be very useful as an outcome for a score since it depends to a large extend on the length of hospital stay [107]. For studies that observed longer-term mortality (30 day or more) loss to follow up after hospital discharge may be an issue as well as the influence the natural course of comorbid disease has on patient survival [7].

Morbidity

There was large variation in reported morbidity (17%-49.6%). There is wide variability in the definition of morbidity which various risk scoring tools have been developed and validated [7 44] and further inconsistencies are apparent in subsequent studies that seek to describe generalisability

of these tools in different clinical settings. Heterogeneity in morbidity definition and classification has been observed among included studies.

Mobility

Beside mortality and morbidity, most studies did not look at functional outcomes. A key theme in hip fracture care after surgery is to get patients safely back to their pre-fracture mobility status. However, limited studies reported ambulation/mobility as one of the outcomes limiting our ability to comprehensively compare the available risk tools on predicting ambulation after hip fracture surgery.

2.6.4 Validity

Three risk score tools, ASA, CCI and O-POSSUM were internationally and externally validated in multicentre studies, though not specifically in hip fracture. The ASA has been validated for categorisation of population risk and not validated for prediction of individual patient risk [7]. The E-PASS and NHFS were both validated in several studies – E-PASS in Japan only and NHFS the UK, Singapore and Netherlands. This could limit the generalisability and reproducibility of E-PASS in a different population outside its validation regions. When making a clinical decision on whether to proceed with a proposed intervention, clinical judgement is imperative when considering the use of these models as they demonstrated variable predictive accuracy as observed among the included studies. As all the studies have shown some degree of good performance, publication bias must be considered, as those studies with positive results are likely to be published.

2.6.5 Prognostic variables

The issue of prognostic variables either subjective or objective have been addressed before [7 44 56]. The range of prognostic variable used by the risk stratification tools are summarised in Table 7. Objective variables include those which are measured instrumentally such as biochemistry and haematology results, or specific such as age, while subjective variables include interpretation of electrocardiograms, x-rays or scan films and patient reported outcomes involve report such as patients' health risk behaviour such as smoking history. There is a debate on the reliability of some of the non-objective data, as literature asserts variation among clinicians on how they interpret such variables [44]. This review observed good to moderate predictive accuracy of some risk scores encompassing some of the subjective variables (CCI and O-POSSUM) [64 67 75]. More importantly, there is a need to assess other variables not currently included in the identified commonly used models (for example, red cell distribution width on admission [108]) that has been shown to be an independent predictor of mortality or morbidity. Routine blood tests including albumin levels [78 109] and some inflammatory markers [110] that may indicate susceptible patients are potential objective variables for future consideration. It is possible that the addition of these or more routinely available biomarker assays to risk scoring tools will lead to improvement in accuracy of peri-operative risk prediction [7]

2.6.6 Study strengths and limitations

We conducted a comprehensive search strategy with strict adherence to Centre for Reviews and Dissemination (CRD) [59] systematic review guidance. Search strategy, data extraction and quality assessment was performed independently by the authors and findings were confirmed within the team.

However, the review has some limitations. Heterogeneity observed in this review, within and among studies, could also have influenced our results. There was variation in outcome analysis and outcome measures. Five different statistical measures were used for showing predictive ability of individual risk score tools, AUROC, r^2, correlation coefficient, O/E and percentages. This was felt necessary to include all high quality studies. Unfortunately, this also reduced our ability to perform appropriate comparison among all the models presented and this lack of uniformity could affect clarity of which risk score is superior to the other. Variation in reported outcomes may explain differences in predictive accuracy of models for predicting one outcome compared to another.

Even though we included various analytical measures of discrimination, calibration was poorly reported for those studies with AUROC values, and this has also been noted in another similar review looking at different patient population [44]. Moreover, despite an extensive literature search, it is possible that some studies which would have been eligible for inclusion may have been missed, with only one functional risk score (Barthel Index) assessed in two studies. Multiple strategies were included to

minimise this, but we acknowledge the possibility that a small number of appropriate articles may have been omitted.

2.6.7 Conclusions and future work

The use of risk prediction scores during the peri-operative period has been accepted by clinicians as the norm, influencing important informed decision making, to help optimise individual patients' care and to support audit and service improvement. However, the predictive accuracy of risk scores could be more robust and multinational validation is currently lacking. This review has highlighted both strengths and weaknesses of the currently available risk scoring models. This study noted that all outcome measures outlined (mortality, morbidity, and ambulation) were medically oriented. Future work could consider the psychological and social dimensional factors that impede early patient discharge in this patient population.

2.7 Review update

2.7.1 Review search

The initial search strategy was performed up until April 2015. An updated search of the same databases (AHMED, CINHAL, Clinical Trials.gov, Cochrane, DARE, EMBASE, MEDLINE and Web of Science), using the same search terms (with limits from 2015 to August 31st 2016) was performed to identify new studies on risk prediction in hip fracture patients.

2.7.2 Results

A total of 305 studies were identified with 12[111-122] studies suitable for full study screening. Eight studies were suitable for inclusion in this review [111-119]Table 8. Three studies [120-122] were abstracts with no full text available, therefore were excluded.

For the studies included in this review update, outcome results are detailed in Table 9. Two studies [112] [113] used the CCI within a sample size of 199 Spanish patients and 759 Chinese patients respectively. The ASA was also considered in two separate cohorts, [114] 1402 subjects and [115] 327 nonagenarians who underwent hip fracture surgery. Two studies were comparative studies [111], validating the NHFS and SORT score in a population of 9017 participants from the ASAP data[107] and [119] comparing NHFS and a new risk model, the Almelo Hip Fracture Score (AHFS) . Two studies looked at development or/validation of new risk adjustment models [116] [117] with the last study looking at pre-operative Waterlow score and its ability to predict post-operative infection in 97 consecutive

patients with fractured neck of femur. The threshold Waterlow score predicting infection within 30 days of surgery was 17 with the sensitivity, specificity and AUROC of 84.4%, 84.1% and 0.89 respectively.

One comparative [111] study of the NHFS and SORT showed the highest sample size and its primary purpose was to recalibrate both tools to ascertain the 30 day mortality accuracy of these models within the changing population pattern within the UK, using national data. Both models showed acceptable AUROC values, NHFS 0.71 and SORT 0.70, with differences observed in their calibration status, NHFS with acceptable calibration H-L, p=0.23 and SORT p=0.001. The second comparative study [119] was a cohort study of 850 patients conducted over a period of five and half years. Model predictive ability improved with the AHFS compared to the NHFS (0.82 vs 0.72). Both models revealed a good fit between observed and predicted values H-L test p>0.05, however the likelihood test showed a significantly better fit of the AHFS contrasting to the NHFS (p<0.001). Among the two studies which used the CCI [113] showed acceptable predictive power for 30 day and 1 year mortality AUROC 0.72 and 0.75 respectively, with no calibration reported. The other study [112] showed poor predictive ability of the CCI 0.623. The differences in results could be explained by the fact that the two studies were performed across two international geographical regions with a potential variation in comorbidity definition. Various forms of CCI definitions or codes have been used which might differ with countries [66].

A combination of ASA score and red cell distribution width, improved the discrimination power of the ASA score alone from AUROC 0.700 to 0.723, $p<0.05$ [114]. The other study measured the ASA's ability to predict post-operative complications and 1 year mortality [115]. The results showed a significant association between ASA grade and both outcomes; complication x^2 86.681 $p<0.0001$ and 1 year mortality x^2 21.313 $p<0.0001$. A new developed and internally validated risk adjustment model for hip fracture repair [116] showed derived model c statistic of 0.8 for mortality and 0.68 for adverse events. The following six variables were considered in this new risk prediction model; age, sex, ASA class, comorbid conditions, laboratory values and vitals-based comorbid conditions. The other new scoring system with an acceptable discrimination value of 0.74 (R^2 =0.272) had the following final variables; sociodemographic data, type of fracture, ASA grade, health related quality of life score (EQ-5D index) and Mini-Mental state Examination (MMSE) score[117].

2.7.3 Overview and conclusion from observed results

The observed review update results concurred with the conclusions drawn from our original review above[123]. The NHFS remains the most widely validated risk predictive tool, with constant predictive ability AUROC ≥ 0.70 and acceptable calibration. The newly developed AHFS has shown better predictive power when compared to the NHFS, which could be explained by the nature of additional variables used to derive the model. The model contains nine variables of which the first seven are similar to

the NHFS model. Two additional variables (Parker Mobility Score and ASA score) have been shown to be independent predictors of mortality[91 124] and [123]respectively. The same concept has been noted in few more studies developing new risk score tools [114 116 117]. In [114] a combination of ASA score and red blood cells width (RDW) showed an improved risk prediction model. A recent study has demonstrated RDW to be an independent predictor of early mortality in hip fracture [108] and increased RDW distribution as a significant predictive value for prognosis in several high mortality diseases [125-127]. However such a test is not normally done routinely in practice within the NHS, it is a special test that incur additional costs which is likely to make it less popular than other currently available validated and reliable tools using routine readily available data. Risk adjustment models require continual assessment and recalibration to best suit the local population. This review update gives the currently available risk scoring tools in practice and their predictive accuracy.

Table 2 Characteristics of included studies

Study ID	Risk scoring Model	Timing	Country	Number of Centres	Patients (n)	Study Purpose	Validation Cohort: Internal vs External vs Temporal	Outcome	End Point d-days m-months	Subject description	Selection Bias
Moerman [58]	RD	Prospective	Netherlands	1	378	Validation	Internal	Morbidity	Hospital discharge	Y	N
Vochteloo [63]	RD	Prospective	Netherlands	1	378	Validation	Internal	Morbidity Mortality	Hospital discharge 90 d 12 m	Y	N
Neuhaus [64]	CCI	Retrospective	USA	National	6,137,665	Validation	External	Mortality	Hospital discharge	Y	N
Burgos [65]	ASA,CCI POSSUM, Barthel Index Goldman Index	Prospective	Spain	1	232	Validation	External	Morbidity Ambulation Mortality	Hospital Discharge 30 d 90 d	Y	N
Tason[66]	CCI	Retrospective	Australia	1	47698	Validation	External	Mortality	Hospital discharge 30 d 12 m	Y	N
Karres [67]	Jiang et al, NHFS,Holt et al E-PASS, CCI 0-POSSUM	Rétrospective	Netherlands	1	1050	Validation	External	Mortality	30 d	Y	N
Dawe [68]	Sernbo Score	Prospective	UK	1	259	Validation	Internal	Mortality	30 d 12 m	Y	N
Radley [69]	CCI (Romano adaptation) CCS,Iezzoni	Retrospective	USA	1	43 811	Comparative	External	Mortality	12 m	Y	N

Bellelli[70]	New predictive risk score, MMSE, BMI Barthel Index	Prospective	Italy	1	398	Tool Development	Internal	Ambulation (mobility)	Hospital discharge >12 m	Y	N
Vochteloo[71]	DHP	Prospective	Netherlands	2	435	Validation	External	Ambulation (mobility)	Hospital discharge	Y	N
Jiang[72]	New Risk score	Retrospective	Canada	2	3981	Tool Development	Internal	Mortality	Hospital discharge 12 m	Y	N
Soderqvist[74]	ASA SPMSQ	Prospective	Sweden	4	1944	comparative study	External	Mortality	Hospital Discharge 120 d 24 m	N	N
Ramanathan[73]	0-POSSUM	Prospective	UK	1	1164	Validation	External	Mortality	30 d	Y	N
Study ID	**Risk scoring Model**	**Timing**	**Country**	**Number of Centres**	**Patients (n)**	**Study Purpose**	**Validation Cohort: Internal vs External vs Temporal**	**Outcome**	**End Point d-days m-months**	**Subject description**	**Selection Bias**
van Zeelan[75]	O-POSSUM ASA	Prospective	Netherlands	1	272	Validation	External	Morbidity Ambulation Mortality	Hospital Discharge	N	N
Bonicoli[76]	O-POSSUM P-POSSUM	Prospective	Italy	1	134	comparative	External	Mortality Morbidity	Hospital discharge	N	N
Wright[77]	O-POSSUM	Prospective	UK	1	230	Validation	External	Mortality Morbidity	30 days	N	N
Steinberg[78]	O-POSSUM	Retrospective	Israel	1	1770	Validation	External	Mortality	Hospital Discharge	Y	N
Hirose[79]	E-PASS P-POSSUM O-POSSUM	Retrospective	Japan	8	722 Grp A 633 Grp B	Validation	External	Mortality Morbidity	Hospital Discharge 30 d	N	N

Hirose [80]	E-PASS	Prospective	Japan	1	419	Validation	External	Morbidity Ambulation Mortality	Hospital discharge	N	N
Hirose [81]	E-PASS	Prospective	Japan	9	421 (Group A 268, B 153)	Validation	External	Ambulation Mortality Morbidity	Hospital discharge 12 m	N	N
Hirose [30]	E-PASS	Retrospective	Japan	7	813	Validation	External	Mortality Morbidity	Hospital discharge	Y	N
Moppett [83]	NHFS	Prospective	UK	1	6123	Validation	Temporal	Mortality	Hospital discharge 30 d 12 m	Y	N
Moppett [82]	NHFS	Prospective	UK	3	7290	Validation	External/ Temporal	Mortality	30 d	Y	N
Wiles [84]	NHFS	Prospective	UK	1	6202	Validation	Temporal	Mortality	30 d 12 m	Y	N
Maxwell [51]	NHFS, ASA Donati Score	Prospective	UK	1	4967	Tool Development and validation	Internal/ External	Mortality	30 d	Y	N
Rushton [85]	NHFS	Retrospective	UK	3	1079	Validation	External	Mortality	30 d	Y	N
Adunsky [86]	MMSE, CDT Cognitive-FIM	Retrospective	Israel	1	143	comparative	External	Ambulation (mobility)	Hospital discharge	Y	N
Foss [87]	CAS NMS	Prospective	Denmark	1	426	Validation	External	Morbidity Mortality	Hospital discharge 30 d	Y	N
Albertsson[88]	FRAMO Index	Prospective	Sweden	1	1248	Validation	Internal	Mortality	24 m	Y	Y

Table 3 Characteristics of excluded studies

Study ID	Risk scoring Model	Timing	Country	Number of Centres	Patients (n)	Study Purpose	Outcome	End Point	Reason for Exclusion (Results presented in other forms/other reason)	Publishing Journal
Kirkland [90]	CCI	Retrospective	USA	1	485	Evaluation	Mortality	30 days	Y	American Journal of Medical Quality
Kristensen [91]	NMS	Prospective	Denmark	1	280	Evaluation	Ambulation	Hospital discharge	Y	Acta Orthopaedica
Ringdal[92]	MMSE	Prospective	Norway	2	364	Evaluation	Morbidity	Hospital discharge	Y	Dementia and Geriatric Cognitive Disorders
Souza [93]	CCI	Retrospective	Brazil	1	390	Evaluation	Mortality	90 days	Y	Cadernos de Saude Publica
Michel [94]	ASA	Prospective	Switzerland	1	114	Validation	Morbidity Ambulation Mortality	90 days 12 months	Y	Aging Clinical and Experimental Research (Aging Clin Exp Res)
Gold[95]	ANSS	Retrospective	Israel	1	269	Evaluation	Morbidity Mortality	Hospital discharge	Y	Archives of Gerontology and Geriatrics
Thomas and Eastwood [96]	Belfast Score, Newcastle Score	Prospective	UK	1	250	Evaluation	Mortality Ambulation Morbidity	Hospital discharge	Y	Injury
Kristensen [103]	CAS	Prospective	Denmark	1	101	Evaluation	Ambulation	Hospital discharge	Y	Denish Medical Journal
Zuckerman [98]	FRS	Prospective	USA	1	603	Validation	Mortality Morbidity	90 days 6 months 12 months	Y	Journal of Orthopaedic Trauma
Hershkovitz [99]	CDT	Retrospective	Israel	1	142	Evaluation	Ambulation	Hospital discharge	Y	Journal of Disability and Rehabilitation

Young [100]	POSSUM	Retrospective	New Zealand	1	225	Comment	Mortality Morbidity	30 days 12 months	No statistical figures recorded	New Zealand Medical Journal
Wang [101]	Modified POSSUM	Prospective	China	1	295	Evaluation	Mortality	30 days	Elective Surgery	Chinese Journal of Traumatology
Cullen[102]	ASA								Elective Surgery (Not Hip fracture specific)	
Zuckerman [97]	FRS	Prospective	USA	1	236	Tool Development	None specified	90 days 120 days 12 months	No statistical results recorded	Journal of Orthopaedic Trauma
Liu [104]	POSSUM	Retrospective	China	1	119	Validation	Mortality	Hospital discharge	Study in Chinese no English translation	Chinese Journal of Surgery

Table 4 Risk scoring models assessed in more than one study

Risk scoring Model	Total Number of Variables	Stage variables were measured	Studies	Study ID	Patients (N)	Outcomes	End Point d = day m = month	Calibration (NR = Not recorded)	AUROC/(*c*-) (95% CI)	Results given in other forms
RD	12	Pre-operative	2	Moerman [58]	378	Morbidity	Hospital Discharge	NR	0.73(0.68-0.77)	NR
				Vochteloo [63]	378				0.722(0.674-0.767)	
CCI	19	Pre-operative	3	Neuhaus [64]	6137,665	mortality	Hospital Discharge	NR	ICD-9 adapted 0.767 age adjusted 0.766 updated 2011 0.768	NR
				Tason [66]	47 698	mortality	Hospital Discharge 30 d 12 m	NR	0.72-0.76 0.72-0.75 0.69-0.75	NR
				Burgos [65]	232	Morbidity Ambulation Mortality	Hospital Discharge 90 d 90 d	NR	0.707(0.602-0.811) 0.634(0.563-0.706) 0.590(0.482-0.698)	NR
				Karres [67]	1050	Mortality	30 d	p=0.291	0.71(0.65-0.77)	NR
				Radley [69]	43 811	Mortality	12 m	overall model performance good	0.72	NR
NHFS	7	Pre-Operative	4	Maxwell [51]	4967	Mortality	30 d	0.79	0.72	NR
				Karres [67]	1050	Mortality	30 d	p=0.039	0.77(0.72-0.82)	NR
				Moppet [82]	7290	Mortality	30 d	p>0.1	NR	NR

Risk scoring Model	Total Number of Variables	Stage variables were measured	Studies	Study ID	Patients (N)	Outcomes	End Point d = day m = month	Calibration (NR = Not recorded)	AUROC/(*c*-) (95% CI)	Results given in other forms
				Moppet [83]	6123	Mortality	Hospital Discharge	NR	NR	High NHFS and home return (r^2=0.949), and patients discharged back to their own home at 7,14 and 21 postoperative days (r^2=0.84,0.94, 0.96 respectively)
				Wiles [84]	6202	Mortality	30 d 12 m	NR	NR	survival higher in the low risk group 96.5% vs 86.3% (P<0.001) survival greater in low risk group 84.1% vs 54.5% (P<0.001)
				Rushton [85]	1079	Mortality	30 d	NR	NR	30day mortality 7.3%
ASA	No specific number	Pre-operative	3	Maxwell [51]	4967	Mortality	30 d	NR	0.72	N/A
				van Zeelan [75]	272	mortality Morbidity	Hospital Discharge	good for mortality poor for morbidity	0.76 (0.66-0.85)	NR
O-POSSUM	18	Pre and Intra-operative	5	van Zeelan [75]	272	Mortality Morbidity	Hospital discharge	good for mortality poor for morbidity	0.83 (0.76-0.89) 0.83(0.76-0.90)	NR
				Kerres [67]	1050	Mortality	30 d	P=0.110	0.69(0.63-0.74)	NR
				Ramanathan [73]	1164	Mortality	30 d	poor fit p<0.00015	0.62	NR
				Bonicoli [76]	134	Mortality Morbidity	Hospital Discharge	NR	NR	(O/E ratio) mortality 0.81 Morbidity 1.1

Risk scoring Model	Total Number of Variables	Stage variables were measured	Studies	Study ID	Patients (N)	Outcomes	End Point d = day m = month	Calibration (NR = Not recorded)	AUROC/(*c*-) (95% CI)	Results given in other forms
				Wright [77]	230	Mortality Morbidity	30 d	NR	NR	(O/E ratio) Mortality1.19 Morbidity0.95
				Steinberg [78]	1770	Mortality	Hospital Discharge	NR	0.63(0.68-0.68) 0.73(0.64-0.83)	Model without serum albumin. Model including serum albumin.
				Hirose[79]	722 Grp A 633 Grp B	Mortality Morbidity	30 d	0.24 0.11	NR	(O/E ratio) mortality 0.60 Morbidity 0.12
Barthel Index,		Pre-operative	2	Burgos[65]	232	Morbidity Ambulation Mortality	Hospital Discharge 90 d 90 d		0.67 (0.565-0.780) 0.737(0.672-0.801) 0.689(0.584-0.794)	NR
				Bellelli [70]	398	Ambulation	Hospital Discharge 12 m	NR	0.8700 0.7344	NR
P-POSSUM	18	Pre and Intra-operative	2	Bonicoli [76]	134	Mortality	Hospital Discharge	NR	NR	(O/E ratio) 2.17.
				Hirose [79]	722Grp A 633Grp B	Mortality	Hospital Discharge	0.30	NR	(O/E ratio) 0.15
E-PASS	9	Pre and Intra-operative	5	Karres [67]	1050	Mortality	30 d	P=0.103	0.72(0.67-0.77)	NR

Risk scoring Model	Total Number of Variables	Stage variables were measured	Studies	Study ID	Patients (N)	Outcomes	End Point d = day m = month	Calibration (NR = Not recorded)	AUROC/(*c*-) (95% CI)	Results given in other forms
				Hirose [79]	722 Grp A 633 Grp B	Mortality Morbidity	Hospital Discharge 30 d	in hospital (mortality p=0.40, morbidity p=0.65) 30 day (mortality p=0.48, morbidity p=0.35)	NR	**Group A** In hospital morbidity CRS, p=0.17, P=<0.0001, PRS, p=0.17, P<0.0001, SSS, p=0.01, P=0.8 In hospital mortality PRS, p=0.16, P<0.0001, CRS p=0.18, P<0.0001 SSS, p=0.01, P=0.8 (**Spearman's rank correlation**) **Group B** (O/E ratio) Hospital Discharge Mortality 0.71, Morbidity 1.06 30 day Morbidity 1.59, Mortality 0.55
				Hirose [80]	419	Mortality Morbidity	Hospital Discharge	NR	NR	**Post-operative morbidity increase** PRS (p=0.19, P=0.0001), CRS(p=0.21, P<0.0001), SSS(p=0.005, P=0.3) **mortality rates correlation** PRS (p=0.19, P=0.0001,) CRS (p=0.21, P<0.0001), SSS(p=0.02, p=0.6) **(Spearman's rack correlation)**
				Hirose [81]	421 (Group A 268, B 153)	Ambulation Mortality Morbidity	Hospital Discharge 12 m	NR	NR	**Group A** **In hospital morbidity** SSS p=0.14, P=0.021, CRS p=0.13, P=0.030, PRS, p=0.09, P=0.08

Risk scoring Model	Total Number of Variables	Stage variables were measured	Studies	Study ID	Patients (N)	Outcomes	End Point d = day m = month	Calibration (NR = Not recorded)	AUROC/(*c*-) (95% CI)	Results given in other forms
										In hospital mortality SSS p=-14, P=0.019, PRS, p=0.05, P=0.220, CRS p=0.001, P=0.494. **1 year mortality** CRS p=0.12, P=0.043, SSS p=0.06, P=0.180 and PRS, p=0.09, P=0.075. **Predictor variables of walking ability at discharge** PRS p=0.34, P<0.001, CRS, p=0.33, P<0.001 ,SSS p=-0.001, P=0.495 walking ability at 1 year, PRS, p=0.41, P<0.001, CRS, p=0.40, P<0.001, SSS p=-0.05, P=0.236 **Group B** predicted walking ability at discharge p=0.60, P<0.001 , 1 year after Surgery p=0.65, P<0.001
				Hirose [30]	813	Mortality Morbidity	Hospital Discharge	NR	NR	Post-op **Complication** PRS (p<0.0001) **CRS(P<0.001) mortality** PRS (p=0.14, p=0.0001) **CRS (p=0.14, p=0.0001**), SSS(p=-0.03, p=0.4) **morbidity** (PRS)) P=0.16, *p*<0.0001) **(CRS) P=0.18, *p*<0.0001)** (SSS) P=0.06, *p*=0.07)**(Spearman correlation)**

Risk scoring Model	Total Number of Variables	Stage variables were measured	Studies	Study ID	Patients (N)	Outcomes	End Point d = day m = month	Calibration (NR = Not recorded)	AUROC/(*c*-) (95% CI)	Results given in other forms
										LOS PRS(R=0.09, p=0.009) SSS(R=0.17, p<0.0001) **CRS(r=0.13, p=0.0001)**
MMSE	11	Pre-operative	2	Bellelli [70]	398	Ambulation	Hospital Discharge	NR	0.7685	NR
							12 m		0.7267	
				Adunsky [86]	143	Ambulation	Hospital Discharge	p<0.001	NR	**Pearson Correlation** MMSE 0.732

Table 5 Outcomes

Study ID	Risk scoring Model	End Point	Morbidity (%)	AUROC Morbidity (95% CI)	Mortality (%)	Calibration (Hosmer-Lemeshow test) (NR = Not Recorded)	AUROC Mortality (95% CI)
Moerman [58]	RD	Hospital discharge	NR	0.73 (0.68-0.77)	NR	NR	**NR**
Vochteloo [63]	RD	Hospital discharge	27	0.72(0.67-0.77)	NR	NR	**NR**
Neuhaus [64]	CCI	Hospital discharge	NR	NR	9	NR	**CCI, ICD-9 adapted 0.767** **CCI, age adjusted 0.766** **CCI, updated 2011 0.768**
Burgos [65]	ASA CCI POSSUM Barthel Index Goldman Index RISK-VAS	Hospital Discharge 30 d 90 d	49.6	Hospital discharge: RISK-VAS 0.833 (0.757-0.910), Barthel 0.67 (0.565-0.780) Goldman 0.652 (0.522-0.781), POSSUM 0.726 (0.615-0.838) CCI 0.707 (0.602-0.811), ASA 0.675 (0.571-0.778)	11.2	NR	**90 d:** **RISK-VAS 0.677 (0.545-0.809)** **Barthel 0.689 (0.584-0.794)** **Goldman 0.432 (0.315-0.548)** **POSSUM 0.635 (0.518-0.751)** **CCI 0.590 (0.482-0.698)** **ASA 0.600 (0.488-0.711)**
Toson [66]	CCI	Hospital Discharge 30 d 12 m	NR	NR	8.2 8.3 26.3	NR	0.72-0.76 0.72-0.75 0.69-0.75
Karres [67]	Jiang et al NHFS Holt et al E-PASS CCI O-POSSUM	Hospital Discharge 30 d	NR	NR	6.0 8.2	P=0.041 P=0.039 P=0.103 P=0.002 P=0.291 P=0.110	0.78(0.73-0.83) 0.77(0.72-0.82) 0.76(0.71-0.81) 0.72(0.67-0.77) 0.71(0.65-0.77) 0.69(0.63-0.74)
Dawe [68]	Sernbo Score	30 d 12 m	NR	NR	NR	NR	**30 d: 0.71(0.65-0.76)** **12 m: 0.68(0.59-0.75)**

Study ID	Risk scoring Model	End Point	Morbidity (%)	AUROC Morbidity (95% CI)	Mortality (%)	Calibration (Hosmer-Lemeshow test) (NR = Not Recorded)	AUROC Mortality (95% CI)
Radley [69]	CCI (Romano adaptation) CCS Iezzoni	12 m	NR	NR	26	overall model performance good	**CCI 0.72** **CCS 0.76** **Iezzoni 0.73**
Jiang [72]	New Risk score	Hospital discharge 12 m	NR	NR	6.3 30.8	p>0.50 goodness of fit	**0.82** **0.74**
Soderqvist [74]	ASA SPMSQ	Hospital Discharge 120 d 24 m	NR	NR	4 16 38	NR	**24 m: Age, gender ASA 0.71** **24 m: Age, gender, SPMSQ 0.70**
Ramanathan [73]	O-POSSUM	30 d	NR	NR	10	poor fit p<0.00015	**0.62**
van Zeelan [75]	O-POSSUM ASA	Hospital Discharge	NR	O-POSSUM 0.83 (0.76-0.90)	9	good for mortality poor for morbidity	**O-POSSUM 0.83 (0.76-0.89)** **ASA O.76 (0.66-0.85)**
Steinberg [78]	O-POSSUM	Hospital Discharge	NR	NR	NR	NR	**0.63(0.58-0.68) model without albumin levels** **0.74(0.65-0.83) model with albumin level**
Moppett [82]	NHFS	30 d	NR	NR	6.6	p>0.1	**NR**
Maxwell [51]	NHFS ASA Donati Score	30 d	NR	NR	10.2	0.79	**NHFS 0.719 (SE0.018)** **ASA 0.718 (SE 0.0163)** **Donati Score 0.717(SE0.0184)**
Albertson [88]	FRAMO Index	24m	NR	NR	NR	NR	**0.75 (0.71-0.79)**
Studies with results presented as observed to expected ratios (O:E) and spearman's rank correlation							
Bonicoli [70]	O-POSSUM P-POSSUM	Hospital discharge	49.25	POSSUM 1.1	9.7	NR	**POSSUM 0.81** **P-POSSUM 2.17**
Wright [77]	O-POSSUM	30 d	41.3	O:E 0.95	10.9	NR	**O:E** **1.19**

Study ID	Risk scoring Model	End Point	Morbidity (%)	AUROC Morbidity (95% CI)	Mortality (%)	Calibration (Hosmer-Lemeshow test) (NR = Not Recorded)	AUROC Mortality (95% CI)
Hirose [79]	E-PASS P-POSSUM O-POSSUM	Hospital Discharge 30 d	**Grp A** 17.2 **Grp B** 20.2	**Grp A** Hospital Discharge Morbidity rates increased linearly with CRS, p=0.17, P=<0.0001 and PRS, p=0.17, P<0.0001, but not with SSS, p=0.01, P=0.8	**Grp A** 1.7 **Grp B** 2.4	**E-PASS** in hospital (mortality 0.40, morbidity 0.65) 30 d (mortality 0.48, morbidity 0.35) **P-POSSUM** in hospital (mortality 0.30) O-POSSUM 30 d (mortality 0.24, morbidity 0.11)	**Grp A** **Hospital Discharge** **Mortality rates correlated with PRS, p=0.16, P<0.0001 and CRS p=0.18, P<0.0001 but not with SSS, p=0.01, P=0.8**
				Grp B Hospital discharge E-PASS 1.06 30d: E-PASS 1.59 O-POSSUM 0.12			**Grp B** **Hospital discharge:** **E-PASS 0.71, P-POSSUM 0.15** **30 d:** **E-PASS 0.55** **O-POSSUM 0.12**
Hirose [80]	E-PASS	Hospital discharge	18.4	Spearman correlation: morbidity significantly increased with both the PRS (p=0.19, P=0.0001) and CRS(p=0.21, P<0.0001), but not with the SSS(p=0.005, P=0.3) The cost of hospital stay was significantly related to the SSS (r=0.6, P<0.0001) and CRS (r=0.4, P<0.0001) (Pearson's correlation)	1.9%	NR	**Spearman correlation:** **mortality rates correlated with PRS (p=0.19, P=0.0001,) CRS (p=0.21, P<0.0001) but not with SSS(p=0.02, p=0.6)**
Hirose [81]	E-PASS	Hospital discharge 12 m	**Grp A** 23.5, **Grp B** 17.0	Grp A Hospital Discharge Spearman correlation In hospital morbidity correlated with the SSS p=0.14, P=0.021, CRS p=0.13, P=0.030, but not with the PRS, p=0.09, P=0.08	**Grp A** 2.2 **Grp B** 2.0 **Grp A** 6.8 **Grp B** 9.8	NR	**Hospital discharge** **Spearman correlation** **In hospital mortality was correlated with SSS p=-14, P=0.019, but not with PRS, p=0.05, P=0.220 and CRS p=0.001, P=0.494.**

Study ID	Risk scoring Model	End Point	Morbidity (%)	AUROC Morbidity (95% CI)	Mortality (%)	Calibration (Hosmer-Lemeshow test) (NR = Not Recorded)	AUROC Mortality (95% CI)
Hirose [30]	E-PASS	Hospital discharge	20	Spearman correlation Post-operative morbidity rates increased linearly and correlated significantly with (preoperative risk score (PRS)) P=0.16, p<0.0001) (comprehensive risk score (CRS) P=0.18, p<0.0001)but not surgical stress score (SSS) P=0.06, p=0.07) Cost of Hospitalisation PRS(R=0.12, p<0.0001) SSS(r=0.44, p<0.0001) CRS(r=0.23, p<0.0001) (Pearson correlation)	1.6	NR	**Spearman correlation mortality rates correlated with PRS (p=0.14, p=0.0001) CRS (p=0.14, p=0.0001)but not with SSS(p=-0.03, p=0.4)**
Moppett [83]	NHFS	Hospital discharge 30 d 12 m	NR	Hospital discharge Increasing NHFS was negatively correlated with eventual return-to-home (r^2=0.949), and with the proportion of patients discharged back to their own home at 7,14 and 21 postoperative days respectively (r^2=0.84,0.94,0.96 respectively)	8.3 29.3	NR	**NR**
Wiles [84]	NHFS	30 d 12 m	NR	NR	8.3 29.3	NR	**30 d** **survival was higher in the low risk group 96.5% vs 86.3% (P<0.001)** **12 m**
Rushton [85]	NHFS	30 d	NR	NR	7.3	NR	**NR**
Foss [87]	CAS NMS	Hospital discharge 30 d	21.6	Chi-squared values for CAS vs NMS were 60.3, 20.2 for the risk of post-operative morbidity and 97.6, 68.3 for the association with patient discharge to own home	30 d: 10.3		**Chi-squared values for CAS vs NMS were 49.1, 20.0 for the association with 30 day mortality**

Study ID	Risk scoring Model	End Point	Morbidity (%)	AUROC Morbidity (95% CI)	Mortality (%)	Calibration (Hosmer-Lemeshow test) (NR = Not Recorded)	AUROC Mortality (95% CI)
Studies presenting ambulation as the outcome							
Burgos [65]	ASA CCI POSSUM Barthel Index Goldman Index RISK-VAS	Hospital Discharge 30 d 90 d	NR	30 d: RISK-VAS 0.700, Barthel 0.737 90 d: RISK-VAS 0.700 (0.628-0.771) Barthel 0.737 (0.672-0.801) Goldman 0.567 (0.491-0.643) POSSUM 0.646 (0.573-0.718) CCI 0.634 (0.563-0.706) ASA 0.624 (0.551-0.698)	NR	NR	
Bellelli [70]	New predictive risk score MMSE BMI Barthel Index	Hospital discharge >12 m	NR	Hospital discharge: Walking independently New risk score 0.8593, MMSE 0.7685 BMI 0.4989, Barthel Index 0.8700 12 m: Walking independently New risk score 0.75, MMSE 0.7267 BMI 0.5209, Barthel Index 0.7344	NR	NR	
Vochteloo [71]	DHP	Hospital discharge	NR	Discharge Location Delft Cohort (0.84, 0.79-0.88) Groningen Cohort (0.75, 0.66-0.82)	NR	NR	
Hirose [81]	E-PASS	Hospital discharge 12 m	NR	NR	NR	**Grp A** Hospital discharge Predictor variables of walking ability at discharge was significantly correlated with PRS p=0.34, P<0.001, CRS, p=0.33, P<0.001 not with SSS p=-0.001, P=0.495	

Study ID	Risk scoring Model	End Point	Morbidity (%)	AUROC Morbidity (95% CI)	Mortality (%)	Calibration (Hosmer-Lemeshow test) (NR = Not Recorded)	AUROC Mortality (95% CI)
						12 m: walking ability at 1 year was significantly correlated with, PRS, p=0.41, P<0.001, CRS, p=0.40, P<0.001 not with SSS p=-0.05, P=0.236. **Grp B** Hospital discharge the predicted walking ability calculated by the logarithm was significantly correlated with the actual ability at discharge p=0.60, P<0.001 and at 12 m: after Surgery p=0.65, P<0.001	
Adunsky [86]	**MMSE CDT Cognitive -FIM**	**Hospital discharge**	**NR**	**NR**	**P<0.001**	**Pearson Correlation between the three cognitive tests resulted in values ranging from 0.607 to 0.732**	

Table 6 Comparison of frequently used tools in hip fracture patients

Scoring system	Description	Original development cohort and outcome	Validation in hip fracture	Strengths	Weaknesses
American Society of Anaesthesiologists Score (ASA)	Classification of patients into one of the five categories (I-V) based on the general medical comorbidities severity on physical status (subjective assessment)	General Surgery patients, [49] Mortality Morbidity Not derived or validated	External; International; Multicentre validation for classification of population risk; not validated for prediction of individual patient risk N = 5 411, [51 65 75].	Common. Simple. Easily applied at bedside not requiring complex calculations. Allows subjective interpretation	Not designed as an operative risk score. Subjective, No differentiation among different types of patient comorbidity, Wide inter-observer variability, Does not use information regarding the surgical procedure itself. Poor sensitivity and specificity for the prediction of morbidity and mortality on an individual patient basis, [44]
Charlson Comorbidity Index (CCI)	Additive score that categorise and assigns weight and severities to 19 different patient comorbidities (Subjective assessment).	Medical patients,[50] 10 year mortality N = 559	External; International; Multicentre validation in different cohorts N = 6 230 456,[64-67 69].	Relatively simple; Easily applied at bedside; accurate predictor of population risk according to assigned score; has different adaptation/modifications could be applied in different clinical areas.	Assessment of patient comorbidity may be subjective; Use no information regarding the surgical procedure itself; has many variants/adaptations which could cause confusion on which is the best for use.
Nottingham Hip Fracture Score (NHFS)	A summative score of 7 preoperative variables (Age, Sex, Admission Hb, MMST, Living in an institution, Number of comorbidities, Malignancy), originally developed to predict 30 day mortality. Each variable is assigned a score of 1, except for age (66-85 years) scores 3 and above 85 years scores 4.	Hip Fracture Patients,[51] 30 day mortality N = 4967	Temporal and Internal Validation; Multicentre; All studies validated the UK only, now has been validated for early hospital discharge and 1 year mortality N =13 799,[67 82-85].	Relatively simple; Easily applied at bedside; Validated for prediction of individual patient risk; Uses objective variables such as blood test (Hb) results therefore reducing inter-observer variability.	Limited to patients above the age of 65 years and above; cannot be used on patients admitted from hospital; Validated in the UK only.

Estimation of Physiologic Ability and Stress Surgical Score(E-PASS)	A comparative audit tool that uses coefficients to combine pre-operative factors (comorbidity and performance status) with Intraoperative parameters (ratio of blood loss to body weight, operative time, type of operation/incision), and is comprised of a preoperative risk score (PRS), a surgical stress score (SSS) and a comprehensive risk score (CRS) that is determined by the PRS and SSS.	Elective Gastro-intestinal patients,[105]] Mortality Morbidity N = 902	Both External and Internal Validation; Multicentre; All studies validated in Japan only. Validated for in hospital, 30 day and 1 year mortality and morbidity and I year mobility outcome N =5832[30 67 79-81].	Use both pre-operative factors and information regarding the surgical procedure itself; Incorporates age and the ASA score	Complex calculations required to derive the score; Uses some subjective variables and patient reported variables (such as physical activity ability to perform work of a light or sedentary nature); The operative variables are not available until during or after surgery; Validated in Japan only.
Orthopaedic Physiological and Operative Severity Score for EnUmeration of Mortality and Morbidity (O-POSSUM)	18 variables (12 physiological and 6 operative). Each variable is assigned a score and the total is scores are entered into logistic regression equations that calculate a percentage mortality and morbidity risk.	General orthopaedic patients,[128] Mortality Morbidity N - 2326	Multicentre; International; This is a modified version of the original POSSUM that has been validated in patients with hip fractures N = 5975, [51 67 75-79].	Validated for prediction of individual patient risk; Validated Internationally; Includes objective variables (such as blood results) therefore reducing inter-observer variability.	Complex calculations required to derive the score; Uses some subjective variables (X-ray, ECG interpretation) carrying the risk of measurement error; The operative variables are not available until during or after surgery; it has been shown to over predict mortality in this group of patients,[73].

Table 7 Comparison of variables characteristics in each risk stratification tool

	Pre–op alone			Pre and Post–op	
	ASA	**CCI**	**NHFS**	**O–POSSUM**	**E–PASS**
Patient characteristics					
Age (years)	+	+	+	+	+
Sex	+	+	+		+
Chronic health (co-morbidities)	+	+	+		+
History of cancer			+		
ASA-PS					+
Cognitive Status			+		+
Place of residence			+		
Weight (kg)					+
Physical status					+
Physiological markers					
Temperature (°C)					
Blood pressure (mmHg)				+	
Pulse rate				+	
Respiratory rate					
Respiratory effort					
Coma				+	
Cardiac signs				+	
Biological markers					
Haemoglobin			+	+	
White blood count				+	
Sodium (Na)				+	
Potassium (K)				+	
Urea nitrogen				+	
Special test					
ECG				+	
CXR				+	
Post–op characteristics					
Type of operation				+	+
Number of operations (≤ 30 days)				+	
Blood loss volume (ml)				+	+
Peritoneal contamination				+	
Presence of malignancy (stage I, II, III or IV)				+	
Timing of operation				+	+

Table 8 Characteristics of included studies - review update

Study ID	Risk scoring Model	Timing	Country	Number of Centres	Patients (n)	Study Purpose	Validation Cohort: Internal vs External vs Temporal	Outcome	End Point d-days m-months	Subject description	Selection Bias
Marufu [111]	NHFS SORT	Prospective	UK	National	9017	Validation/ Comparative	External	Mortality	30 d	Y	N
Gonzalez - Zabaleta [112]	CCI	Prospective	Spain	1	199	Validation	External	Mortality	12 m	Y	N
Lau [113]	CCI	Retrospective	China	1	759	Validation	External	Mortality	30 d 12 m	Y	N
Liu [115]	ASA	Retrospective	China	1	327	Validation	External	Morbidity Mortality	Hospital Discharge 12m	Y	N
Schilling [116]	Hip Fracture Repair	Retrospective	USA	National	7000	Development and Validation	Temporal	Mortality Morbidity	30 d 30 d	Y	N
Yin [114]	ASA and RDW Jiang' and RDW	Rétrospective	China	1	1402	Validation/ comperative	Eternal	Mortality	24 m	Y	N
Bliemel [117]	New Model – Pre-fracture quality of life	Prospective	Germany	1	391	Development	Temporal	Mortality	12 m	Y	N
El-Daly [118]	Waterlow score	Prospective	UK	1	97	Validation	External	Morbidity	30 d	Y	N

Table 9 Outcomes - review update

Study ID	Risk scoring Model	End Point	Morbidity (%)	AUROC Morbidity (95% CI)	Mortality (%)	Calibration (Hosmer-Lemeshow test) (NR = Not Recorded)	AUROC Mortality (95% CI)
Marufu [111]	NHFS SORT	30 d	NR	NR	5	0.23 0.001	**0.7190.67-0.750** **0.70(0.66-0.74)**
Gonzalez – Zabaleta [112]	CCI	12 M	NR	NR	19.19	NR	**0.623**
Lau [113]	CCI	30 d 12 m	NR	NR	2.5 16.3	NR NR	**0.72** **0.75**
Yin [114]	ASA and RDW Jiang' model and RDW	24 m 24 m	NR NR	NR NR	14	0.816 0.461	**0.723** **0.694**
Liu [115]	ASA	Hospital Discharge 12 m	58.4	NR	NR NR	NR NR	**NR** **NR**
Schilling [116]	Hip Fracture Repair (HFR)	30 d	NR	0.68	8.2	0.23	0.80
Bliemel [117]	New Model – Pre-fracture quality of life	12 m	NR	NR	NR	0.272	0.74(0.68-0.79)
El-Daly [118]	Waterlow score	30 d	68%	0.89(0.82-0.96)	NR	NR	**NR**
Nijmeijer [119]	NHFS AHFS	30 d	NR	NR	NR	0.03 0.02	**0.72** **0.82**

CHAPTER 3

Comparison of the Nottingham Hip Fracture Score (NHFS) with the Surgical Outcome Risk Tool (SORT) in predicting 30-day mortality after hip fracture surgery: Tool Recalibration

3.1 Introduction

Accurate risk prediction models facilitate the pre-operative identification of patients at higher risk following surgery, enabling targeted intra- and peri-operative interventions aimed at improving their outcomes. At an institutional level, accurate case mix adjustment using risk models allows outcomes to be compared between hospitals and, longitudinally, within hospitals [44].

Since 2010, the National Hip Fracture Database (NHFD, www.nhfd.co.uk) has published institutional 30-day mortality data for hip fracture patients in England, Wales and Northern Ireland[11]. A new case mix adjustment tool (CEU 17) has recently been developed by the NHFD to compare 30-day mortality between hospitals, involving six variables that are routinely collected: age, sex, premorbid walking ability, American Society of Anaesthesiologists (ASA) physical status, source of admission (premorbid residential status) and fracture type. Statistically, this tool shows poor calibration but moderate discrimination [143].

The Nottingham Hip Fracture Score (NHFS) accurately predicts 30-day [51] and 1-year [84] postoperative mortality and likelihood of early discharge after hip fracture surgery, has been validated and recalibrated using audit data from other hospitals in England [82] and has been used for risk adjustment of outcomes associated with mode of anaesthesia [34]. In comparison to other risk models for predicting 30-day mortality following hip fracture surgery, the NHFS was found to be the most discriminatory and extensively validated [67 123]. However, to date, the NHFS has not been

validated using a national data set, or recalibrated to more accurately predict outcome nationally, and so cannot yet be compared to the CEU 17 test currently used by the NHFD.

The National Hip Fracture Database routinely collects four out of seven variables used to calculate the NHFS (age, sex, abbreviated mental test score, premorbid residential status). As part of the Anaesthesia Sprint Audit of Practice (ASAP) [107], data were collected for the remaining 3 variables (number of comorbidities, malignancy within the previous 20 years, haemoglobin concentration on admission to hospital [129]). We originally intended to use these data to validate the NHFS and recalibrate it for future use in England, Wales and Northern Ireland.

However, during analysis of the ASAP data in 2014, Protopapa et al. [52] reported the development and validation of a new risk stratification tool, the Surgical Outcome Risk Tool (SORT), using National Confidential Enquiry into Perioperative Death (NCEPOD) data from 16 788 non-cardiac patients (including hip fracture patients). They demonstrated better discrimination with SORT than the ASA physical status score in terms of predicting 30-day mortality. The SORT is an attractive tool for risk assessment partly due to its robust development and validation and also because it is applicable across a wide range of surgical patients. We therefore used the ASAP to investigate the ability of both SORT and NHFS to predict outcome following hip fracture.

3.2 Methods

Data used in this analysis were collected as part of the Anaesthesia Sprint Audit of Practice (ASAP)[107]. The audit aimed to profile individual UK hospitals' compliance with the peri-operative care guidelines set by the Association of Anaesthetists of Great Britain and Ireland (AAGBI)[40]. Data were collected for all hip fracture patients aged 60 years and above who underwent surgery between 1st of May and 31st July 2013. All hospitals which routinely contribute to the NHFD were invited to take part with specific data collection team members given access and responsibility to upload data onto the NHFD online data collection tool. All regulatory and ethical approvals were granted before data collection commenced (pages 9-11 of the Report [107]).

Results of the primary analysis of ASAP are detailed in one of the published paper [34]. Ethics Committee (Integrated Research Application System (IRAS) ref: 93261) approval was granted through the proportionate review mechanism (North of Scotland NRES Proportionate Review Sub-Committee reference 14/NS/0024, 12th February 2014). Data release from the Royal College of Physicians Falls and Fragility Fractures Audit Programme (FFFAP) was approved on 19th August 2014. Encrypted, password-protected, anonymised data were transferred electronically to a double password-protected National Health Service (NHS) e-mail account for analysis.

Data fields specific to this study were analysed in isolation from all data released for secondary analysis. These included categorical data common

to NHFS and SORT score calculations (age and malignancy (within the last 20 years but excluding non-melanomatous skin malignancies), those specific to NHFS calculation [51] (male sex, abbreviated mental test score ≤ 6/10, premorbid institutionalisation, two or more comorbidities (previous/current myocardial infarction, angina, atrial fibrillation, valvular heart disease, hypertension, cerebrovascular accident, transient ischaemic attack, asthma, chronic obstructive pulmonary disease, renal disease), and anaemia on hospital admission [Hb] < 100g.L^{-1}) and those specific to SORT score calculation [52] (ASA physical status, urgency and severity of surgery and surgical specialty). For the purposes of SORT score analysis, surgical specialty was assigned a value of 0 (i.e. not 'high-risk' gastrointestinal, thoracic or vascular), urgency of surgery was classified as 'urgent', and severity of surgery was classified as 'Xmajor complex' (and assigned a value of 1) for all procedures except hemiarthroplasty (classified as 'Major' according to SORT criteria/AXA Specialist Procedure Codes, and assigned a value of 0).

From these, NHFS and SORT scores were calculated for each patient. Patients were grouped according to each score. For each group, expected 30-day mortality was calculated and compared to observed 30-day postoperative mortality data recorded by the National Hip Fracture Database (confirmed by cross-reference to EMIS data (Egton Medical Information Systems Ltd., Leeds, UK)).

As both NHFS and SORT were expected to require recalibration, the available data set of 9 017 eligible patients was split randomly into two groups (development set and validation set, 70:30 ratio). Simple logistic regression, using NHFS or SORT as a single continuous predictor was used to generate new model beta coefficients on the development data set. The relative weighting of the individual item scores was kept unchanged. Model performance or internal validity was then assessed using the new derived coefficients on the validation set.

3.2.1 Analytical methods

Two analytical approaches were used;

(i) Complete case (listwise deletion) – Analysis was performed in all patients with both NHFS and SORT data available.

(ii) Multiple data imputation was performed on the missing values within the whole data set and analysis was redone including all patients.

3.2.2 Data imputation a brief over view

Data imputation refers when missing values are systematically replaced by substituted values. Across all fields of research, missing data are inevitable. Missing data that are present in one or more variables can cause special challenges [130]. By default statistical package software, use complete case analytical approaches to handle missing data [131-133] (that is subjects with missing data are automatically excluded from final analysis). The approach is simple, efficient and gets reliable results mainly

when the number of missingness is not large and the missing values are missing at completely random (MACR) or missing at random (MAR) [132]. Missing data has been attributed to cause the following key issues a) bias, b) create reduction in efficiency by c) making the handling and analysis of data more arduous [133].

Therefore, complete case analysis could potentially undermine study validity. Information attrition is more apparent in the scenario where one has a large dataset with many variables. Listwise deletion can result in a substantial proportion of cases excluded as it is based on missingness of data on one or more variables. As a result there would be substantial loss of power and precision. Bias from missing data is more influenced by the reasons why data are missing. Table 10 is a classification of missing data. Where observations with missing data differ systematically from completed cases, complete case analysis could be biased as analysed cases are not representative of the original sample or population [134].Current diverse statistical packages now have data imputation capabilities making it plausible to handle missing data [132].

Table 10 missing data classification

Missing completely at random – No systematic variations between the missing and observed values.
Missing at random – Observed systematic variations between the missing and observed values, can be attributed to differences in observed data.
Missing not at random – Systematic variations remain between the missing and observed values even after the observed data are taken into account

3.2.3 Imputation techniques

There are two types of imputation techniques, single imputation [135 136] and multiple imputation [137].

3.2.3.1 Single imputation

Single imputation demands less computation and provides the dataset with a specific number in place of missing data. There are four ways of computing single imputation; mean imputation, regression imputation, hot deck and last observation carried forward (LOCF) (Table 11). This approach relies on data analysis to identify the most likely (or an array of the most likely) values and then randomly choose one of those possible responses to replace the missing data [135].

Table 11 Single imputation methods

Mean imputation – replacing missing values with mean values of the available cases
Hot deck – replacing missing values with a randomly chosen value among the available cases
LOCF – replacing missing values with the last observed value of that individual. Appropriate for longitudinal designs only.
Regression imputation – substitute value is predicted from regression equation

3.2.3.2 Multiple imputation

Multiple imputation approach allows for the un-certainty about missing observations by averaging the outcomes across multiple simulation models taken from a set of plausible imputed data sets and appropriately combining the results to obtain each of the final value [132 135]. It is the method of choice for complex incomplete data problems [130]. There are three stages of multiple imputation;

Imputation – multiple (*m*) copies of the dataset are created with missing values replaced by imputed values. Imputed values are drawn from predictive distribution based on the observed data, thus multiple imputation is based on Bayesian approach. At the end of this step there should be *m* completed datasets.

Analysis – standard statistical methods are applied to fit the model of interest to each of the imputed datasets. At the end of this step there should be *m* analysis.

Pooling – m results are consolidated into one result by calculating the mean variance and confidence interval of the variables concerned [130]. Rubin's rule [137] is used to calculate standard errors, which take account of the variability in the results between the imputed datasets, reflecting the uncertainty associated with the missing values. Valid inferences are obtained because we are averaging over the distributions of the missing data given the observed data [132].

We used multiple imputation as it is recognised to be the method of choice for complex data problems as observed in our case. The multivariate imputation by chained equation (MICE) package [138] was used.

3.2.4 Statistical analysis

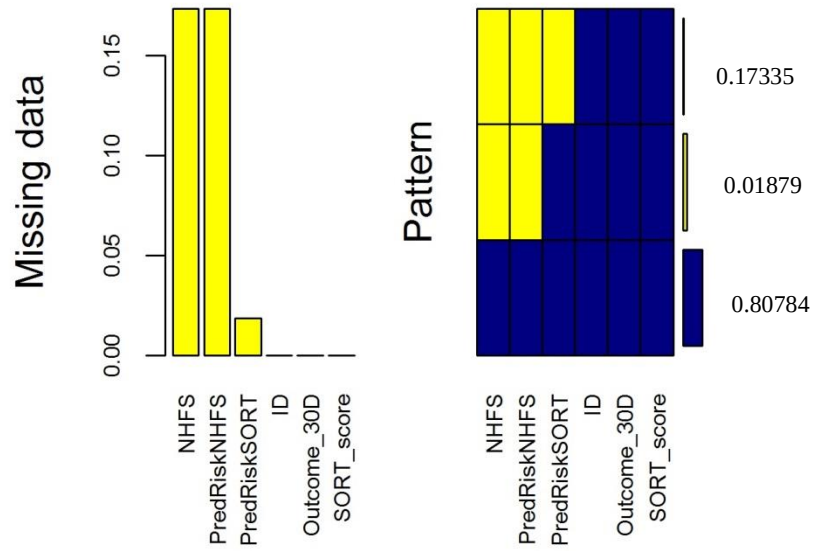
Descriptive statistics were used to characterise the patients included in the study. Mortality analysis included all cases. Models were assessed for discrimination (i.e. how well the models separated those who did and did not die) and calibration (i.e. how well predicted mortality rates agreed with actual observed mortality rates) in relation to 30-day mortality. Discrimination was measured using area under the receiver-operating characteristic curve (AUROC). AUROC values were pre-defined as acceptable/good (0.70 – 0.79), moderate (0.80 – 0.89) or excellent (≥0.9) [139]. For each regression analysis, confidence intervals for AUROC were calculated using DeLong's method [140]. The Hosmer-Lemeshow statistic was used to evaluate calibration over the entire range of prediction. This 'goodness of fit' test is a comparison of the predicted

versus observed mortality [53], with $p \leq 0.05$ was taken as the threshold for evidence of lack of fit. The analysis plan was similar to that performed by the developers of both models and has been used in validation of other scoring systems [67] [123]. Data analysis was performed using R statistical package, version 3.1.2 [141].

3.2.4.1 Inspecting the missing data

Figure 1 is a visual representation of missing data from the six variables in the final dataset. The plot denotes that about 81% of samples are not missing values, 17% are missing in both variables NHFS and PredRiskNHFS and 2% are missing in variable PredRiskSORT.

Figure 2 Missing data



3.2.4.2 Imputing the data

The following code was used to run the imputation:

mice(data = SORTT1, m = 5, method = "pmm", maxit = 50, printFlag = FALSE, seed = 245435)

Number of multiple imputations: 5

Imputation methods:

ID Outcome_30D NHFS SORT_score PredRiskNHFS PredRiskSORT

"pmm" "pmm" "pmm" "pmm" "pmm" "pmm"

m = 5 refers to the number of imputed datasets, which is the default value. There are various imputation methods to use. ID, Outcome_30D, NHFS, SORT_score, PredRiskNHFS and PredRiskSORT are the variables. We used the predictive mean matching (pmm) imputation method [130]. It is a general purpose semi-parametric imputation method. Its main advantage is that it can preserve non-linear relations even if the structural part of the imputation model is wrong. In comparison to other methods, it is a good overall imputation method [130].

3.2.4.3 Diagnostic checking of the distribution of original vs imputed data

In multiple imputation, assessment of whether imputations are plausible is a key requirement. Imputations should be close to the data, since they should have been values that could have been obtained had they not been missing. Diagnostic checks using density plot and strip-plot Figures 2 and 3 respectively allowed us to check the plausibility of the imputations. Blue points/lines are observed values and red are imputed. Variables containing blue dots only are complete. The matching shapes Figure 3 and the red points following the blue points reasonably well Figure 4 tell us that imputed values are plausible.

Figure 3 Strip plot of imputed data

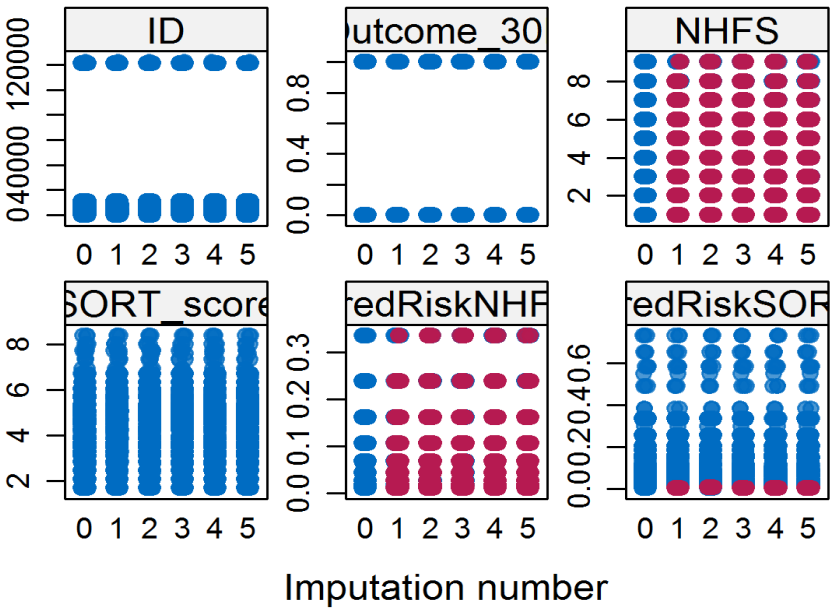
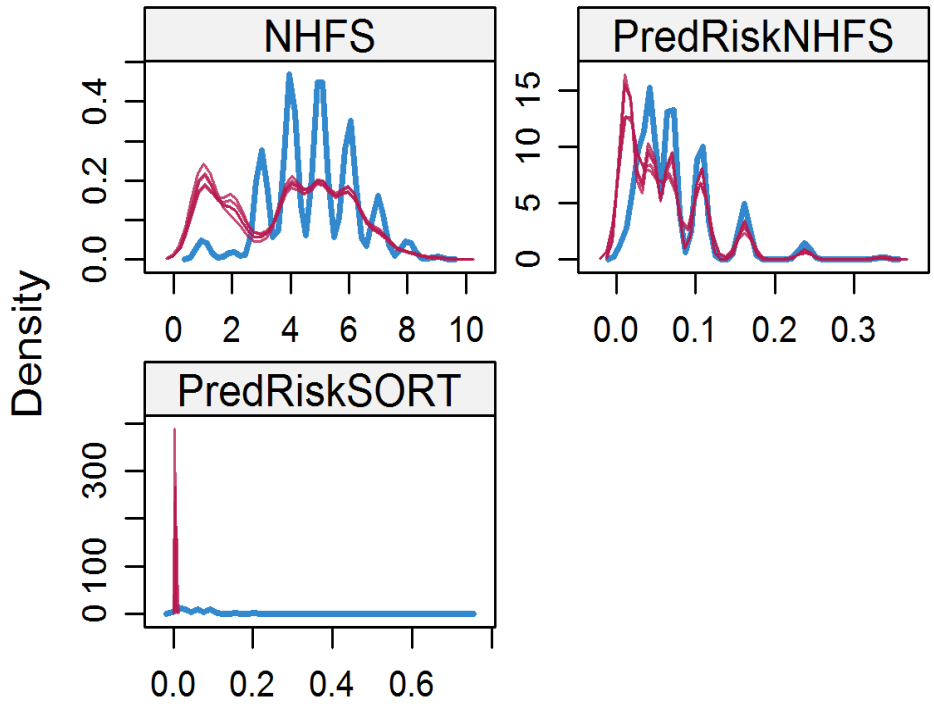


Figure 4 Density plot of imputed data



3.3 Results from case complete analysis

NHFS and SORT variables were available for 10 908 patients in this study. However, individual data field omissions meant that either a NHFS or SORT score was not calculable for 1721 (15.8%) and 170 (1.6%) patients, respectively, who were excluded from further analysis. A total of 9 017 (82.7%) patients were included in the final analysis, the descriptive statistics for which are shown in Table 12.

The overall 30-day mortality rate was 5% among the included patients. A uniform death rate was observed between the risk model development and validation cohorts. Across all data sets, moderate mortality rate was observed in the highest age group (80 years and above 6.1%), those with ASA-PS grade III (4.5% – 5.5%) and in severity of surgery (4.1% - 6.1%). High mortality rates were observed in patients with ASA-PS grade IV and V (10.1% - 50%) and those with malignancy (6.3% - 10.6%).

The NHFS median score(IQR)[range]) was 5.0 (4.0,6.0) [1.0-10.0]) and SORT 4.7 (3.6 ,5.0) [1.7-8.4]) . There were insufficient data to fully describe the characteristics of the excluded patients.

Table 12 Descriptive characteristics of 9017 included in complete case analysis of NHFS and SORT models including 30 day mortality

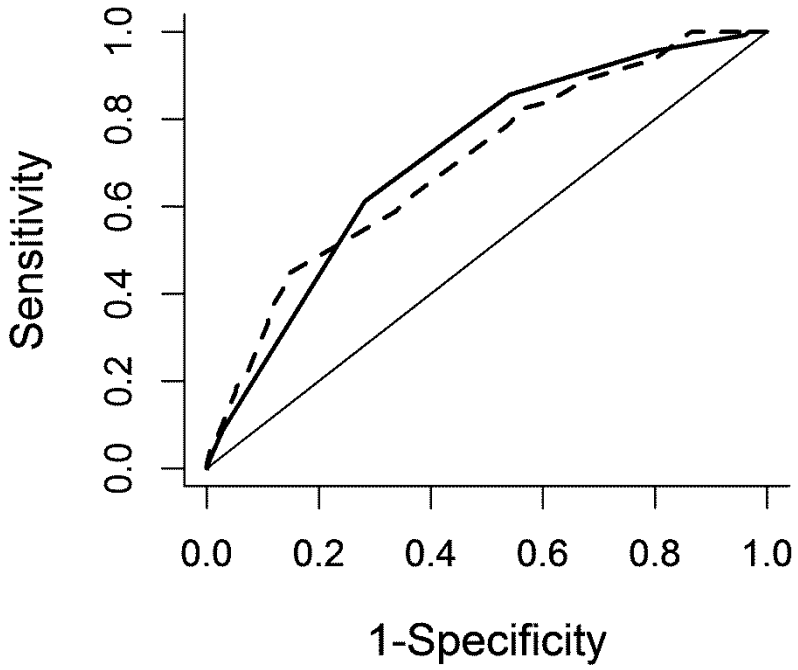
Data set				Age (years)			ASA-PS grade					Surgery severity		Malignancy	Median score (IQR [range])	
			All patients	<65	65-79	>=80	I	II	III	IV	V	Major	Complex		NHFS	SORT
Whole data set	Number of patients	N (%)	9017 (100.0)	320 (3.5)	2450 (27.2)	6247 (69.3)	2 (0.0)	0 (0.0)	5087 (56.4)	1100 (12.2)	14 (0.2)	4016 (44.5)	5001 (55.5)	1054 (11.7)	5.0 (4.0,6.0, [1.0-10.0])	4.7 (3.6,5.0, [1.7-8.4])
	30-day mortality	N (%)	455 (5.0)	4 (1.3)	71 (2.9)	380 (6.1)	0 (0.0)	0 (0.0)	279 (5.5)	127 (11.5)	11.5 (35.7)	244 (6.1)	211 (4.2)	80 (7.6)		
Development set	Number of patients	N (%)	6317 (100.0)	217 (3.4)	1699 (26.9)	4401 (69.7)	1 (0.0)	0 (0.0)	3569 (56.5)	756 (12.0)	10 (0.1)	2793 (44.2)	3524 (55.8)	732 (11.6)	5.0 (4.0,6.0, [1.0-10.0])	4.7(3.6,5.0, [1.7-8.4])
	30-day mortality	N (%)	316 (5.0)	2 (0.9)	46 (2.7)	268 (6.1)	0 (0.0)	0 (0.0)	211 (5.9)	76 (10.1)	3 (30.0)	171 (6.1)	145 (4.1)	46 (6.3)		
Validation set	Number of patients	N (%)	2700 (100.0)	103 (3.8)	751 (27.8)	1846 (68.4)	1 (0.0)	0 (0)	1522 (56.4)	344 (12.7)	4 (0.2)	1223 (45.2)	1477 (54.7)	322 (11.9)	5.0 (4.0,6.0, [1.0-10.0])	4.7 (3.6 ,5.0, [1.7-8.4])
	30-day mortality	N (%)	139 (5.1)	2 (1.9)	25 (3.3)	112 (6.1)	0 (0.0)	0 (0.0)	68 (4.5)	51 (14.8)	2 (50.0)	73 (6.0)	66 (4.5)	34 (10.6)		

Values in parenthesis are percentages, ASA-PS, American Society of Anaesthesiologists Physical Status, NHFS, Nottingham Hip Fracture Score, SORT, Surgical Outcome Risk Score Tool, IQR, Interquartile range.

3.3.1 Discrimination

Sensitivity and specificity using recalibrated equations for both models are shown as receiver operating characteristic (ROC) curve in Figure 5. Both risk stratification models demonstrated acceptable discrimination in the validation cohort (NHFS 0.71 (95% confidence interval (CI), 0.67-0.75) SORT 0.70 (95% CI, 0.66-0.74).

Figure 5 Receiver operator characteristic curves for recalibrated NHFS (—) and the recalibrated SORT (----) for the 2,700/9,013 validation group.



3.3.2 Calibration

The H-L and x^2 test was used to test 'goodness of fit'. New risk model coefficients were derived using the development cohort (NHFS 0.50779, Intercept -5.56999, SORT 0.8250, Intercept -6.7896) and then applied to the validation cohort. The new and old risk model logistic regression models to calculate 30-day mortality are shown on Table 13 (NHFS) and Table 14 (SORT).

Table 13; NHFS old equation [82] 30 day mortality (%) = $100/(1+e^{[5.012-(NHFS \times 0.481)]})$. Recalibrated equation 30 day mortality (%) = $100/(1+e^{[5.569-(NHFS \times 0.508)]})$.

		Predicted and Observed 30-day mortality (%)		
Quantile	No. of patients	Original NHFS Predicted	Recalibrated NHFS Predicted	Observed
1	516	2.4	1.6	1.2
2	679	4.4	2.9	2.1
3	698	6.9	4.7	4.9
4	496	10.7	7.6	10
5	228	16.2	12.3	10.1
6	83	25.4	22	14.5

Table 14 SORT old equation [52] 30-day mortality (%) = 100/(1+e(7.366-SORT score)). Recalibrated equation 30 day mortality (%) =100/(1+e[6.79-(SORT score x 0.825)]).

		Predicted and Observed 30-day mortality (%)		
		Original SORT	Recalibrated SORT	
Quantile	No. of patients	Predicted	Predicted	Observed
1	335	0.8	1.3	0
2	215	1.4	1.9	4.7
3	285	2.7	2.5	1.3
4	331	3.5	3.4	3
5	525	6.1	5.2	5.3
6	574	8.8	6.9	4.2
7	223	13.2	14	14.3
8	212	21.9	15	14.2

Calibration for both NHFS ($p < 0.0001$) and SORT ($p < 0.0001$) was poor using the original equations finding higher predicted values than observed 30-day mortalities. Using newly derived model coefficients (Table 13 and Table 14), the NHFS showed good calibration/better evidence of fit ($p=0.2285$), whereas the calibration of SORT remained poor ($p=0.001$) (Figure 6).

Figure 6. The observed vs predicted 30-day mortalities before (a and b) and after c and d) recalibration for the NHFS (a and b) and SORT (c and d).

Figure 7. Predicted 30-day mortalities and 95% confidence intervals (CI) for the NHFS (top) and SORT (bottom) and their respective observed mortalities.

Figure 6 The observed vs predicted 30-day mortalities before (a and b) and after c and d) recalibration for the NHFS (a and b) and SORT (c and d).

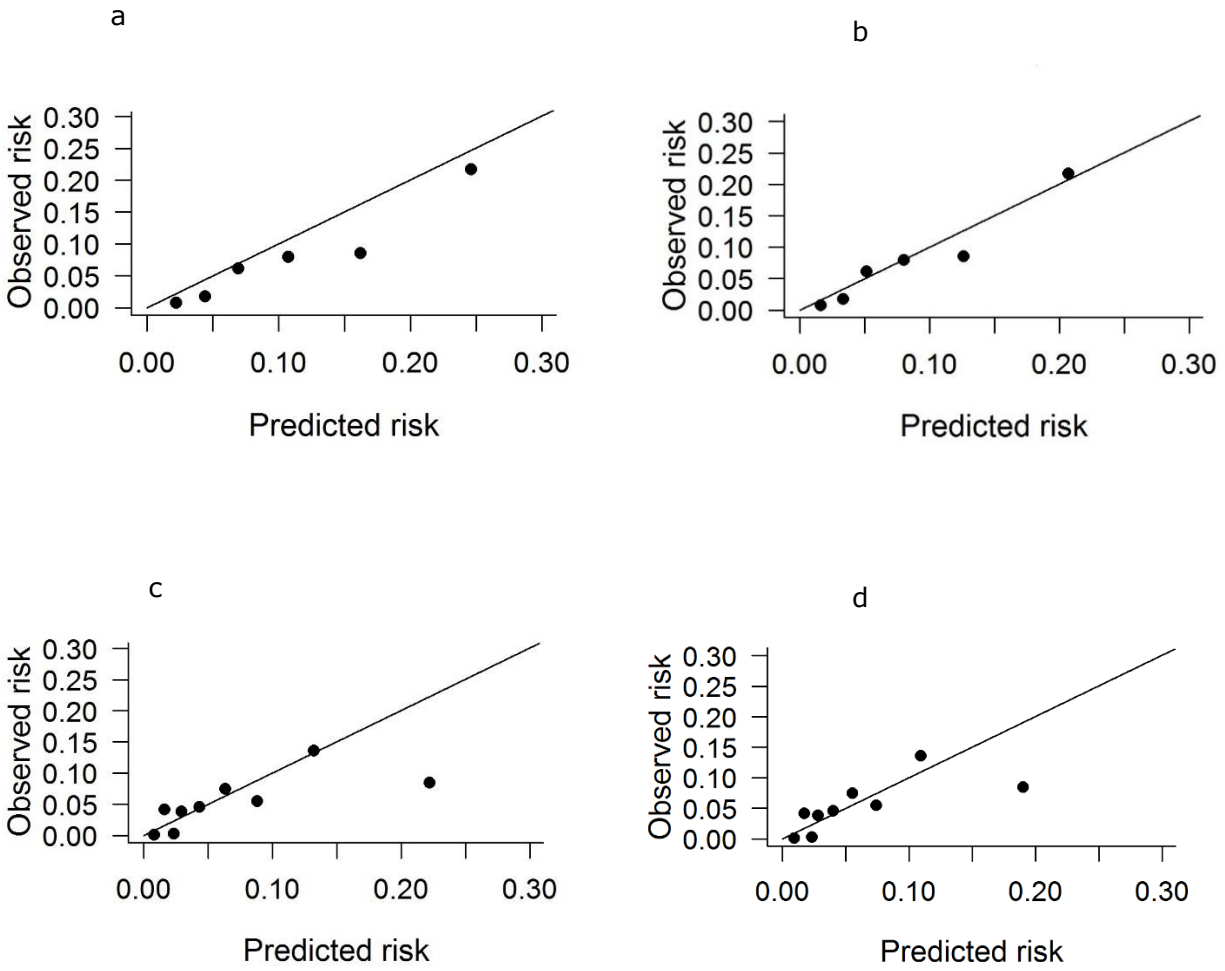
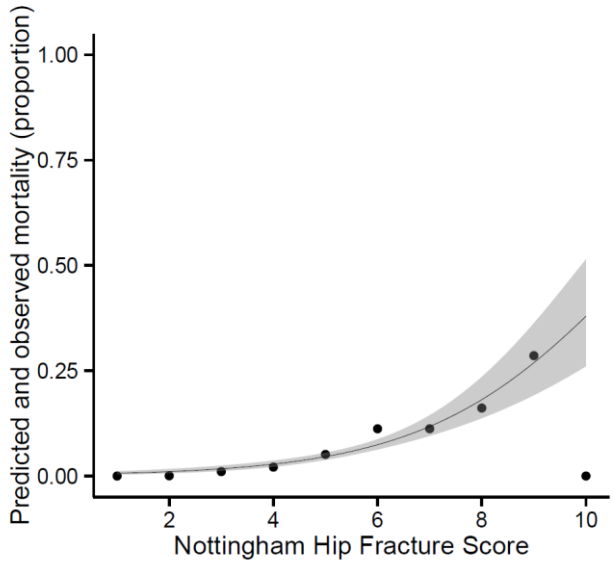
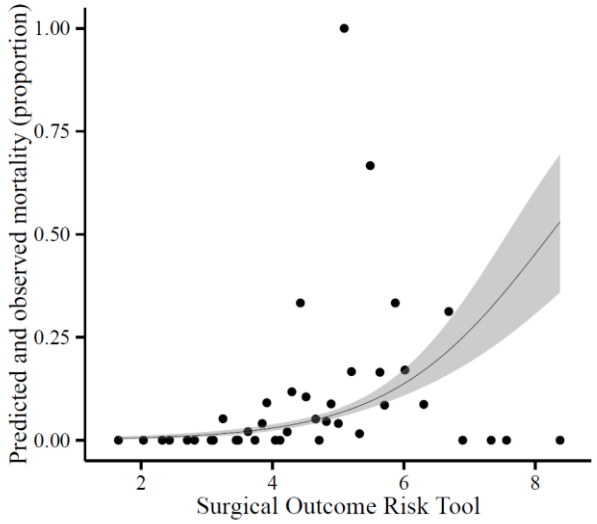


Figure 7 Predicted 30-day mortalities and 95% confidence intervals (CI) for the NHFS (top) and SORT (bottom) and their respective observed mortalities.



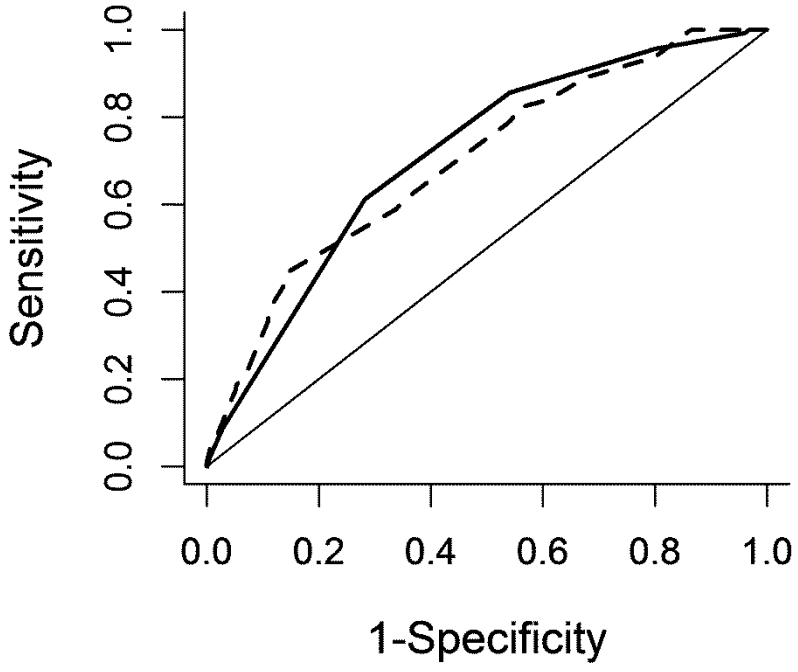


3.3.2 Results from analysis after data imputation

3.3.2.1 Discrimination

AUROC values for NHFS was 0.73 (95% CI 0.69 – 0.76) and for SORT was 0.70 (95% CI 0.66 – 0.73) similar to values observed in the complete case analysis.

Figure 8 Receiver operator characteristic curves for recalibrated NHFS (—) and the recalibrated SORT (----) for the 3157/10, 908 validation group.



3.3.2.2 Calibration

Similar calibration process was performed as above. New risk model coefficients obtained, NHFS 0.450233, intercept -5.226391, SORT 0.8200654, intercept -6.716973. Using the H-L and x^2 test to test 'goodness of fit', the NHFS showed a x^2 of 13.88 and p value of 0.085 showing a good fit while the SORT had a $x^2$of 44.737 and p value 0.001 showing lack of fit.

Table 15 Recalibrated equation 30 day mortality (%) after data imputation = 100/ (1+e $^{[5.226-(NHFS \times 0.450)]}$).

Predicted and Observed 30-day mortality (%)				
		Original NHFS	Recalibrated NHFS	
Quantile	No. of patients	Predicted	Predicted	Observed
1	719	15.47	11.79	6
2	796	34.71	25.90	14
3	756	51.93	38.58	47
4	561	59.80	44.91	45
5	233	37.70	29.26	20
6	92	22.67	19.02	20

Table 16 Recalibrated equation 30 day mortality (%) after data imputation = $100/(1+e^{[6.72-(SORT\ score\ x\ 0.820)]})$.

		Predicted and Observed 30-day mortality (%)		
Quantile	No. of patients	Original SORT Predicted	Recalibrated SORT Predicted	Observed
1	511	4.09	4.85	1
2	240	3.79	4.12	10
3	377	8.50	8.71	1
4	180	5.16	5.09	7
5	285	12.17	11.30	13
6	480	30.03	26.51	36
7	640	56.07	47.63	35
8	221	29.17	24.00	30
9	223	49.44	42.37	19

3.4 Discussion

This analysis of a large national cohort of hip fracture patients using two separate analytical methods (case complete and multiple imputation) demonstrates that both the Nottingham Hip Fracture Score and the Surgical Outcome Risk Tool have acceptable discriminatory ability. However, recalibration of both scores using adjusted coefficients found acceptable 'goodness of fit' (i.e. statistically similar predicted and observed 30-day mortality) for the Nottingham Hip Fracture Score only.

Both the NHFS and SORT predict mortality and morbidity risk using available pre-operative data, with no complex tests required [52 142]. The variables in both models were selected using logistic regression of known risk factors for poor outcome, although certain variables (for example, 'number of comorbidities >= 2' in the NHFS) may be prone to interpretation bias). The NHFS was developed in a cohort of 4 967 patients [51], and has previously shown good predictive power for 30-day [51] and 1-year mortality [84], and early hospital discharge [83 84] , in multicentre UK national [82] and two non-UK international cohorts [67 142].

The SORT model developed and validated by Protopapa et al. [52] in a heterogeneous cohort of 16 788 patients undergoing non-cardiac surgery, demonstrated excellent discrimination (AUROC 0.91 (95% CI 0.88-0.94) particularly among 1958 orthopaedic patients (AUROC of 0.93). Two of the SORT variables are moderately subjective. American Society of Anaesthesiologists Physical Status (ASA-PS) has been shown to have only

moderate inter-rater reliability, despite its wide use as a surrogate for operative risk [44], and 'severity of surgery' is based on a pre-defined classification for private health insurance payments, rather than any real-time assessment of the physiological insult of surgery.

Conceptually, the NHFS can be considered as a short-form frailty scale, whereas SORT, which includes surgical aspects, might be considered as a hybrid of a physiological score and prediction of a surgical stress test.

The National Hip Fracture Database currently uses 'CEU17' as a case-mix risk adjustment model to compare performance between hospitals treating hip fracture patients in England, Wales and Northern Ireland [143]. This model has undergone internal validation using the 2012/13 NHFD dataset (n = 59 654) for both 30-day mortality and home-to-home return within 30 days of surgery. It includes ASA grade (1-2/3 and unknown/4-5), sex, source of admission (grouped), walking ability indoors and fracture type, and can be viewed conceptually as a frailty/physiology/surgical stress hybrid score. CEU17 has similar discrimination to the original NHFS [51] (AUROC 0.751 vs 0.719, respectively), but calibration is statistically poor ($p<0.001$) [143], probably resulting from the large sample size analysed. The model coefficients for CEU17 have not been published to our knowledge, so we were unable to compare the performance of CEU17 against NHFS and SORT in this study. In comparison to the NHFS, both SORT and CEU 17 have not been validated externally.

Other risk-prediction tools for hip fracture are available, but none of them achieve excellent discrimination (AUROC > 0.8) despite wide inclusion of physiological and functional variables [67 72 144].

3.4.1 Study limitations

When using complete case analysis, approximately 17.3% of the eligible study population were excluded from analysis due to missing data. Therefore we were unable to comprehensively describe and explore the characteristics of excluded patients, which could have introduced bias, although we think that this is unlikely, as hip fracture patients tend to display a similar frequency distribution of characteristics both institutionally and geographically [107]. Furthermore we used multiple imputation which is a robust method of getting missing values. Data was imputed only for variables required in calculating and predicting 30 day mortality. Comparison between both analyses gave an overall similar results for both risk stratification tools making the results plausible. Thirty-day mortality (5.0%) in the cohort studied is lower than the national average (~8%), which suggests higher mortality among hospitals that did not submit data. Analysis of a complete national dataset would require further recalibration of the NHFS to account for this. Nevertheless, the NHFS recalibration presented above represents 'best case' data based on the best 30-day mortality outcomes that are currently achievable by UK NHS hospitals. This is in line with the concept of NHFS recalibration being a continuous process based on contemporaneous outcomes.

3.5 Conclusion

In conclusion, both NHFS and SORT show moderate discrimination for 30-day mortality following in hip fracture surgery. Neither model is perfect, though calibration is better with the NHFS. That SORT did not demonstrate as good calibration as the NHFS is perhaps not surprising, given both that it was not developed specifically as a hip fracture risk assessment tool and that the Hosmer-Lemeshow statistics can overestimate the lack of fit, such that minimal differences can become significant using large sample sizes [145] [146]. Indeed, we support the use of the SORT score as a 'gold standard' comparator during the development of risk prediction scores for other surgical conditions. Further validation studies are required to discern the accuracy of the NHFS as a risk stratification tool internationally, and to compare the NHFS with the CEU17 risk stratification tools currently used by the NHFD when comparing the quality of care provided by hospitals for hip fracture patients in the United Kingdom. Furthermore, research is needed to identify how the NHFS might be used specifically to improve a range of outcomes, including mortality, morbidity, resource use and patient experience.

CHAPTER 4

Towards a 'gold' standard in identification, quantification and measurement of morbidities post-surgery - postoperative morbidity survey (POMS) clinical utility review.

4.1 Introduction

Improving postoperative patient outcomes following hip fracture surgery are a priority for patients, clinicians and healthcare policy makers Historically, the focus of outcome measurement has mainly been mortality, morbidity and surgical implant success [7] [147] [148]as reflected by data outcomes reported by the National Hip Fracture Database (NHFD) [11] and the post-operative morbidity survey tool (POMS)[149] [150]. Short term complications are a more frequent occurrence and vary depending on the surgery type, patient risk factors and how morbidities are classified [151].They have also been shown to be the strongest predictors of mortality [152], significantly associated with length of hospital stay, and reduced long term survival and functional independence after discharge [153] [154]. Postoperative complications measurements are significant to the outcome of the health event, in evaluating resources management, and performance within and between hospitals and healthcare services in national quality improvement programmes.

In current practice, there is a widely acknowledged call to widen patient outcome reporting. This may be attributed to the increasing recognition of the various factorial domains (medical, physical, psychological, mobility and social) affecting the holistic nature of hip fracture care. This has led to the evolution, creation and advocacy for the use of a number of outcome scales such a) general quality of life (QoL), b) activities of daily living (ADL), c) mobility and physical performance scales, d) disease

specific scales and e) hip-specific scales [147 155]. These outcome scales are collectively described as patient reported outcome measures (PROMs). They assess how patients function and feel about their health condition and/ or associated treatment [156]. They are an attempt to capture elements of the quality of care against patient expectations [157]. However while the current PROMs focus on specific aspects, there is not a PROM specific to the assessment of hip fracture, and robust evidence of the quality and acceptability of non-hip fracture specific PROMs following completion by patients sustaining a fracture is limited [158].

While POMS is not a PROM by development, some of its aspects could and should be considered complementary to PROMs and could be embedded within PROMs (for example – the pain domain aspects are already considered in both tools). Accurate detection and quantification of postoperative factors that cause mortality and prolonged hospitalisations in hip fracture patients remains a continual challenge. The postoperative morbidity survey (POMS) has been developed [149] and validated [150 159-161] to potentially address this issue; consensus in measurement and reporting of outcome following surgery. Originally, the POMS [149] was developed with nine domains, each with specific defined criteria, with subsequent modification to criteria definition [150 161] and additional of domains [159] (Table 17). The tool was designed as a simple method of prospectively recording the absence or presence of morbidity after surgery

Table 17 The POMS and CPOMS

Morbidity type	Criteria
Pulmonary	Presence of one or more of the following: The patient developed a new requirement for oxygen or respiratory support (**including nebulizer therapy or request for chest physiotherapy on or after D5); **Pleural effusion requiring drainage.
Infectious	Presence of one or more of the following: Currently on antibiotics Has had a temperature of >38®C in the last 24 hr; **Has a white cell count/CRP level requiring in hospital review or treatment
Renal	Presence of one or more of the following: Presence of oliguria <500 mL/24hr (**Presence of decreased urine output requiring intervention (including IV frusemide)); Increased serum creatinine (>30% from preoperative level); Urinary catheter in situ; **New urinary incontinence, **Serum potassium abnormalities requiring treatment.
Gastrointestinal	Presence of one or more of the following: Unable to tolerate an enteral diet for any reason including nausea, vomiting, and abdominal distension (*use of antiemetic); **The presence of a nasogastric tube; **Diagnosis of a gastro intestinal bleed; **Presence of diarrhoea
Cardiovascular	Presence of one or more of the following: **The use of inotropic therapy for any cardiovascular cause; Diagnostic tests of therapy within the last 24hr for any of the following: (1) new MI or ischemia, (2) hypotension (requiring fluid therapy >200mL/hr or pharmacological therapy, ** or omission of pharmacological therapy), (3) arterial or ventricular arrhythmias, (4) cardiogenic pulmonary oedema, thrombotic event (requiring anticoagulation), (5) **hypertension

	(pharmacological therapy or omission of pharmacological therapy), (6) *** limb ischaemia
Neurological	New focal neurological deficit, confusion/ delirium, coma, **lack of coordination, **drowsy or slow to wake, **poor swallow, **blurred vision, **sedated, **changing loss of consciousness.
Haematology	Presence of one or more of the following: Requirements for any of the following within the last 24 hr: packed erythrocytes, platelets, fresh-frozen plasma, or cryoprecipitate. **Unthereapeutic INR requiring pharmacological therapy or omission of pharmacological therapy.
Wound	Presence of one or more of the following: Wound dehiscence requiring surgical exploration or drainage of pus from the operation wound with or without isolation of organism; ** Presence of chest drains; ** Wound pain significant enough to require continuing or escalating analgesic intervention
Pain	Surgical wound pain significant enough to require parenteral opioids or regional analgesia; **Postoperative pain significant enough to require parenteral opioids and/or continuing or additional analgesia.
**Endocrine	**New or additional requirements for blood sugar management
**Assisted Ambulation	**A new or escalated postoperative requirement for mobility assistance including all walking aids
**Review	**Remaining in hospital for further review, investigations, and or procedure

POMS domain and/ or criteria definition change: *[150], ** [159] C-POMS, cardiac postoperative morbidity survey, ***[161]; Abbreviations: CRP, C-reactive protein, IV, intravenous, INR, international normalized ratio, MI, myocardial infarction, *refer to individual studies.

4.2 POMS development and validation

The POMS was developed in a non-cardiac elective major surgery (orthopaedic, general, urology, vascular and gynaecology) cohort of 438 patients [149]. Overall mortality rate was 1.6% and complications occurred in 118 patients 27% (95% CI; 23-31). Patients were followed up on postoperative days (POD) 5, 8 and 15. Non-cardiac elective major surgical patients were used as the sample for such tool development as they are not considered to be 'at risk' in comparison to cardiac and emergency surgery patients. Most patients will have come through the pre-operative assessment admission route ensuring their suitability for surgery. This allows a degree of study results generalisability and development of speciality specific stratification tools.

The tool has since been validated in three studies[150 160 161], used in one emergency surgery study [151] and five studies [154 162-165] assessing postoperative morbidity association with both clinical and non-clinical (socioeconomic) factors impacting on patient outcome after major surgery. It has also been applied in the development and validation of a speciality specific score – cardiac postoperative morbidity score (C-POMS) [159] for assessment of morbidity burden after heart surgery. Currently there are no published studies available which have validated the C-POMS as a discharge predictive score.

The POMS validation study by Grocott and colleagues [150] had a similar sample size (n = 439), inclusion and exclusion criteria, and surgical

specialties as the development cohort [149]. Davies et al [160] and Goodman et al [161] validated POMS specifically in elective major abdominal surgery (colorectal, vascular, urology and upper gastrointestinal) in a sample size of 51, and elective abdominal aortic aneurysm (AAA) repair in 64 participants respectively. In the two earlier studies, POMS domain items inter-rater reliability showed high percentage agreement in both studies and overall near perfect correlation; Kappa (k) coefficients closer to 1 (0.94 [150] and 0.91 [160]). However specific domains in both studies showed fairly weak correlation. In the later study [161], compliance with POMS completion was observed at 99.5%. The gastrointestinal domain [150] required a criteria definition change from assessment of nausea, vomiting or abdominal distension to the current criteria that includes administration of antiemetics. Other aspects of importance in this domain include; dysphagia and recurrent aspiration complications which are unusual and less commonly reported [166]. For the frail elderly, the process of the surgical journey alone takes a negative toll with a likelihood of reducing their oral intake, with a loss of appetite as a common observation from clinical experience.

Saunders et al [159] sought to assess the performance of POMS in elective cardiac patients. They used a similar patient sample size to the tool development study; a sample size of 450 cardiac surgery patients were assessed on postoperative days 1,3,5,8 and 15 using the POMS criteria and additional cardiac specific variables. In comparison to the POMS, a 13 domain model C-POMS was derived with an observed internal consistency

above 70% on POD 3, 5, 8 and 15. Cross validation data collection was not performed during the development of this tool, as all data was collected by one researcher due to limited study personnel. However, as a discharge prediction score, C-POMS showed acceptable predictive accuracy.

4.3 Prevalence and incidence of morbidities

The motivation of POMS development was to show the overall incidence and pattern of postoperative morbidity rather than comparing prevalence of individual domain complications. In the tool developmental study [149], total number of patients with recorded complications decreased from 176 (40.2%) on POD5, 114 (26.0%) on POD8 to 21 (4.8%) on POD 15. Frequently observed morbidities were in the following domains; gastrointestinal 51% (42-60%), pulmonary 25% (17-33%), renal 21% (14-28%) and infectious 13% (7-19%). In the validation study by Grocott et al [150], morbidity was observed in 325 (75.1%), 231 (56.8%), 138 (42.2%) and 70 (63.1%) of patients remaining in hospital on POD 3, 5, 8 and 15 respectively. Domains with more prominent morbidities were as follows; gastrointestinal 208 (47.4%), infectious 204 (46.5%), pain 177 (40.3%), pulmonary 171 (39.4%) and renal problems 146 (33.3%). Davies et al [160] reported 258 and 362 total POMS on POD 3 and 5 respectively. Goodman et al [161] followed patients daily from POD 1 to POD 6, with morbidity prevalence of 100%, 88%, 70%, 58%, 52% and 45% respectively.

All the studies (Table 18) observed a gradual decrease in overall morbidity with increase in postoperative days. The progressive improvement in POMS count could be the most appropriate indicator and/ or health measure of individual patients' recovery towards an appropriately directed targeted discharge planning once morbidity recorded is zero [161]. Conversely, if an individual patient's POMS count remains static or increases, this should trigger appropriate action from clinicians, which might require immediate specific test and/ or treatments. On assessing the POMS in 144 patients undergoing emergency laparotomy, 14.6% overall mortality rate was observed, and significantly higher in the above 80 years age group; 33.3% [151]. Similar trends have been observed by the UK Emergency Laparotomy Network (ELN) [167]. The study reported measured POMS on POD3 and POD5 and identified infectious, pulmonary and gastrointestinal as the most common prominent morbidity categories each occurring in >60% of patients postoperatively.

Five studies [149-151 160 161] observed gastrointestinal, pulmonary, renal and infectious complications domains as the most common. Two studies which looked specifically at abdominal surgery [151 160] had the highest overall gastrointestinal morbidities 63% and 53% respectively showing that site of surgery and disease is an important determinant of this complication [149]. Howes et al [151] observed higher morbidities in the ≥80 years age group in line with previous studies showing age as a significant

perioperative risk factor of morbidity and mortality following surgery [168] [169].

In comparison between elective studies [149] [150] [160] [161] and [151] emergency surgery study, there were greater rates of POMS defined morbidities within the emergency patient population, in most cases more than five times higher. This reflects higher risk experienced by patients admitted for emergency surgical procedures. Emergency surgery comprises complex interdependent components (between staff, equipment and resources), that must exist in order for all elements of the service to be delivered safely and effectively. Moreover, patients undergoing emergency surgery commonly have acute life threatening conditions with some operations time critical [167]. Numerous papers in all surgical specialties have shown that surgical delay for the sick is detrimental both in terms of patient's outcome (morbidity and mortality) [29] [32] [170], and the immediate and long term costs to the NHS and society in general.

4.4 POMS and other surgical risk outcome factors

There are a number of both medical and non-medical risk factors that impact patient outcome after surgery [167], and these factors are likely to influence the presence or absence of morbidity postoperatively. Depending on the severity and complexity of the surgical procedure, undergoing surgery could exacerbate some pre-operative comorbidities. The POMS was used to collect morbidity in 526 elective surgical patients [162] with 27%(142 patients) diagnosed with chronic kidney disease (CKD).

Reported POMS was measured on POD5. Total number of POMS observed in patients with CKD was 253 and 416 in patients without CKD. CKD patients sustained excess POMS odds ratio (OR) 2.1 (95% CI; 1.2-3.7; p=0.0001) and took longer to be morbidity free hazard ratio (HR) 1.6 (95% CI; 1.2-1.9; P=0.0001). CKD patients sustained more pulmonary, cardiovascular, infectious, renal, pain and neurological POMS. Two studies using the same cohort of patients, one with reduced sample size [164] 560 patients and [165] 129 patients looked at the association between POMS and modified revised cardiac risk index (mRCRI) and high-sensitivity C-reactive protein (hsCRP) respectively. Postoperative morbidity occurred more frequently in patients with higher mRCRI ≥3 on days 3, 5 and 8. Morbidity domains with high frequent were; pulmonary, infectious, cardiovascular, renal, wound and neurological. Patients with higher pre-operative hsCRP were more likely to develop morbid events (p=0.04).

One study [163] looked at the association between socio-economic variations in surgical risk and POMS in major elective joint replacement surgery (Total Hip Replacement/Total Knee Replacement). Overall presence of POMS defined morbidity was 53%, 33%, 18% and 7% on days 3, 5, 8 and 15 respectively, with infectious and renal complications most common. There was no evidence of association between socio-economic status and overall postoperative morbidity and between POMS and an income-based measure of deprivation (Index of Multiple Deprivation).

In assessing the influence of POMS on long-term survival in 1362 non-cardiac elective major surgery patients, occurrence of POMS defined morbidities was observed to be associated with reduced long-term survival p=0.001 [154]. There was a significant variation in survival between patients who develop and those who did not develop the following pulmonary, renal, gastrointestinal, neurological, cardiovascular, pain and haematology morbidities. Patients with prolonged postoperative morbidity had a HR of 3.51 (95% CI; 2.28-5.42; p<0.001) death in the first year and 2.44(95% CI; 1.62-3.65; p≤0.001) in the second year.

4.5 POMS and LOS

In the validation study [160], presence of any POMS defined morbidity on POD5, conferred an OR for a prolonged hospital length of stay of 11.0 (95% CI; 5.02-11.92). Difference in LOS in days for those without and with morbidity on POD3; 6 (IQR 4-7) Vs 11 (IQR 8-15), p<0.0001, POD5; 7 (IQR 6-10) Vs 13 (IQR 9-19), p<0.0001. CKD patients with morbidity had a time to hospital discharge delay of 4 days (HR 1.4 (95% CI;1.2-1.7), p=0.001 [162]. Similar observations were also made in the other two studies [164] [165] patients with higher mRCRI frequently experienced morbidities with prolonged hospital stay and hsCRP was associated with LOS mean 7.5 days (95% CI; 6.2-8.8) vs 6.0 days (95% CI; 5.5-6.5), p=0.03 and POMS predicted prolonged LOS, p=0.0001. Goodman et al [161] observed that the median time to discharge after recording any POMS morbidity was 13 days vs. 2 days after scoring zero for POMS morbidity.

Similar trend has been observed in the development of the C-POMS, patient's LOS in days was 1.7, 2.2, 4.5 and 6.2 longer on days 3, 5, 8 and 15 respectively on every unit increase in C-POMS. Several more studies have also shown the association between POMS and LOS [171-173].

Table 18 Studies using POMS

Study	Country	Participant*(n)*	Speciality and type of surgery	Outcome	Postoperative morbidity
Bennett-Guerrero [149] POMS development	USA	438	Elective non-cardiac major surgery	Mortality rate 1.6%, complications occurred in 118 patients, ASA PS associated with postoperative complications p = 0.001	***Complication type*** / **POD 5** (n=176) / **POD 8** (n=114) / **POD 15** (n=21) Gastrointestinal 55(48-62) 51(42-60) 52(34-70) Pulmonary 17(11-23) 25(17-33) 29(12-46) Renal 26(20-32) 21(14-28) 19(5-33) Infectious 12(7-17) 13(7-19) 43(25-61) Wound 3(0-6) 12(7-17) 24(8-40) Pain 23(17-29) 22(15-29) 10(0-27) Cardiovascular 9(5-13) 9(4-14) 14(1-27) Neurological 14(9-19) 10(5-15) 5(0-13) Haematological 8(4-12) 16(10-22) 14(1-27)
Grocott [150] POMS validation	UK	439	Elective non-cardiac major surgery	Inter-rater reliability Kappa=1.0, 0.94 for 11/18 and 6/18 items respectively	**POD 3** (n=876) / **POD 5** (n=441) / **POD 8** (n=231) / **POD 15** (n=130) Gastrointestinal 40.11 30.04 15.51 7.71 Pulmonary 37.37 7.54 5.46 2.70 Renal 31.43 14.16 4.34 1.81 Infectious 34.16 24.85 15.47 9.56 Wound 1.01 4.07 5.93 3.63 Pain 44.87 10.75 3.65 2.04 Cardiovascular 1.37 2.07 0.43 0.23 Neurological 1.67 0.47 0.66 0 Haematological 7.55 6.40 0.89 1.97
Saunders [159] C-POMS development	UK	450	Elective cardiac surgery	A 13 domain model was derived with internal consistency > 70% for D3-D15. C-POMS defined morbidity explained the variance in subsequent LOS by 16.5% (D3), 22.3% (D5), 43.1% (D8) and 82% (D15).	**C-POMS Day** / **C-POMS domain** / **Adjusted difference in LOS (d)** / **95% CI** / **P-values** 3 Renal 3.0 0.58 – 5.50 0.015 Gastrointestinal 2.2 0.18 – 4.31 0.034 Neurological 2.5 0.31 – 4.77 0.026 Haematological 3.2 0.27 – 6.15 0.032 Wound 8.8 3.66 – 13.23 0.001 5 Pulmonary 2.3 0.02 – 4.64 0.048 Renal 3.9 0.84 – 7.01 0.013 Neurological 5.4 2.37 – 8.35 0.000 Pain 3.7 0.19 – 7.30 0.039 Endocrine 3.5 0.16 – 13.23 0.040

					8	Renal	6.5	1.30 – 11.80	0.015
						Haematological	5.7	1.38 – 10.08	0.01
						Wound	24.7	16.06 – 33.28	0.000
					15	Renal	10.7	0.06 – 21.36	0.049
						Pain	77.4	45.92 – 108.99	0.000
						Endocrine	-15.1	-28.91 – 1.24	0.034
						Electrolyte	74.1	43.27 – 104.84	0.000
Davies [160] POMS validation	UK	51	Elective abdominal Surgery (colorectal, Vascular, Urology, upper gastrointestinal)	Inter-rater reliability showed 97.7% agreement, Kappa = 0.912 (95% CI: 0.842-0.982), LOS *d* absence or presence of POMS on – D3 [6(IQR 4-7) vs 11(IQR 8-15) p<0.0001], D5 [7(IQR 6-10) vs 13(IQR9-19) p<0.0001] prolonged LOS due to presence of POMS D5 – OR [11.0 (95% CI:5.02-11.92)]		**POD 3** (n=258)	**POD5** (n=362)		
					Gastrointestinal		53.6	31.9	
					Pulmonary		54.7	42.1	
					Renal		46.7	26.3	
					Infectious		157	17.4	
					Wound		0	1.2	
					Pain		70.5	28.7	
					Cardiovascular		9.2	6.1	
					Neurological		10.0	3.2	
					Haematology		3.8	1.2	
Howes [151] POMS validation	UK	144	Emergency abdominal surgery	30 day mortality rate 14.6% higher in the elderly ≥80 years than <80 years; (10/30 (33%) vs 11/114 (9.6%), p=0.008), LOS longer (median (IQR[range]) 17(13-35[6-62]) days vs 11(7-21[2-159], days p=0.006), overall LOS for survivors 12(7-23[2-159])		**All patients**	**Patients <80 years**	**Patient ≥80 years**	
					Infectious		76.4	79.0	66.7
					Pulmonary		71.5	72.8	66.7
					Gastrointestinal		63.9	64.9	60.0
					Haematological		24.3	22.8	30.0
					Wound		20.8	21.9	26.7
					Cardiovascular		18.8	17.5	23.3
					Neurological		17.4	14.9	17.7
					Renal		11.8	11.4	13.3

Study	Country	Participant*(n)*	Speciality and type of surgery	Outcome	Postoperative morbidity			
Ackland [162] CKD and POMS	UK	526 CKD patients (n-142; 27%)	Elective Orthopaedic surgery	CKD patients sustained excess POMS D5(OR 2.1 [95% CI; 1.2-3.7, p=0.0001], took longer to become morbidity free (HR 1.6[95% CI;1.2-1.9; p=0.0001], delayed discharge 4 days (HR 1.4 [95% CI;1.2-1.7; p=0.001], sustained		**Normal** (n= 416)	**CKD patients** (n= 253)	**P value**
					Pulmonary	13	23	0.002
					Infectious	25	37	0.01
					Cardiovascular	6	13	0.01
					Gastrointestinal	17	23	0.10
					Wound	10	15	0.09
					Renal	27	45	<0.0001
					Neurological	1	6	0.005
					Pain	10	15	0.04
					CKD patients sustained more– pulmonary, infectious, cardiovascular, renal, neurological and pain POMS OR: 2.2[95% CI; 1.3-3.6; p=0.002], 1.7[95% CI; 1.1-2.7; p=0.01], 2.4[95% CI; 1.2-4.8; p=0.01], 2.3 [95% CI; 1.5-3.5; p=0.0001], 4.3[95% CI; 1.3-17.7; p=0.005] and 1.8[95% CI; 1.03-3.1; p=0.04] respectively.			
Hollowell [163] SEC and POMS	UK	655	Elective Hip and Knee replacement surgery (THR/TKR)	No evidence of an association between SEC and POMS	Overall occurrence of POMS; 53%, 33%, 18% and 7% on days 3, 5, 8 and 15 respectively.			
Ackland [164] mRCRI and POMS	UK – two centres	560	Elective primary and revision hip and knee procedures.	Postoperative morbidity occurred more frequently in patients with higher mRCRI ≥3 on days 3, 5 and 8; [RR 1.3 (95% CI; 1.1-1.6; p= 0.01)], [RR 1.7(95% CI; 1.4-2.1, p=0.0001)] and [RR 1.7 (95% CI; 1.3-2.2; p=0.0002)] respectively. Prolonged hospital stay was observed in this group of patients.	Pulmonary [RR 1.9 (95% CI; 1.2-3.0; p=0.0001)] Infectious [RR 1.5 (95% CI;1.1-2.1;p=0.001)] Cardiovascular [RR2.3 (95% CI;1.3-4.1; p=0.0003)] Renal [RR 1.6 (95% CI;1.2-2.2; p=0.0001)] Wound [RR 1.7(95% CI;1.1-2.9; p=0.04)] Neurological [RR 4.1 95% CI; 1.5-11.3; p=0.01)]			

Study	Country	Participant*(n)*	Speciality and type of surgery	Outcome	Postoperative morbidity
Ackaland [165] Pre-operative hsCRP and POMS	UK	129	Elective orthopaedic patients	Higher pre-operative hsCRP was associated with LOS mean 7.5 days (95% CI; 6.2-8.8) vs 6.0 days (95% CI; 5.5-6.5; p=0.03).	The presence of any complication on POD5 prolonged hospital stay p<0.0001. 66.7% patients had identifiable POM modalities on POD8. Morbid events were more likely higher in hsCRP patient group p=0.04. POMS predicted prolonged LOS p=0.0001
Moonesinghe [154] Long term survival and POMS	UK	1362	Elective non-cardiac major surgery	Occurrence of POMS morbidities was associated with reduced long term survival, p=0.001.	Differences were observed in survival between patients who developed and those who did not develop pulmonary, renal, gastrointestinal, neurological, cardiovascular and pain morbidities, p=0.001, haematological p=0.002, no difference on wound p=0.42. Neurological (prevalence 2.9%) HR 2.0 (95% CI; 1.32-3.04; p<0.01) associated with long term mortality. Prolonged postoperative morbidity (prevalence 15.6%) HR for death in the first 1 yr 3.51 995% CI; 2.28-5.42; p<0.001), 2 years 2.44(95% CI; 1.62-3.65; p=<0.001).
Goodman [161] POMS validation	UK	64	Elective Abdominal Aortic Aneurysm (AAA)	HR for live discharge with any POMS Vs no morbidity 0.130 (95% CI; 0.070-0.243). Median LOS 13 days after recording any POMS Vs 2 days after scoring no POMS morbidity	POMS present (y/n) in percentage in all patients Day % 1 100 2 88 3 70 4 58 5 52 6 45

Abbreviations: POMS, postoperative survey, C-POMS, cardiac postoperative morbidity survey, CKD, chronic kidney disease, LOS, length of stay, SEC, socio-economic , HR, hazard ratio, CI, confidence interval, hsCRP, high sensitivity C-reactive protein, mRCRI, modified revised cardiac risk index, RR, risk ratio, OR, odds ratio, IQR, interquartile range, POD, postoperative day.

4.6 Discussion

The background review of this chapter presents an overview performance and implication to practice on the use of the POMS in current practice. The following observations were made; a) there is strong evidence that the POMS fulfil its primary developmental principle as a tool to capture morbidity that is of a type and severity influencing delay discharge from hospital, b) has been widely validated nationally (UK), but not internationally which might limit its use in other countries, c) has shown to be associated with LOS and pre-operative comorbidity d) can be used as a comparative tool for long term survival for patients with vs those without morbidity defined criteria, and e) it is easy to use as a bedside tool.

4.6.1 Data collection

All data required for recording the presence or absence of morbidity as defined by the POMS is readily available from various sources. These include; patient's medical notes, treatment charts, observational charts, biochemistry results, fluid balance charts and pathology results. Assessment further conducted by patient observation, examination, speaking to the patient and/or consulting with the patient's caregivers. Essentially, no unnecessary interventions or extra tests are required and it can successfully and accurately be used by novices [160], making it suitable for application within current busy healthcare environments.

4.6.2 Outlined potential uses of POMS

Audit tool: As a widely validated tool within the UK (especially in abdominal surgery) [150 151 160 161], POMS could be applied as a standard framework providing criterial definition of postoperative complications. Discrepancies and inconsistencies in post-operative morbidity definitions are reflected in wide differences in morbidity rates range among individual surgical specialities e.g. in hip fracture surgery reported complications range from 17-50% [123]. In its current application, one could view POMS as a foundational 'core outcomes measurement' criteria definitions, which is imperative in quality assurance through audits, both within and across healthcare institutions. Such a guiding standard is important for not just policy makers, commission groups and clinical decision making, but also contains measures relevant to patients. Therefore using such a definitive framework could act as a legitimate indicator for improving the services and strategic goals for the NHS as required by the Department of Health (DoH)[174].

Resource utilisation modelling tool: Studies have shown that postoperative morbidity has a huge impact on length of hospitalisation, resulting in greater utilisation of healthcare resources and impedes patient throughput. Summarising the total POMS domains present for an individual patient or within a patient population into a score, might enable accurate analysis and prediction of healthcare costs and resource utilisation [159] which is particularly pertinent within the current healthcare economic environment.

Early morbidity detection: Considering high volumes of surgery performed every year, even a low rate of avoidable harm will be associated with many preventable deaths, complications or healthcare cost implications [153] . One key element of the POMS is its ability to track morbidity [161] against individual patients for early detection and early intervention when complications do occur[151]. While POMS can be applied to all patients, where there are staff challenges, the tool could be used for targeted intervention on monitoring those patients who have been identified as at risk through the use of preoperative risk stratification tools such as the POSSUM, ASA, E-PASS, NHFS, etc. [123]. Generally, individual patient morbidity trend would be expected to progressively narrow down to zero as LOS increase. Where the trend is opposite, POMS allows early identification of complications [161], enabling immediate engagement of relevant clinicians to optimise the patient and or admission to critical care where required [175].

Discharge guiding tool: Early patient discharge where possible is viewed as part of high quality service provision as evidenced by the introduction of enhanced recovery or 'fast-track' programs aimed at improving patient outcome and lower healthcare costs [176]. Other reasons for drive towards enhanced discharge include reducing the risk of hospital acquired infections. However a small number of patients might fall through the net, and get discharged before they are truly ready resulting in significant rates of readmissions [177] [178], which could mean financial penalty implications for the NHS [179] and poor patient satisfaction. The objective

and daily morbidity tracking ability of the POMS tool would be useful to avoid unwarranted early discharge [161]. As a standard discharge guide framework, POMS could be used to categorise patients at different levels within the discharge pathway allowing nurse led discharge initiatives and reduction in burden on senior medical staff [161]. Moreover, this might determine discharge destination, weather the patient will be transferred from acute care to a community hospital, intermediate care or residential home for further rehabilitation or they will be discharged back to their own home.

4.6.3 POMS limitations

The POMS is not a 'one size fit all tool' that is, while it was developed in several general surgical specialities [149], its use and performance is likely to vary when applied to specific patient populations. This had been reflected in the modification of the original POMS from a nine-domain item to C-POMS [159], which is a 13 domain discharge predictive scoring tool. There was also an observed variation in individual domain definitions as the C-POMS seeks to cater for cardiac surgical patient population. The nature and distinct pattern of morbidity type and occurrence across surgical specialities (for example in neurosurgery, paediatric surgery), necessitates the need for a POMS speciality specific tool [150]. It has been observed that patients undergoing abdominal surgery are more likely to express high morbidity in the gastrointestinal domain [149-151] [160], we hypothesise that patients undergoing fragility hip fracture surgery are most likely to express high morbidity within the mobility, and pain

domains due to both mechanical injury and surgical trauma [12 18]. After hip fracture from a fall, there is psychological implications such as fear and anxiety of walking again. Within the current POMS domain model, mobility is not considered, however it is an additional domain within the C-POMS model and no psychological aspects. We therefore envisage that there is a need for a hip fracture specific POMS tool/ discharge scoring tool (HF-POMS). In this patient population, a careful evaluation of patients is required, as some of the patients might already had limited mobility before the fall. POMS should be considered as a complimentary tool rather than a replacement of mobility or physiological post-surgery assessment tools already in clinical use [161].

Non-medical reasons have also been observed to greatly contribute to increase LOS [159]. Social issues, awaiting rehabilitation bed or home equipment delivery, transport not boked, follow up arrangement are some of the reasons. In considering POMS as a discharge tool, the influence of the social domain in delayed discharged need to be considered, and included separately in its overall discharge scoring potential. Careful attention, evaluation and consideration needs to be taken as further unnecessary addition of domains, would increase the complexity of the tool, making it not user friendly.

In the recent report, the ESA and ESICM outlined current post-surgical outcome measurement tools [180]. Among all the outlined tools, the Clavien-Dindo grading of complications; which classifies complications in

accordance with treatment management [181] has widely been used. Its limitations include, difficulties in categorising some morbidity cases, differing complications potentially classified similarly and/ or same morbidities classified differently depending on the treatment given [161]. While this tool offer a generic grading system according to complications severity status, the organ specific nature of the POMS may enhance clinician diagnostic and treatment decision making process. In depth comparative assessment for the two tools is limited as the two tools have never been compared within the same patient population.

Study Strengths and Limitations

To our knowledge this is the first review on the POMS as an early morbidity indicator tool. We have considered most of the studies that have developed, validated and applied the POMS tool up-to-date. This paper provides a general overview of the trend and use of POMS and put forward the need to consider psychological and social aspects affecting early patient discharge.

We did not perform a systematic review. All studies were identified by one author who also performed all the data extraction. However we used systematic review strategies to identify all potential studies included and data extraction process.

4.7 Conclusion

This brief review highlights the current clinical utility of the POMS on patients undergoing various surgical procedures. There is greater need for

further research to validate this tool in other more specialised clinical areas such as hip fracture surgery (covered in the next three chapters) with an intention to apply necessary criteria/domain modifications to successfully capture all factors influencing discharge delay. Non-morbidity domain must be considered to enhance a complete picture of healthcare resource utilisation by patients exhibiting zero morbidity according to POMS criteria

CHAPTER 5

Methodology

5.1 Introduction

This section details methodological aspects of conducting the following two studies:

Study 1 Qualitative: Factors influencing postoperative LOS after fragility hip fracture surgery: public perceptions – a mixed methods study.

Study 2 Quantitative: Short-term morbidity factors associated with length of hospital stay (LOS): development of a Hip Fracture postoperative morbidity score (HF-POMS).

5.2 Clinical measurement scales a brief over view

Clinical measurement scales are developed in two stages. Firstly, items are identified and selected thorough item generation, item selection and exploration of item scaling properties [182]. This is followed by further scale assessment for reliability and validity. Two approaches are available for scale test development and validation – psychometrics and clinimetrics. Psychometrics is the field of study concerned with the objective measurement of skills, knowledge, techniques and educational achievements. Its centred on measurement of unobservable phenomenon such as intelligence or depression. However, clinimetrics focus on the quality of measurement scales used to assess physical symptoms, physical signs and other distinctly clinical aspects in medical research and clinical practice. Examples of clinimetric scales include Glasgow Coma Scale (GCS) [183] and The American Society of Anaesthesiology physical status scale (ASA PS) [49].

Below are the six core principles underpinning the clinimetric approach [184];

1. Selection of items based on clinical expertise rather than statistical technique alone

2. Weighing of items based on clinicians or patients experience or preferences (not unit weights)

3. Heterogeneity of items, so as to capture all symptoms pf process that contribute to the construct (rather than homogeneity)

4. Ease of use (pen and paper or mental arithmetic not computer analysis)

5. Face validity based on inclusion of all relevant clinical phenomena

6. Using the patient's report of what is troublesome or bothersome as the source of information for subjective data

5.2.1 Validity and reliability

Reliability refers to the extent to which the measurement tool is consistent over time in yielding the same results on repeated using similar methods. This is based on the concept that measurement of any phenomenon always contains a certain amount of chance of error; the goal is to have the smallest chance of error as possible. Three aspects of reliability are commonly used interchangeable; (i) the degree to which a measurement given repeatedly remains the same, (ii) the stability of a measurement over time, and (iii) the similarity of measurements within a given time period [185]. Tool validity determines whether the specific individual tool truly measures that which it is intended to measure.

Validity elements include; face and content validity, reliability and empirical validity [182].

5.3 Rationale for the Study

Within current literature; a) public views on inpatient factors affecting length of stay after hip fracture surgery have not been explored and b) the POMS has not been validated in patients with fragility hip fracture. Our aims in this study were: to first, establish the public's (patients, patient's carers and healthcare professionals (HCP)) perceptions of immediate in-hospital complications using the POMS [149] and CPOMS [159] (pulmonary, infectious, renal, gastrointestinal, cardiovascular, neurological, wound complications, haematology, pain and mobility) domains as reference; secondly, to validate the POMS within a hip fracture patient population with an intention to develop a hip fracture specific POMS tool (HF-POMS). The influence of psychological and social aspects on early discharge will also be explored. We hypothesised that there would be no differences in views between patients and their families and the healthcare professional teams delivering direct care regarding morbidity factors (reasons) that affect length of hospital stay. Moreover, clarity with classification of currently identified morbidities individual stakeholder groups consider relevant and important does not exists. We seek to find which POMS domains are important to patients, relative or HCP in terms of their LOS.

5.4 Methods

This was a prospective clinical observational cohort study conducted across three, National Health Service (NHS) Foundation Trust Teaching hospitals (University Hospitals of Leicester (UHL), Nottingham University Hospitals (NUH) and Sheffield Teaching Hospitals (STH)). Study recruitment was commenced at the co-ordinating site in April 2015, the second site received local approval in November 2015 and the third site received local approval in May 2016. Study recruitment at all sites was closed on the 31st of July 2016. Appropriate research ethics committee and local NHS research and development (R&D) approvals were received before study commencement and the study complied with Good Clinical Practice (GCP) standards set forth in the Declaration of Helsinki of 1975 [186]. All ethical approvals were received from the East Midlands – Northampton NRES Committee – study ethics number 15/EM/0054. For all approvals and study, documents see Appendix 5.

5.4.1 Study 1

Factors influencing postoperative LOS after fragility hip fracture surgery: public perceptions – a mixed methods study.

The study employed a two phase mixed methods approach *(phase I – semi structured interviews and phase II - questionnaire completion)*. For comprehensiveness of findings and methodological rigour, the use of a concurrent mixed method approach was viewed as the appropriate choice to provide a strong base for answering the aims and objectives outlined in the present study. The qualitative phase was conducted first allowing the participants to identify from their experience or opinion reasons why patients stay in hospital after hip fracture surgery and to explain and explore their views of factors of importance. The interview was immediately followed by *phase II* completion of a study questionnaire outlining identified morbidity domains for consideration as per POMS and CPOMS [149 159].

5.4.1.1 Study interviews and questionnaire content guide

The content aspects and validity of both the interview questions and questionnaire were established by a) an extensive review of the current literature on the currently identified complications after hip fracture surgery and b) the involvement of a team of six ortho-geriatric speciality team, who were asked to identify from their experience and in their current practice, factors that influence delayed discharge. Both POMS and

CPOMS are validated tools with specific criteria definition offering face validity and reliability of questionnaire content.

5.4.1.2 Participant Identification

Patients

Patients were recruited from acute orthopaedic and trauma wards following hip fracture surgery. Those deemed to have capacity for consenting based on clinical observation and post-operative Abbreviated Mental Test Score (AMTS) ≥7 [187], ≥70 years, emergency admission and male or female were considered for interviews and questionnaire completion. *Exclusion criteria*: terminal illness, cognitive impairment and/ or dementia, pathological or in hospital fall fracture.

Relatives/carers

Patient relatives were identified and recruited during hospital visiting times. Permission was sought from the relevant patient before their relative is approached. Inclusion criteria: relative or carer of the patient with a hip fracture. Exclusion criteria: unable to give written consent.

Healthcare Professionals (HCP)

All healthcare professionals involved in direct care delivery to hip fracture patients were eligible for the study. Exclusion criteria: non- permanent member of staff.

5.4.1.3 Participant recruitment and informed consent

Individuals were approached, and group specific participant study information sheets current version approved by ethics, was given.

Participants were given ample time to ask any questions with all queries clarified and had sufficient time to consider participating in the study. Written informed consent was provided by every participant before study activity commencement.

5.4.1.4 Interview process

All interviews took place within an acute hospital setting. Semi-structured (focused) interview procedure was deemed the most appropriate methodology to comprehensively cover the subject matter, and in guiding and directing the interview conversation appropriately. The interview included open ended questions to prevent the researcher from leading the discussion and participants were reassured and encouraged to talk freely about the topic under discussion. While the questions asked remained the same, they were asked in various ways to participants depending on the participant group. 'Topic guides' and 'probes' were used as prompts, helping to address any omissions and allowance of in-depth clarification.

Patients were interviewed during their hospital stay before discharge; relatives were interviewed during their visiting time to the hospital. Interview times were pre-arranged and agreed in advance to avoid any inconveniences. HCP were interviewed during their free time on the days they were on duty. The study interviews were conducted in a private, quiet confidential area.

All interviews were performed by TM. Participants were interviewed alone unless there was a special consideration. Participants were briefly given

an overview of the interview process to alleviate any anxiety. The aim of the interview was outlined to the participants in layman terms – 'identifying reasons patients remain in hospital after hip fracture surgery and identify which of these factors are important to you'.

The main open-ended question asked was:

- In your opinion and / or experience, why do patients stay in hospital after hip fracture surgery?

Prompt statements used; medical reasons, mobility reasons, social and psychological reasons. Participants were encouraged to speak out about their personal experiences in any order they choose using terms meaningful to them. Towards the end of the interviews, participants were asked directly which of the factors they have identified and which of the three categories they feel is more important by asking the question;

- From reasons you have given so far which of these do you feel are more important?
- What makes you say that?

We acknowledged the potential challenges associated with recruiting and interviewing frail older adults [188]. Taking this into consideration, our questions were simplified and stream lined to allow individuals room for self-expression within subject boundary thereby minimising burden and fatigue [189]. The interview process, questions and prompts were structured in a manner not to overload the participants. Interviews were audio recorded. For five interviews audio recording was not feasible due

to the ward environment, therefore extensive field notes were taken. For all interviews, the researcher made reflective field notes to assist interpretation of audio data.

5.4.1.5 Questionnaire completion

A 5 point Likert scale questionnaire consisting of currently identified postoperative hip fracture morbidity outcomes in literature was used. Likert scales are typically given to measure attitudes, beliefs and or perceptions (views) of individuals. It allows easy data gathering and interpretation because of the numbering assigned to each option[190]. Participants were asked to explore each item to determine which factors they considered of more importance and rank them accordingly. Each morbidity domain statement had a scale numbered 1-5 besides it. Participants were asked to put a cross in the box which they feel best describes how important the statement is in relation to hospital stay and complications after hip fracture surgery where; 1 = strongly disagree, 2 = disagree, 3 = neither agrees nor disagrees, 4 = agree and 5 = strongly agree.

5.4.1.6 Data analysis

Recorded interviews were listened to and transcribed verbatim by TM before uploaded into Nvivo 11.4 software for analysis [191]. Data was assigned nodes (categories) within various segments of text. Nodes (themes) were informed and constrained by domains derived from prior literature search. The process facilitated reflection and interpretation

using aspects from Colaizzi's analysis framework [192] (**Box 1**). Constructed themes were verified by researcher triangulation (TM and DA) before sharing with the rest of the team. Questionnaire data was analysed using R statistical package[141]. Median and interquartile range (IQR) were used to summarise the results, with a median of >3 considered significant.

Box 1 Colaizzi process of phenomenological data analysis [192]

1. Transcribe audiotapes verbatim immediately after the interview and read/listen to the interview in its entirety to gain a sense of the whole.

2. Extract significant statements from each transcript.

3. Formulate meanings as they emerge from the significant statements using significant insight.

4. Organize formulated meanings into clusters of themes. Validate the clusters of themes by referring back to the original transcript to ensure no data has been ignored or added to.

5. Integrate the results into an exhaustive description of the topic being studied.

6. Formulate the essential structure of the phenomenon.

7. Validate the descriptive results by returning back to the participants to confirm if this analysis describes their experience. (If any data is deleted or added to, this new data is incorporated into the final product)

5.4.2 Study 2

Short-term morbidity factors associated with length of hospital stay (LOS): development of a Hip Fracture postoperative morbidity score (HF-POMS).

5.4.2.1 Patient recruitment

Patients were identified and recruited from acute orthopaedic and trauma wards post-surgery. Inclusion criteria; male or female, ≥ 70 years old, emergency admission with primary fracture of the hip and able to gain written informed consent from the patient or personal consultee. Exclusion criteria include the following; severe illness malignancy and or terminal illness, pathological fracture, in-hospital fractures, and patients enrolled in an investigational medicinal product (IMP) interventional trial.

5.4.2.2 Item generation (Outcome items of interest)

Study items of interest and criteria definitions (standardised definitions denoted dichotomously – as presence/absence) were initially identified from both the POMS [149 150] and CPOMS [159] which are validated and acceptable tools. Literature search, to identify any additional commonly observed complications after hip fracture surgery was performed. Outlined hip fracture specific items of consideration were compiled to produce a case report form which was send via email to six ortho-geriatricians for their views, comments and additions of any items they consider imperative from clinical experience.

5.4.2.3 Item reduction strategy

Three steps were taken to identify redundant items, a) a pairwise correlation matrix of all items on the data collection form was performed, b) we checked item prevalence within the study population and c) all new identified items were sent to a team of ortho-geriatricians for comments on item clinical severity and importance and the likelihood of being captured by the original POMS [159]. Items with a correlation of > 0.8 were excluded. Using feedback and comments from the specialty team, items for inclusion had to meet three of the following criteria:

(i) Morbidity item prevalence ≥ 5%

(ii) Likelihood of the morbidity item to be captured by the original POMS: 5-point Linkert scale median threshold <3

(iii) Likelihood that the patient remains in acute care due to this morbidity item: 5-point Linkert scale median threshold ≥3.5.

(iv) Severity of the morbidity item in explaining post-operative morbidity requiring clinical management: 5-point Linkert scale median threshold ≥3.5.

Each morbidty item was further reviewed independently by the research team and final items for inclusion agreed by discussion.

5.4.2.4 Data Collection and management

All study, clinical and outcome data were collected on case report form. Participants were followed up on days 1,3,5,8 and 15 post surgery during their hospital stay at the primary admission hospital, documenting

present or absence of morbidities as per item defined criteria. Data was gathered from various sources (patient notes, treatment charts, biochemistry results, patient questioning and patient observation). Peri-operative risk score data was measured using the Nottingham Hip Fracture Score (NHFS)[82] and the American Society of Anaesthesiology physical status (ASA-PS)[102]. LOS was defined as the difference in days between the date of discharge from the acute orthopaedic ward and the date of admission in the index episode. Current comorbidities and prescribed medications on admissions were recorded. Data was coded and entered into a Microsoft Access database.

5.4.2.5 Statistical analysis

Descriptive statistics was used for demographic data and summary results of the preoperative comorbidities. The prevalence of each morbidity domain at a specific time point post-surgery was calculated and reported as a percentage. Logistic regression was used to determine the association between LOS and individual HF-POMS domains. Where appropriate 95% confidence interval (CI) were calculated. Internal consistency was measured using Cronbach alpha for validity and reliability. Cross data collection validation (interrater reliability) was measured using Cohen's Kappa. Results were considered significant with a cut off p values <0.05. All calculations were done using R statistical package[141].

5.5 Conclusion

Detailed discussion and conclusion for this section are outlined in the next two chapters.

For ***study 2*** all data required for recording the presence or absence of morbidity as defined on the CRF is readily available from various sources. These include; patient's medical notes, treatment charts, observational charts, biochemistry results, fluid balance charts and pathology results. Assessment was further conducted by patient observation, examination, speaking to the patient and/or consulting with the patient's caregivers.

We careful evaluated individual patients as some of the patients already had limited mobility before the fall. The use of specific validated and reliable mobility/ ambulatory scores (e.g. Cumulated ambulatory score (CAS) [103] or New mobility score (NMS) [91]) as part of methodology to formally assess mobility and requirements of rehabilitation was used to help to explain some of the unexplained discharge delays.

We followed up patients during their hospital stay and collected data on specific days, D1, D3, D5, D8 and D15. This might have limited our ability to capture all potential short-lived morbidities which might be initial catalysts consequently influencing other morbidity domains causing delay in discharge. It has also been argued that certain morbidity domain item criterial definitions, such as in the renal and pain domains on D1 and D3 are expected and part of the normal care, and this is reflected by some of the studies, which started recording POMS morbidity from D5 onwards [162]

[164] [165]. However, we perceived it imperative to record data for all five days for methodology rigour.

CHAPTER 6

Study 1 Results

Factors influencing postoperative LOS after fragility hip fracture surgery: public perceptions – a mixed methods study.

6.1 Introduction

This section is an overview presentation of the mixed methods study. Identified themes through qualitative analysis are detailed below with specific phrases pertaining to individual themes outlined.

6.2 Overall Results

Twenty-nine participants were enrolled in the study 26 (90%) were both interviewed and completed questionnaire and 3 (10%) completed questionnaires only as they could not identify any particular reason why they were still in hospital (Figure 9). More than half, n= 15 (51.7%) of the participants were healthcare professionals (HCP), 8 (27%) were patients and 6 (21%) relatives. Patient participants mean age (SD [range] was 81 (7 [72 – 94]). Twenty-four percent (7) of participants were males and 75.9% (22) were females (Table 19)

Figure 9 recruitment flow chart

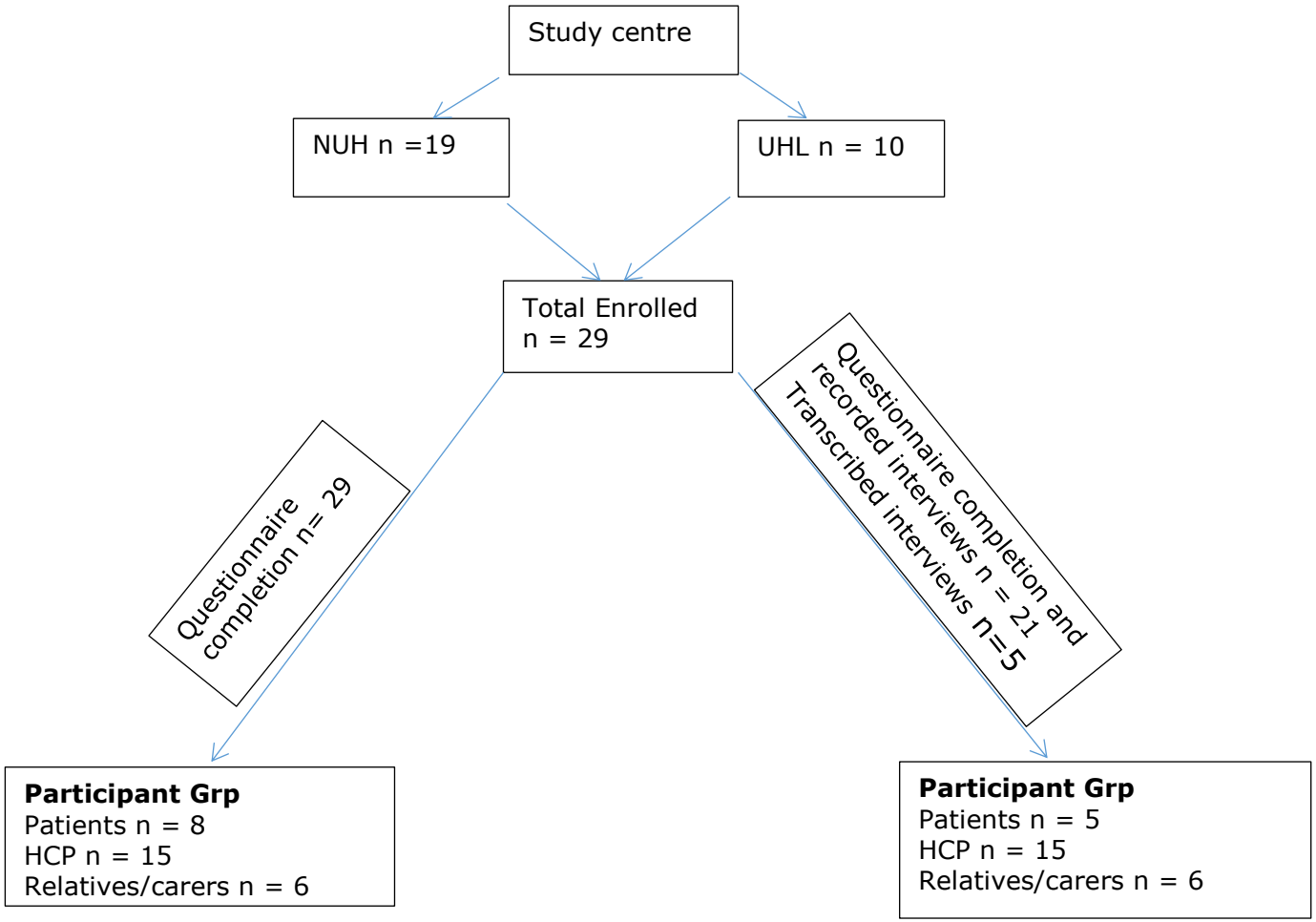


Table 19 Descriptive characteristics of included participants n= 29

	Participation			**Participant group**		
	Whole population	Interview and questionnaire completion	Questionnaire completion only	HCP	Patients	Relatives
Number n (%)	29 (100)	26 (89.7)	3 (10.3)	15 (51.7) Nurses 8 (27.6) Doctors 4 (13.8) Physio 2 (6.2) OT 1 (3.4)	8 (27.6)	6 (20.7)
Age (mean ± sd [range])	58 ((22)[25-94])	56 (22)[25-94])	78 ((9)[72-84])	38((10)[25-57])	81((7)[72-94])	73((7)[66-86])
Gender Male/Female	7 (24.1) 22(75.9)					
Race n (%)	White 23 (79.3) Asian/Asian British 3 (10.3) Black/Black British 3 (10.3)					

Abbreviations: SD, standard deviation, physio, physiotherapist, OT, occupational therapist, HCP, healthcare professionals, n, number

6.2.1 Themes

Figure 10, is a general over view of thematic formation process. Key terms and phrases from participants were summarised to inform broad themes.

Five key themes and two subthemes were identified from the analysis (Figure 11). Individual themes are presented below with detailed supporting extracts from individual participants. Themes complement each other though there is some overlap.

6.2.1.1 Medical conditions

This theme broadly encompasses both medical and surgical complications and its classified further into two sub- themes; comorbidities and post-operative morbidities. Both medical and surgical complications identified include; infections (wound, chest, urine), pain, delirium/confusion, dementia, cardiac issues, bleeding, DVT, blood transfusion, low blood pressure, GI (constipation, ileus) etc.

Pre-fracture comorbidities

The impact of an individual patient's previous medical conditions as opposed to their current main reason of admission (fractured hip) was one of the key concepts outlined by many participants. They acknowledged the complex nature of certain medical issues that individuals already have before the fracture. Furthermore, most patients are admitted with multiple medical problems.

"A lot of our patients are elderly with a lot of complex medical problems for example dementia", MOHF 096 (HCP).

"Some of them have high comorbidities unfortunately", UHL 01 (HCP).

"The fact that they just don't come with a hip fracture, they got multiple other medical issues going on", UHL 06 (HCP).

Circumstances relating to the current fall and underlying causes of fracture was seen to be influenced by inter-current illness and potentially undiagnosed or new medical conditions. Once patients are admitted, it is more likely to take some time for other new medical conditions to be fully diagnosed and treated. Even though the hip has been fixed, patients remain in hospitals for other things.

"It can be numerous things that could have gone wrong with them that they may be unaware of any or they could be under treatment with the GP and these are things that actually go wrong with the fracture more than the main fracture, and that is one of the biggest causes that keep patients in hospital. The comorbidities as we call them. That's what keeps them mainly here", UHL 01(HCP).

"One of the reasons could be the reason that caused them to break their hip in the first place. If it isn't like trauma fracture, they could have a back history of falls. They could have medical reasons why they have fallen and broke their hip. They could have heart problems, blood pressure and things like that so it could be like that. They could have poor mobility" UHL 05 (HCP).

Post-operative morbidities

Nearly all participants gave detailed interview reports of factors involving post-operative complications. Complications arising from hip fracture surgery were perceived to be common; significantly prolong hospital stay and a likely cause of patient death.

"If someone has got a chest infection, which is the most common cause of death after hip fracture, normally, it approximately delay discharge for 5 days, 4-5 days. If their original plan was to be discharged in 10 days, it takes about two weeks", UHL 04 (HCP).

"And other things you have got, infection of the wounds and quite a major one for keeping people here longer is leaky wounds. So that can hold people back because rehab destinations may not take patients with a leaky wound. And chest infections are another biggy", UHL 08 (HCP).

"Some people come in with pneumonia already, or chest infection already or UTI already. Some people get them from us obviously we are catheterising them they can get the infection from that. So infection is a big one as well", MOHF 198 (HCP).

"And so we have got cases of developing DVT", UHL 07 (HCP).

Effects of delirium and memory loss;

"In all the medical clinical memory tests she had, they gave her 3 or 5 words and 30 seconds later asking her these words and mum said "did you give me, what! I don't remember you giving me any" no she does not remember the words does not even remember the questions or the incident unfortunately", MOHF 202 (relative).

Pain influenced other functional aspect of recovery.

"It hurts" MOHF 156 (patient)

"It's painful and unbearable" MOHF 157 (patient)

"Because she is in pain and she is not able to function properly", UHL 11 (relative).

"Pain is a big issue, they suffer in pain and don't want to weight bear on it", UHL 02 (HCP)

6.2.1.2 Age

Age and frailty, particularly from HCP and relatives point of views, were considered precursors of the fracture itself with further influence on other themes such as medical conditions and recovery process. They reported that most fractures are due to falls, and elderly frail patients are unable to avoid falls possibly due to slow of reflex/reaction deficit attributed to age. It also limits expected recovery ability performance of patients such that there is an expectation for them to stay in hospital longer.

"Parents stay in hospital to recover and that recovery depend upon age and characteristics of each patient", MOHF 202 (relative).

"We are talking about patients 70 years plus. They are not the strongest of the patients and unfortunately some of them take a long time to get back from this, sometimes they don't that's why the mortality is high in our wards", UHL 01 (HCP).

"She finds it difficult to function anywhere at 95 years old. I thought she would be here for another two weeks. The state of her and her age", UHL11 (relative).

6.2.1.3 Psychological aspects

Concerns of vulnerability, mental well-being and fear of falling were prominent factors, for example, they result in reduction and avoidance of activities patients remain capable of performing. Consequently the degree of confidence in carrying out daily activities with the inhibition of fear of falling impact considerably on the physical, social and mental status [193].

"If you are living alone, you lose confidence in yourself thinking I might fall over again", MOHF 155 (patient).

"Not doing well in themselves, they become depressed, frightened to go home if they are alone", MOHF 189 (patient).

"Patients become apathetic worried about coping", MOHF 191 (HCP).

"Some patients its fear, some patients don't want to go home, some patients are not motivated", UHL 02 (HCP).

While the fear of falling was evident, there was a concern that some patients would not freely express their concerns making it challenging to progress with their discharge plans.

"So if you sit and talk to them, you will find out its probably just fear, but they don't want all the people to see that they are frightened about falling. So all that, can delay their going home", UHL02 (HCP).

6.2.1.4 Recovery process

Mobility and rehabilitation aspects were considered to be part of the recovery process - where patients have to regain their minimal or baseline ability to perform daily activities of living before discharged. As part of rehabilitation, patients' usual environment might require some

modification to assist with post fracture functioning and serve to reduce the likelihood of future falls. Comparison between pre and post fall functioning as related to changes in activities was a concern. There was an expected reduction in flexibility and physical strength and inability to function as well as before hip fracture. Performing simple tasks around the house once discharged was perceived to be going to be a challenge by many participants as a result of stamina and dexterity loss.

"They never quite seem to get back to the same level of mobility as they had before falling and breaking their hip, and that means they cannot look after themselves, or if a patient has a hip fracture and they are from a residential home for example, that can be managed there if they are fairly mobile, then they have a fall they may not be able to get back to the same care home, then you have to get through the process of finding another one, that means a referral to social services assessments etc., and that might take sometime", MOHF 096 (HCP).

Association between themes;

"We cannot get them out of bed or do much with them in the early stages, so that kind of impact, everything impact on each other because they are not mobilising", MOHF 197 (HCP).

6.2.1.5 Social aspects

Compromised social interaction after hip fracture was associated with self-limited activities. This may have repercussions on quality of life by limiting and changing social contacts and/ or leisure activities. Being alone was a huge concern associated with lack of family support.

"We have to look after ourselves, no reason to go home if I can't look after myself", MOHF 157 (patient).

"Depends on home situation, if they are going to be on their own they will like it here", (staying in hospital) MOHF 158 (patient).

For those who require social care or placement in nursing or residential institutions, the process is perceived to be unnecessarily long.

"Socially it can be difficult for patients who are unable to return back to their homes and needing to have discharge to nursing and care homes, so that can be quite a lengthy process. There have been recently, there have been a couple of patients, who have been having a discharge to complete in the ward and that was because they have behavioural problems, due to cognitive issues and it did feel like most of the care homes don't want to take these particular patients, and then he was in hospital for quite a long time when perhaps he didn't need to be if there had been a care home happy to assess him out there, but it was about perception. So that's difficult. Socially people mostly stay because the care agencies at home are not able to provide these packages of care, whether that might be funding needs too", UHL 06 (HCP).

"And in terms of some discharge destinations, arranging that can take time and obviously you have got to get the whole team input, so if you are arranging a package of care, that's what usually holds people back most or sort of trying to work out whether it suits everyone", UHL 08 (HCP).

6.2.3 Variations in aspects of importance

When asked which factors are highly important, of the eight participants who answered the question in detail, six participants pointed out medical reasons were the most important. However, one participant considered all aspects to be of equal importance and one considered mobility to be important. Further analysis of data reveal a distinctive variation in aspects identified by different participatory groups; HCP identified a broad spectrum of factors outlining all themes, while relatives and patients focused more on the recovery process and the functional ability (psychosocial) aspects. They appeared to be more concerned about individual patients' coping abilities after the fracture.

Table 20 and Figure 12 shows the overall median scores and individual participating group scores per domain as measured by a 5-point Linkert scale. Eight domains: pulmonary, infectious, gastrointestinal, cardiovascular, neurological, haematology, wound and pain are observed to be significant with overall median agreement of above three. There is a similar reflection among individual participant groups, with some discrepancy in agreement on the endocrinology and mobility factors.

6.3 Discussion

This study had identified five broad themes that healthcare professionals, patients and their relatives (caregivers) consider important in delaying discharge after hip fracture surgery: a) medical status – pre-fracture comorbidities and postoperative morbidities b) age, c) psychological aspects – fear of falling and anxiety, d) the recovery process – mobility and rehabilitation, and e) social aspects – social care arrangements and discharge destination.

There were some differences between the importance attributed by the rating scales and the qualitative themes generated. The quantitative data suggested medical factors. The interviews however highlighted the functional and social aspects of recovery as key for the patients and relatives participants. Reduced levels of mobility are associated with fear of falling, physical limitations and social/environmental factors [194]. Death may not be perceived as the worst outcome following hip fracture. One study assessing the quality of life related to fear of falling after hip fracture reported 80% of older women preferred death than experiencing loss of independence and quality of life that resulted from a bad hip fracture and subsequent admission to a nursing home [188 193 195].

The perceptions of our participants are consistent with previous literatures. Both medical and surgical complications are extensively associated with mortality and prolonged hospitalisation [196-200]. A German study that explored factors influencing hospitalisation in similar patient participants observed that surgical complications prolonged hospital stay

by 10.8 days [199]. A similar study reported a delayed discharge of around one day in hip fracture patients with chronic comorbidities [200].

Various qualitative studies that focused on the recovery and healthcare delivery experiences of patients and their caregivers, reported similar domains as outlined in this study. A recent UK study identified mobility (stable mobility allowing participants to function performing daily activities of living without fear of falling), pain and mental wellbeing as factors of importance [188]. The fear of falling again was a very evident aspect identified by most participants. Patients felt vulnerable wondering how they will manage by themselves. HCP recognised the need for patients to gain their confidence, especially those living alone. The impact of age on health status and recovery process was reckoned a surrogate of other factors. One Swedish [201] study reported patients experiencing unbearable pain during hospitalisation, prolonging their length of stay despite the existence of evidence based and established guidelines for pain management. Another study conducted at a UK teaching hospital identified injury experience, pain experience, recovery experience and disability experience as key themes derived from patients after hip fracture surgery [202]. The authors concluded that pain management, meeting psychological and physical needs for patients would ensure timely patients discharge ensuring reasonable quality of life.

Social reasons delaying discharge include social service assessment, awaiting package of care, and waiting for placement (nursing or residential care). These aspects have been identified as non-medical

reasons for delayed discharge [150] [159]. Recently, variation of patient LOS in hip fracture patients (median LOS varied from 14.9 days to 23.4 days) was attributed to Clinical Commissioning Group (CCG) which the patient originates [203].These aspects brings in a notion of dependency upon the patient, which has adverse effect on mood, self-esteem and impact upon quality of life. Inability to resume independent functioning, relocating to an assisted living or long-term care setting, loss of family environment can exert psycho-social pressure upon the patients [193].

There is a clear link between all the identified themes in influencing LOS. For example, early prompt participation in physiotherapy and mobilisation after hip fracture is clinically significant for quick recovery. However, uncontrolled pain postoperatively can hinder early physical therapy delaying mobility. Concurrently, overdose with opioids drugs can also delay ambulation and rehabilitation [204] and delaying discharge. From current clinical experience, patients are referred to the social service team for assessment for social care requirements and or for placement consideration in nursing or residential care once they are considered 'medically fit'. As outlined by participants in this study, the process can sometimes be 'complicated and unnecessarily lengthy' – consequently, the patient remains in hospital with no medical issues adding extra costs to the overall healthcare system.

6.3.1 Study strengths and limitations

Our sample size provided adequate representation of all participating groups recruited from stakeholders whose interests are of great importance in hip fracture care delivery and postoperative outcomes. Understanding what is important to HCP, patients and their relatives could facilitate effective models of care to address issues of interest fulfilling patients' expectations enabling early discharge. Study interviews with opened ended questions enabled us to identify and explore views and experience of participants and participants could speak candidly about their experience and expectations [205]. Results highlighted that factors affecting LOS are multidimensional and participant generated data are affected by perception. This subjectivity can create methodological problems including reporting bias [206]. We used a mixed method approach to overcome this challenge. For consistency all interviews were performed by one person within a hospital setting.

The study interviews took place in an acute care setting only, requiring patients to concentrate and relieve their hip fracture experienced while they are still recovering. All our patient participants were elderly and frail which could have limited some of their ability to give a detailed account of their views[189]. Patients were reassured and supported given enough time during the interviews. Due to the ward environment, five interviews were not recorded. We relied on detailed transcribed field notes with potential omission and/ or interviewer bias. However when comparing data to other participant's, similar themes emerged. Furthermore, three patient

participants could not account for any reason why they were still in hospital, which could reflect need for more information requirement during hospital stay. Relative participants were limited to those who attended hospital visits.

6.4 Conclusion

The study demonstrates that the public is aware of the common factors associated with delayed discharge. Identifying these and how important they are to individual stakeholders will help clinicians to develop targeted patient centred comprehensive hip fracture information of what to expect, potential complications and quality of life adjustment requirements. This enhance reporting and monitoring of patient safety concerns. Further studies are needed to investigate PROMs during hospitalisation after hip fracture surgery.

Figure 10 thematic formation process

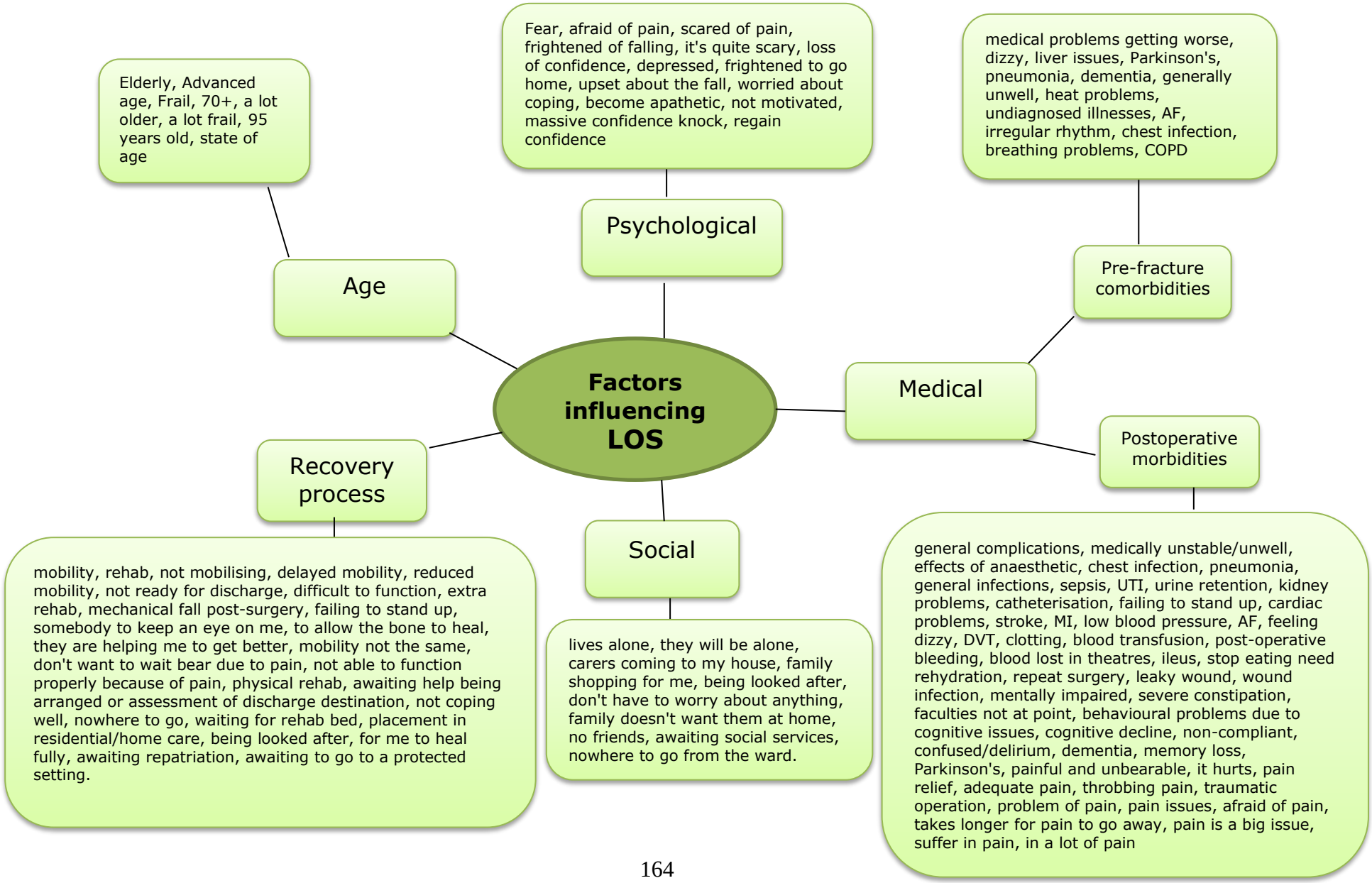


Figure 11 Identified Themes

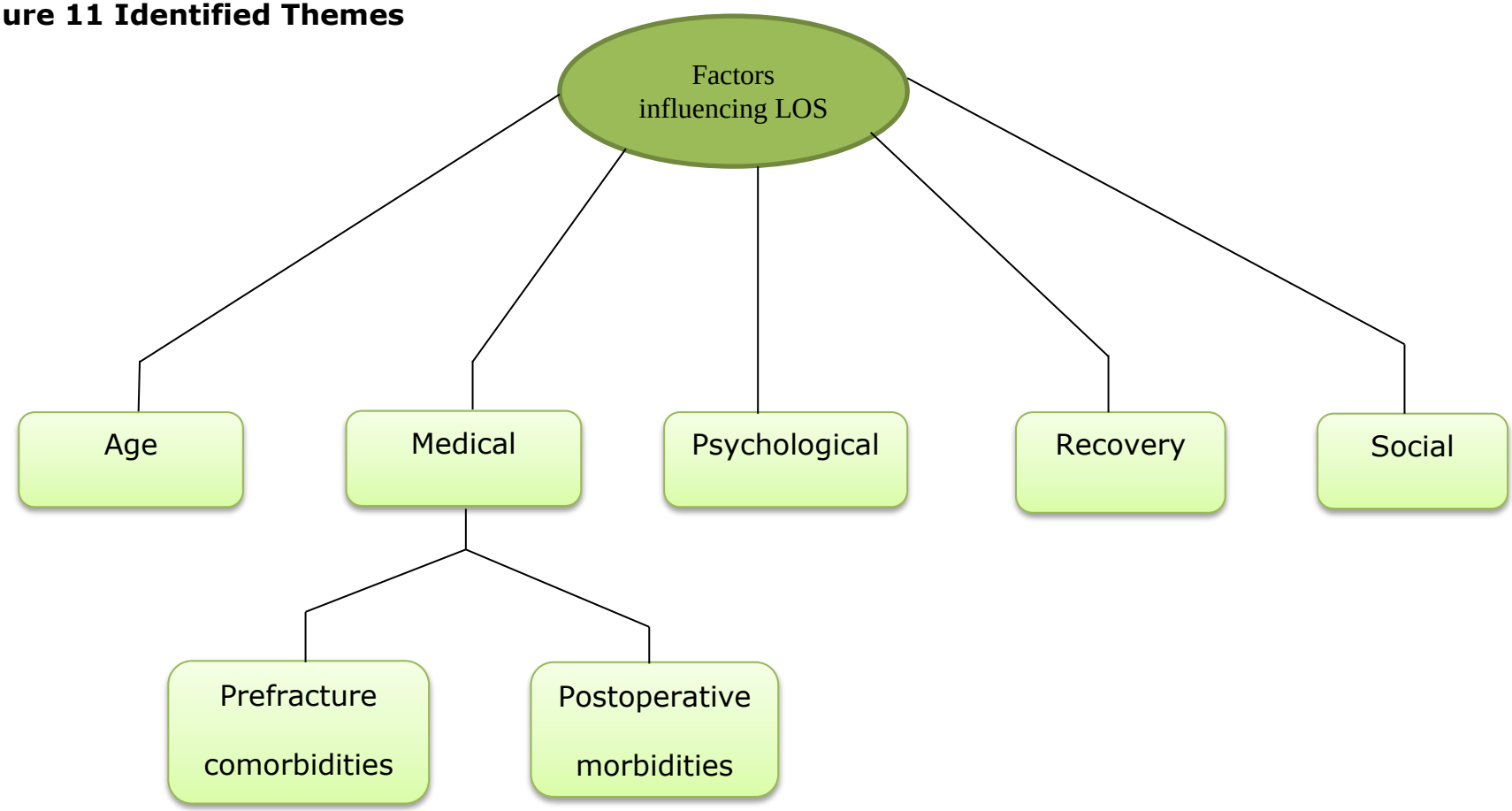
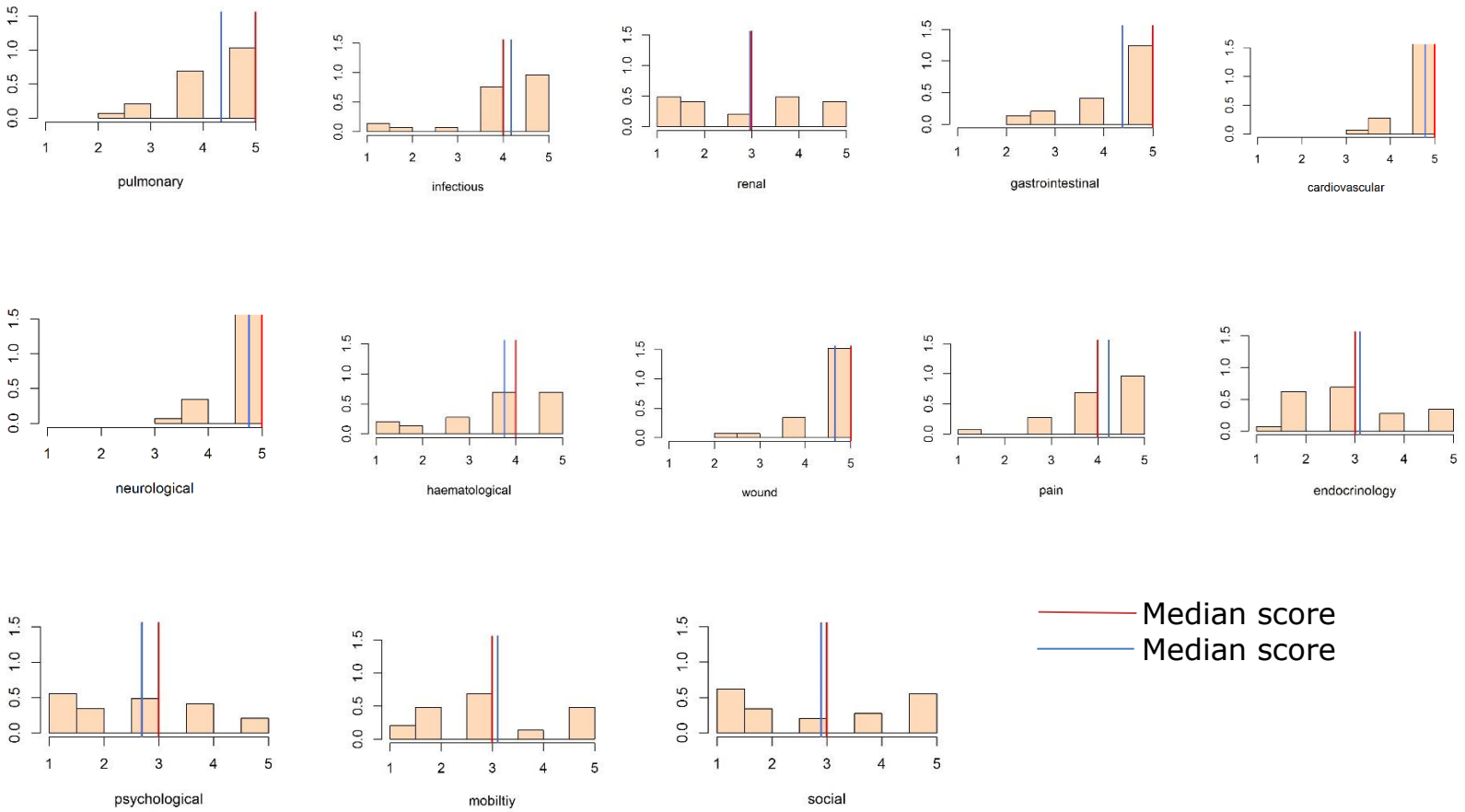


Table 20 Significance of factors influencing LOS after hip fracture surgery as perceived; patients, relatives and healthcare professionals (Total *n=29*)

	Overall Median and (Q_1,Q_3) IQR		**Median by participant group**		
Domain/criteria	**Median**	**IQR**	**HCP** ***n=15***	**Patients** ***n=8***	**Relatives** ***n=6***
Pulmonary	5	4-5	5	4	5
Infectious	4	4-5	5	4	4
Renal	3	2-4	2	4	4
Gastrointestinal	5	4-5	5	5	5
Cardiovascular	5	5-5	5	5	5
Neurological	5	5-5	5	5	5
Haematological	4	3-5	4	4.5	4
Wound	5	5-5	5	5	4.5
Pain	4	4-5	5	4	4.5
Endocrinology	3	2-4	3	4	3.0
Mobility	3	2-4	2	3	4.5
*Psychological	3	1-4	3	2.5	3
*Social	3	1-5	3	1.5	2.5

Median >3 was considered significant, HCP, healthcare professionals, IQR, interquartile range, Q_1 , first quartile, Q_3 , third quartile.

Figure 12 Median and mean comparative scores by factor



CHAPTER 7

Study 2 Results

Short-term morbidity factors associated with length of hospital stay (LOS): development of a Hip Fracture postoperative morbidity score (HF-POMS).

7.1 Introduction

This section describes and explores results of a quantitative data analysis in the development and validation of the HF–POMS tool.

7.2 Descriptive Characteristics

Six hundred and forty-seven (647) patients were screened across all three sites and 347 were recruited into the study (Figure 13). Six patients were withdrawn, one participant had an in hospital fracture and the other five participants were < 70 years old leaving 341 patients for final analysis. Observed in-hospital mortality rate was 2.4% (8). Seventy-four (21.7%) of the participants were male and 267 (78.3%) female. Mean age and standard deviation (SD), 83.5 (7) years, [range 70 - 108]. Most participants were white 336 (98%) with the other 5 (2%) Asian/Asian British. Three hundred and three (89%) of the patients were admitted from their own home with the rest 38 (11%) admitted from residential institutions. Comparatively, 188 (55.1%) were discharged home, 86 (25%) to rehabilitation/community hospitals while 59 (17.3%) went to long-term institutions (Table 22).

Two hundred and thirty-five (69%) of the patients had a history of cardiac diseases, with diabetes, malignancy, arthritis and cognitive impairment accounting for 53 (15.5%), 38 (11.1%), 65 (19.1%) and 78 (22.9%) respectively. Arthroplasty was performed in just over half of the participants, 175 (51.3%) and hip screws in 164 (48.7%). More than half of the participants, 204 (59%) had an ASA score of III, IV and V

combined. The NHFS median score (IQR [range]) was 4.0 (4.0, 5.0[3.0-9.0]). Mean (sd) LOS was 16.9 (11.2) days and ranged from 4-87 days. A variation in LOS across study sites (Figure 15) (UHL 12.9 days, NUH 17.4 days, and STH 26.5 days) and across age groups (Figure 16) (70-79 years 14.1 days, 80-89years 16.5days and ≥90 years 21.7days) was observed (Table 21). All participants (*n* = 341) were in patients on days 1 and 3, day 5 *n* = 329, day 8 *n* = 303 and day 15 *n* = 167.

7.2.1 HF-POMS development

Using the item generation and reduction strategies detailed in the methodology section (5.3.2.2 and 5.3.2.3), in addition to the original POMS items, 19 new items were identified in this study. Six items had a prevalence <5%, all of which items were observed to have a low likelihood to be captured by the original POMS tool (median score threshold <3). Thirteen items where considered to have a high likelihood of influencing patient stay in hospital and eight items were considered to be highly important in describing and quantifying post-operative complications requiring clinical management after hip fracture surgery (median score threshold ≥3.5). Table 23 outlines the new items eligibility criteria. Assisted mobility, pain and psychological domains new items were automatically included according to criterion definition.

All of the original POMS domains had a prevalence ≥ 5% except the wound and pain domains with 1.47% and 1% respectively (Figure 17). Parenteral opioids use is the key criteria definition of the pain domain in POMS, however after hip fracture surgery intravenous opioids use is

highly avoided accounting for the low observed rates of this domains in this study.

Two new items pain score and pain limiting walking had a high correlation ≥0.8 (0.85) and were excluded. Thirteen items (Table 23 – highlighted) met the inclusion criteria requirements, therefore were included in the final proposed HF-POMS, with twelve morbidity domains. Within the pain domain criteria definition, oral opioids specifically relates to oral morphine and oxycodone as required (PRN) for pain related to surgery, excluding codeine phosphate.

7.2.2 Reliability

Internal consistency was measured using Cronbach alpha. Overall raw alpha value was 0.54 (95% CI 0.47 - 0.60) and for individual postoperative days alpha values were low moderate, D1 = 0.38, D3 = 0.42, D5 = 0.47, D8 = 0.47 and D15 = 0.63. This reflects that the tool might not be suitable to be used as a summary score as reflected by Grocott [150]. Inter-observer variation measurement showed substantial agreement, Kappa 0.68, p = 0.001.

7.2.3 Construct validity

We observed that patients with higher perioperative risk scores (NHFS > 4 and those with ASA grades III-V) developed more HF –POMS defined morbidities. A significant trend ($p < 0.05$) among lower and high-risk groups was observed across all HF–POMS days using the ASA grade and a similar pattern with the NHFS on days 5, 8 and 15 (Table 24). Figure 18

and Table 25 shows the number of patients with morbidity per day by risk category and risk scoring tool. Patients with high NHFS and high ASA had increased subsequent LOS and were observed to have prolonged morbidity presence. A unit increase in NHFS and ASA predicted an increase in LOS by 1.98 days (95% CI 0.51 – 3.45, p = 0.008) and 2.54 days (95% CI 0.60 – 4.48, p = 0.012). However, on evaluating individual morbidity domains across all participants, only two domains, neurological and assisted ambulation showed a significant difference (Table 35).

Figure 13 Recruitment flow

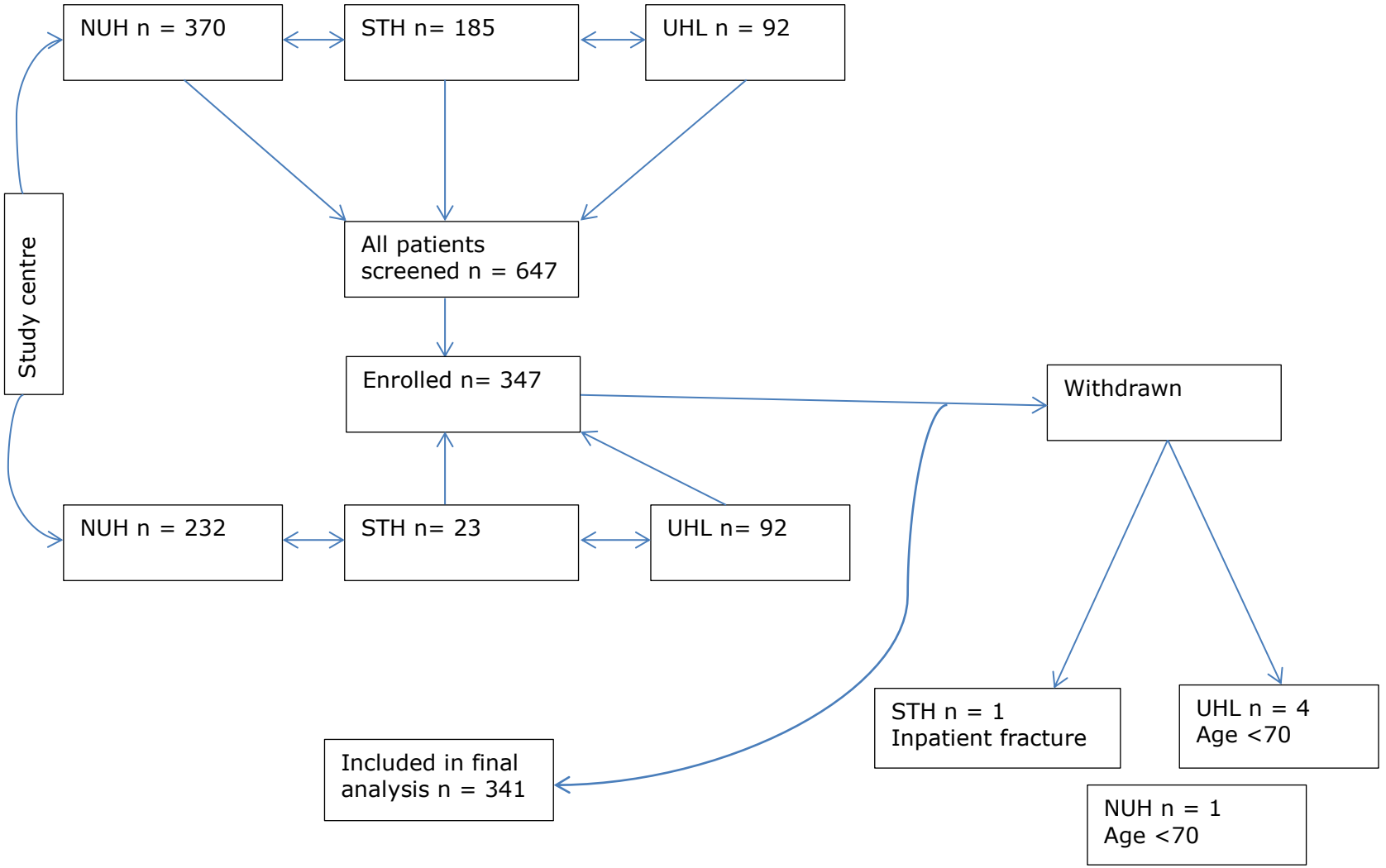


Table 21 Descriptive characteristics of all patients included in the study, by study site *n* = 341.

	All Patients	**Study Site**		
	Number of patients, N (%)	NUH	STH	UHL
All patients	341 (100)	232 (100)	22 (100)	87 (100)
Age (years)				
70-79	96 (28.2)	66 (28.5)	4 (18.2)	26 (29.9)
80-89	178 (52.2)	125 (53.9)	12 (54.6)	41 (47.1)
>=90	67 (19.7)	41 (17.7)	6 (27.3)	20 (23.0)
Mean (SD)	83.5 (7)	83.4 (6.7)	85.5(7.4)	83.4(7.6)
Gender				
Male	74 (21.7)	42 (18.0)	8 (36.4)	24 (27.6)
Female	267 (78.3)	190 (82.0)	14 (63.6)	63 (73.5)
Race				
White	336 (98.53)	232 (100)	22 (100)	82 (94.3)
Asian	5 (1.47)	0 (0.0)	0 (0.0)	5 (5.8)
Risk score Assessments				
ASA-PS grade				
I	6 (1.8)	4 (1.7)	1 (4.6)	1 (1.2)
II	84 (24.6)	61 (26.3)	2 (9.1)	21 (24.1)
III	148 (43.4)	101 (43.5)	5 (22.7)	42 (48.3)
IV	50 (14.7)	32 (13.8)	3 (13.6)	15 (17.2)
V	6 (1.8)	6 (2.6)	0 (0.0)	0 (0.0)
Missing	47 (13.8)	28 (12.1)	11 (50.0)	8 (9.2)
NHFS				
3	43 (12.6)	40 (17.2)	1 (4.6)	2 (2.3)
4	101 (29.6)	86 (37.1)	6 (27.3)	9 (10.3)
5	82 (23.1)	68 (29.3)	5 (22.7)	9 (10.3)
6	39 (11.4)	28 (12.1)	7 (31.8)	4 (4.6)
7	10 (2.9)	7 (3.02)	2 (9.1)	1 (1.2)
9	1 (0.3)	1 (0.4)	0 (0.0)	0 (0.0)
Missing	65 (19.1)	12 (5.2)	1 (4.6)	*62 (71.3)
Median score (IQR [range])	4.0 (4.0,5.0[3.0-9.0])			

	All Patients	**Study Site**		
	Number of patients, N (%)	NUH	STH	UHL
Common co-morbidities				
Cardiac history	235 (68.9)			
Hypertension	145 (42.5)			
CVA	43 (12.6)			
Diabetes	53 (15.5)			
Cognitive impairment	78 (22.9)			
osteoporosis	24 (7.0)			
arthritis	65 (19.1)			
Malignancy	38 (11.1)			
Fracture Classification				
Intra-capsular	198 (58.1)	177 (76.3)	17 (77.3)	61 (70.1)
Displaced	170 (49.9)	133 (57.3)	10 (45.5)	47 (54.0)
Un-displaced	28 (8.2)	13 (5.6)	6 (27.3)	9 (10.3)
Extra-capsular	143 (41.9)	55 (23.7)	5 (22.7)	26 (29.9)
Displaced	35 (10.3)	32 (13.8)	0 (0.0)	3 (3.5)
Un-displaced	51 (15.)	23 (9.9)	5 (22.7)	23 (26.4)
trochanteric	57 (16.7)	51 (22.0)	1 (4.6)	5 (5.7)
Type of Surgery				
Hemi-arthroplasty	175 (51.3)	109 (47.0)	15 (68.2)	51(58.6)
cemented	164 (48.1)	100 (43.1)	13 (59.1)	51 (58.6)
Un-cemented	11 (3.2)	9 (3.9)	2 (9.1)	0 (0.00)
Hip Screws	166 (48.7)	123 (53.0)	7 (31.8)	36 (41.4)
DHS	129 (37.8)	97 (41.8)	7 (31.8)	25 (28.7)
IMHS	37 (10.9)	26 (11.2)	0 (0.0)	11 (12.6)
Pre – fracture mobility aid	208 (70.0)	145 (62.5)	9 (40.9)	54 (62.1)
Outcomes				
LOS (days)				
Mean (sd)	16.9(11.2)	17.4 (10.8)	26.5 (17.5)	12.9 (8.1)
Median (IQR) [range]	14(11,19)[4-87]	15.0	21.5	11.0
In hospital mortality	8 (2.4)	3 (1.3)	2 (9.1)	3(3.5)

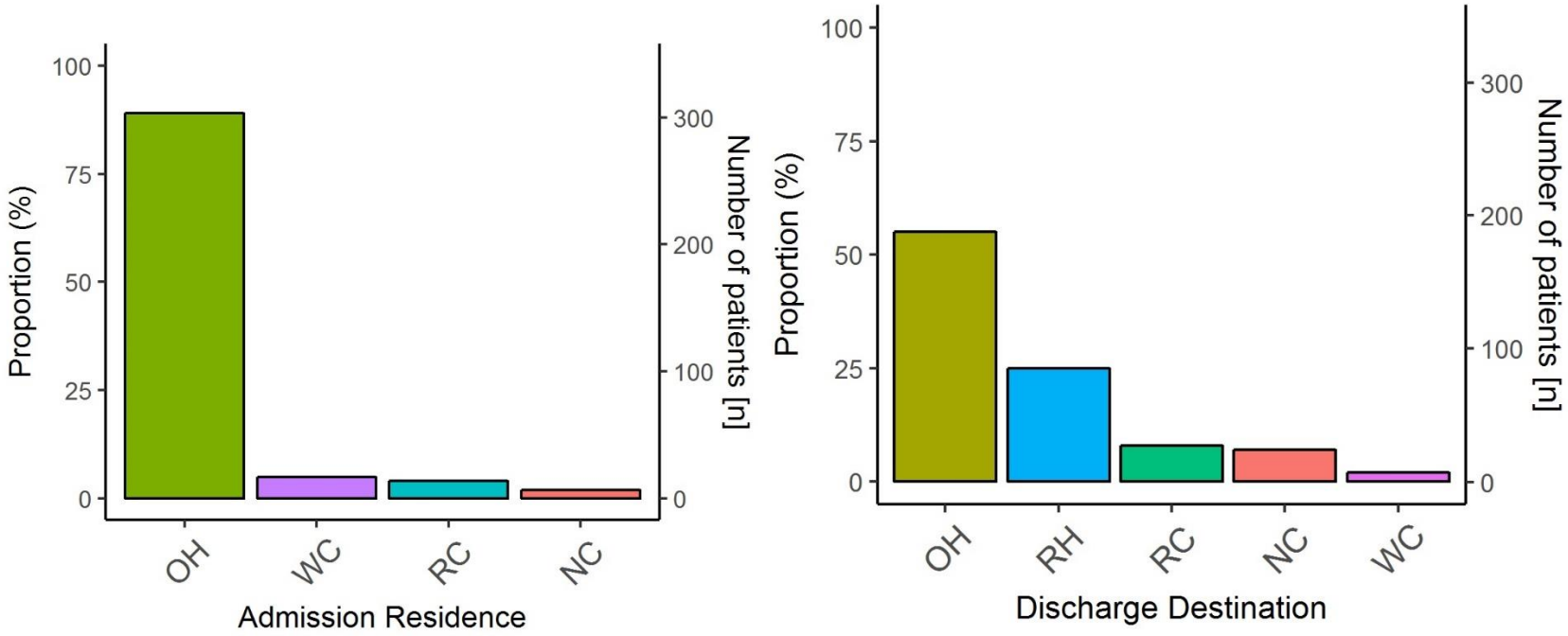
Abbreviations: NUH; Nottingham University Hospitals, STH; Sheffield Teaching Hospitals, UHL; University Hospitals of Leicester, SD; standard deviation, N; number, ASA-PS; American Society of Anaesthesiologists Physical Score , NHFS; Nottingham Hip Fracture Score, IQR; inter quartile range, CVA; cerebral vascular accident, DHS; Dynamic hip screw, IMHS; intramedullary hip screw , LOS, length of hospital stay. *Study centre does not use NHFS routinely and we were unable to calculate NHFS due to missing AMT data on admission.

Table 22 Comparative summary of permanent residence and discharge destination

Place of residence before surgery					**Discharge destination**			
	All patients n=342	NUH n= 232	STH n=22	UHL n=87	All patients n=342	NUH n=232	STH n=22	UHL n=87
Own home	303 (88.86)	208 (89.66)	21 (95.45)	74 (85.06)	188 (55.13)	149 (64.22)	7 (31.83)	32 (36.78)
Warden controlled	17 (4.99)	13 (5.60)	1 (4.55)	3 (3.45)	6 (1.76)	5 (2.16)	0 (0.00)	1 (1.15)
Residential care	13 (3.81)	6 (2.59)	0 (0.00)	7 (8.05)	28 (8.21)	21 (9.05)	2 (9.09)	5 (5.73)
Nursing care	8 (2.35)	5 (2.16)	0 (0.00)	3 (3.45)	25 (7.33)	17 (7.33)	2 (9.09)	6 (6.90)
Rehab hospital					86 (25.23)	37 (15.94)	9 (40.91)	40 (45.98)
Died					8 (2.35)	3 (1.29)	2 (9.09)	3 (3.45)

Abbreviations: NUH; Nottingham University Hospitals, STH; Sheffield Teaching Hospitals, UHL; University Hospitals of Leicester.

Figure 14 Admission and Discharge place of residence.



Abbreviations; OH, own home, WC, warden controlled, RC, residential care, NC, Nursing care (home), RH, rehabilitation hospital

Table 23 Eligibility criteria for new HF-POMS criteria

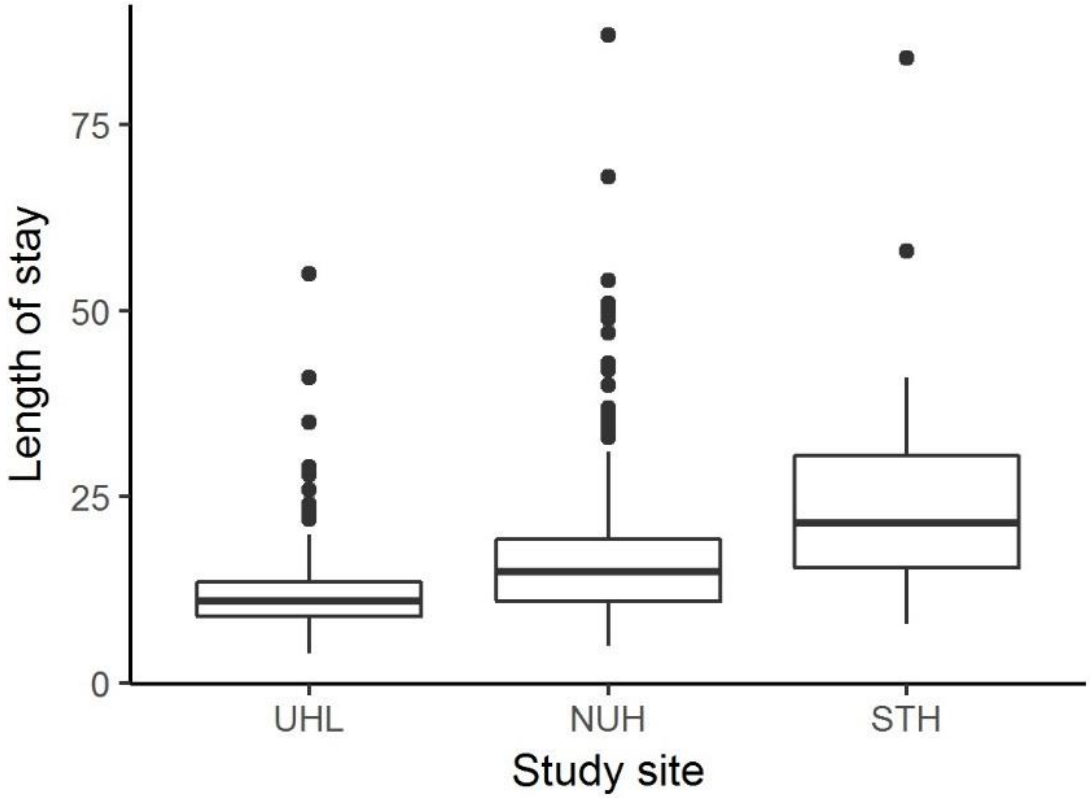
		Item Eligibility criteria using 5-point Linkert scale median score threshold			
Domain	**New items**	**Prevalence threshold: ≥ 5 %**	**Likelihood to be captured by existing POMS: median score < 3**	**Likelihood that patient remains in acute care due to this morbidity: median ≥ 3.5**	**Severity of the item in explaining post-operative morbidity requiring clinical management: median ≥ 3.5**
Pulmonary	Chest physio	N	N	Y	Y
Cardiovascular	**Dizziness**	**Y**	**Y**	**Y**	**N**
cardiovascular	Omit antihypertensive drugs	N	N	N	N
Gastrointestinal	**Poor appetite**	**Y**	**Y**	**Y**	**Y**
Gastrointestinal	Constipation	Y	Y	N	N
Gastrointestinal	**diarrhoea**	**N**	**Y**	**Y**	**Y**
Infectious	**Raised WCC**	**Y**	**Y**	**Y**	**N**
Infectious	Blood and urine cultures	N	Y	Y	N
Renal/cardiovascular	Iv frusemide	N	Y	Y	N
Wound	**Leaky wound**	**Y**	**Y**	**Y**	**Y**
Endocrinology	**High or low BMs**	**Y**	**Y**	**Y**	**Y**

Endocrinology	**Sliding scale**	**N**	**Y**	**Y**	**Y**
***Pain**	**PRN Oral opioids**	**Y**	**Y**	**N**	**N**
Pain	**Pain limiting sitting out on the chair**	**Y**	**Y**	**Y**	**Y**
Pain	**Pain limiting sitting up in bed**	**Y**	**Y**	**Y**	**Y**
Pain	Pain limiting walking	Y	Y	N	N
New - Psychology	**Anxiety**	**Y**	**Y**	**Y**	**Y**
***Assisted Mobility**	**Physiotherapy**	**Y**	**Y**	**N**	**N**
***Mobility**	**Fatigue**	**Y**	**Y**	**N**	**Y**
Total eligible items per criteria		13	17	13	9

*Automatically included after morbidity domain criteria definition change

New Items meeting the inclusion criteria

Figure 15 Mean Length of hospital stay by study site



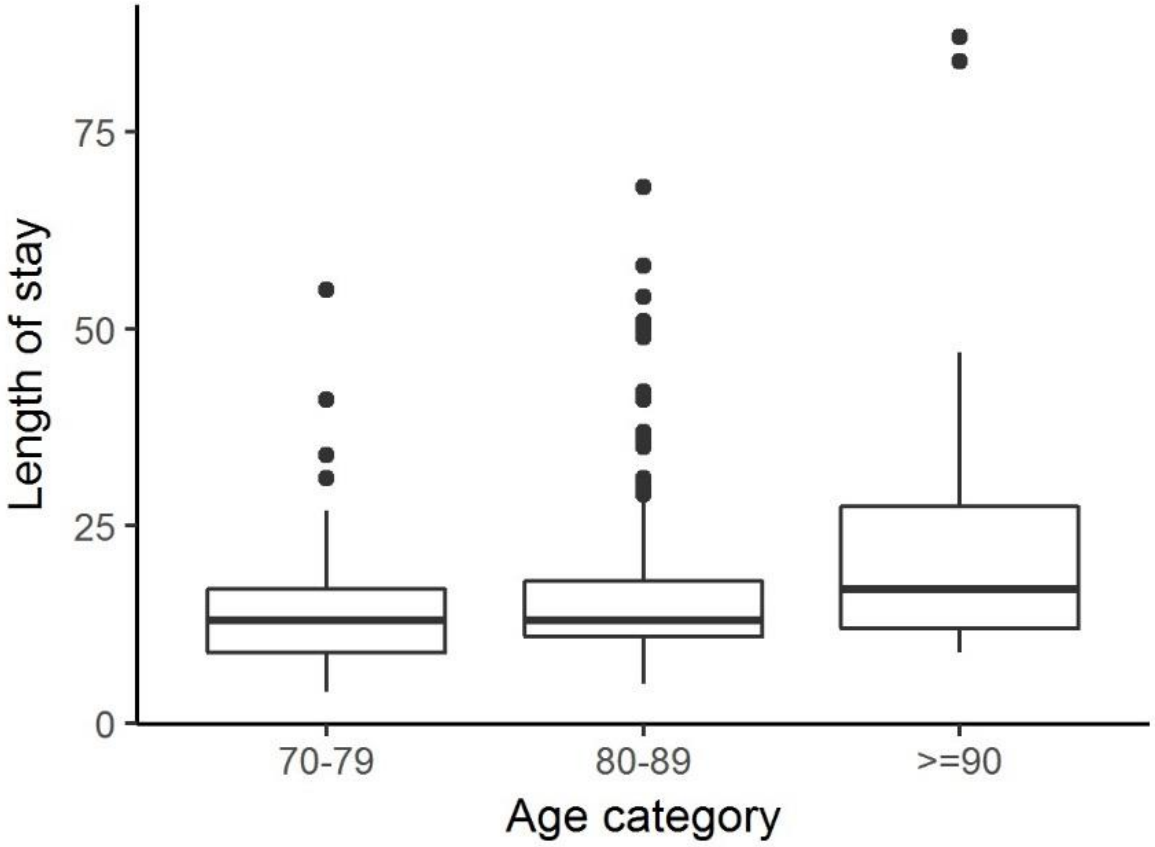
Mean LOS by hospital

UHL 12.9 days

NUH 17.4 days

STH 26.5 days

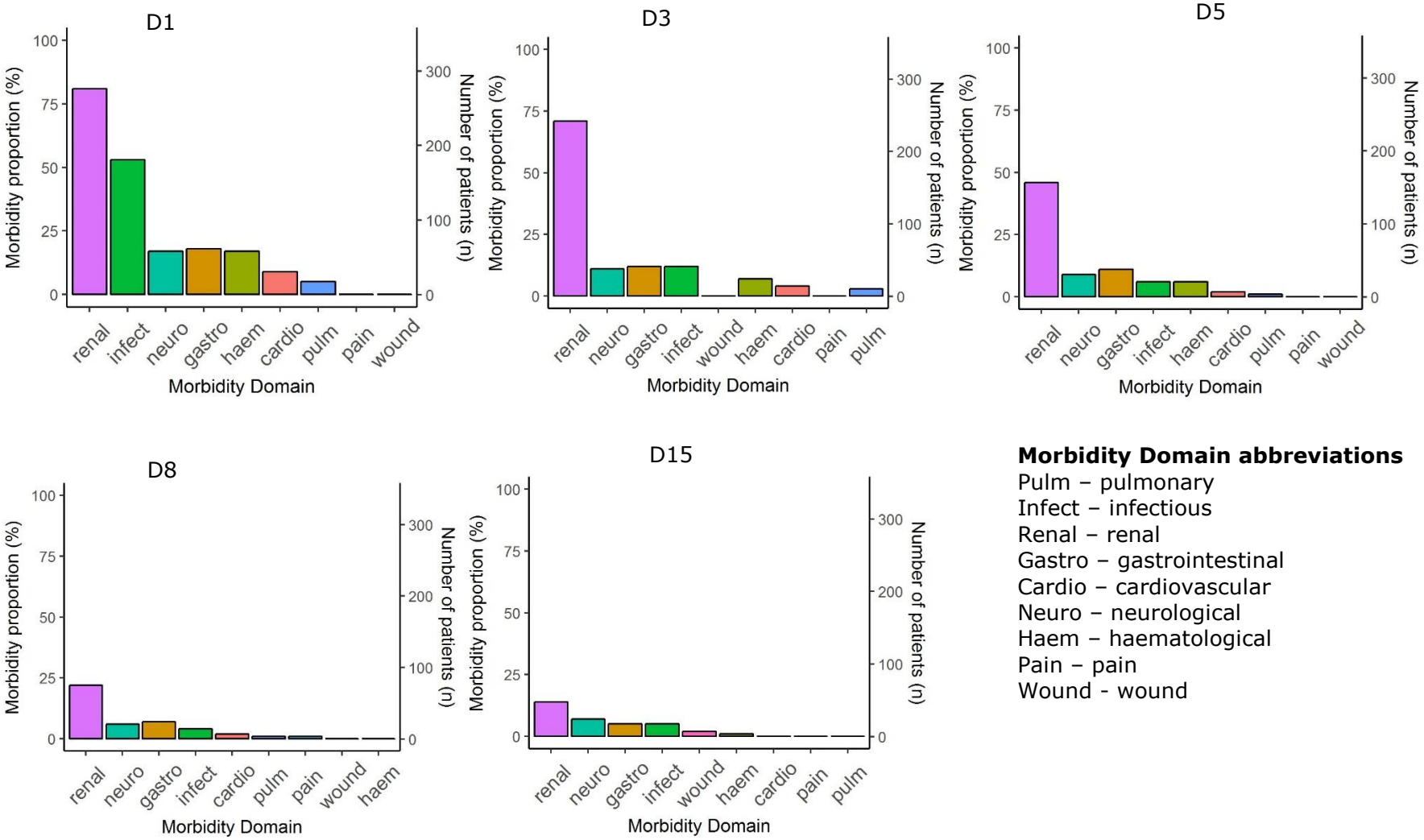
Figure 16 Mean Length of hospital stay by age



Mean LOS by age category

70-79 years	14.1 days
80-89 years	16.5 days
≥ 90 years	21.7 days

Figure 17 Original POMS daily prevalence



Morbidity Domain abbreviations
Pulm – pulmonary
Infect – infectious
Renal – renal
Gastro – gastrointestinal
Cardio – cardiovascular
Neuro – neurological
Haem – haematological
Pain – pain
Wound - wound

Table 24 HF-POMS defined morbidity rates (%) per day in patients with different NHFS and in different ASA grades defined morbidity risk categories.

	NHFS			ASA grade		
	≤4	>4		I/II	III/IV/V	
HF – POMS Day	n=144	n=132	*P value*	n=90	n=204	*P value*
1	51.18	47.83	0.338	29.93	69.39	0.032
3	48.91	46.01	0.352	26.53	66.67	0.003
5	37.68	42.03	0.001	18.37	58.50	0.001
8	25.72	31.16	0.008	11.56	42.86	0.001
15	6.88	14.13	0.001	2.04	16.67	0.001

*P <0.05 for chi-square test of different between low and high-risk patient groups

[a]based on 276 of the total patients with NHFS, missing 65

[b]based on 294 of the total patients with ASA grade, missing 47

Table 25 HF-POMS defined morbidity per day in number of patients with different NHFS and ASA grade defined morbidity risk categories.

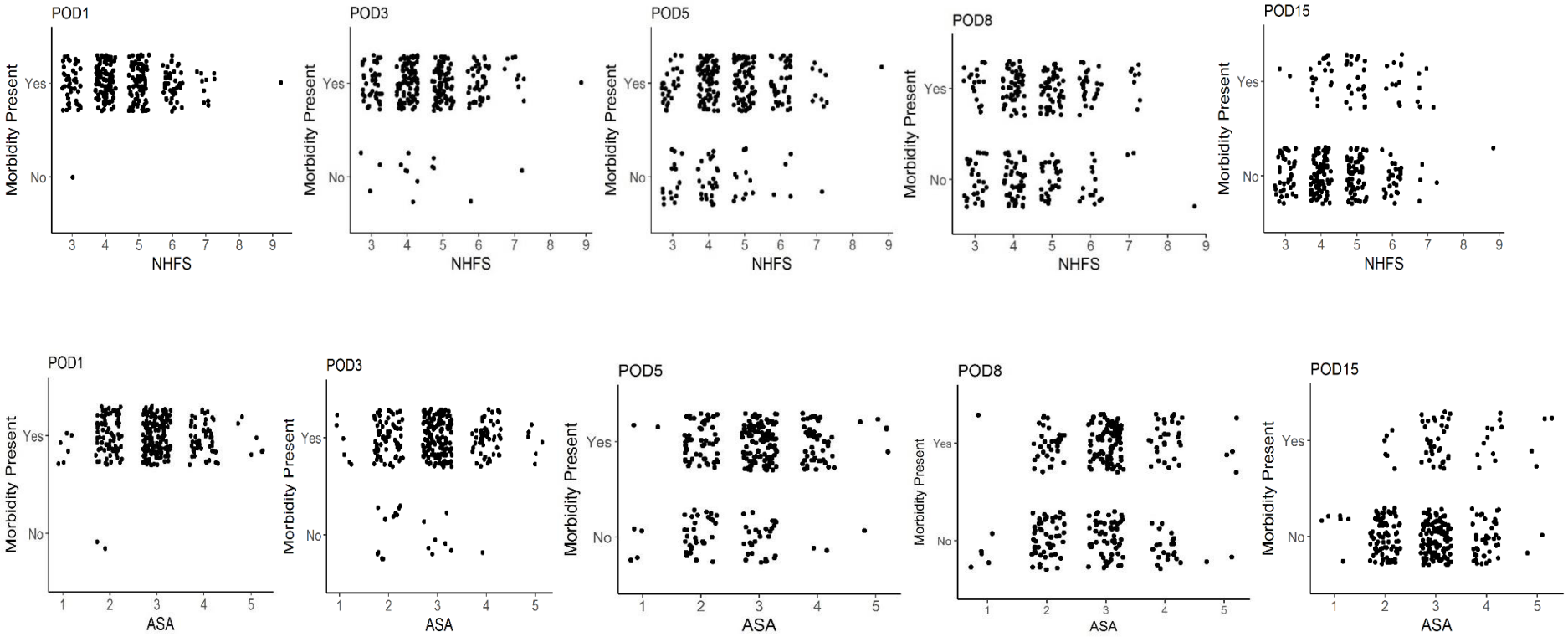
	NHFS				
HF-POMS day	3	4	5	6	7-9
1	42	101	82	39	11
3	40	95	79	38	10
5	27	77	71	35	10
8	17	54	53	25	8
15	2	17	22	11	6

	ASA			
HF-POMS day	1/2	3	4	5
1	88	148	50	6
3	78	141	49	6
5	54	119	48	5
8	34	93	29	4
15	6	34	11	4

[a]based on 276 of the total patients with NHFS, missing 65

[b]based on 294 of the total patients with ASA grade, missing 47

Figure 18 Presence of morbidity per day by risk category and risk scoring tool



7.2.4 Prevalence of HF-POMS

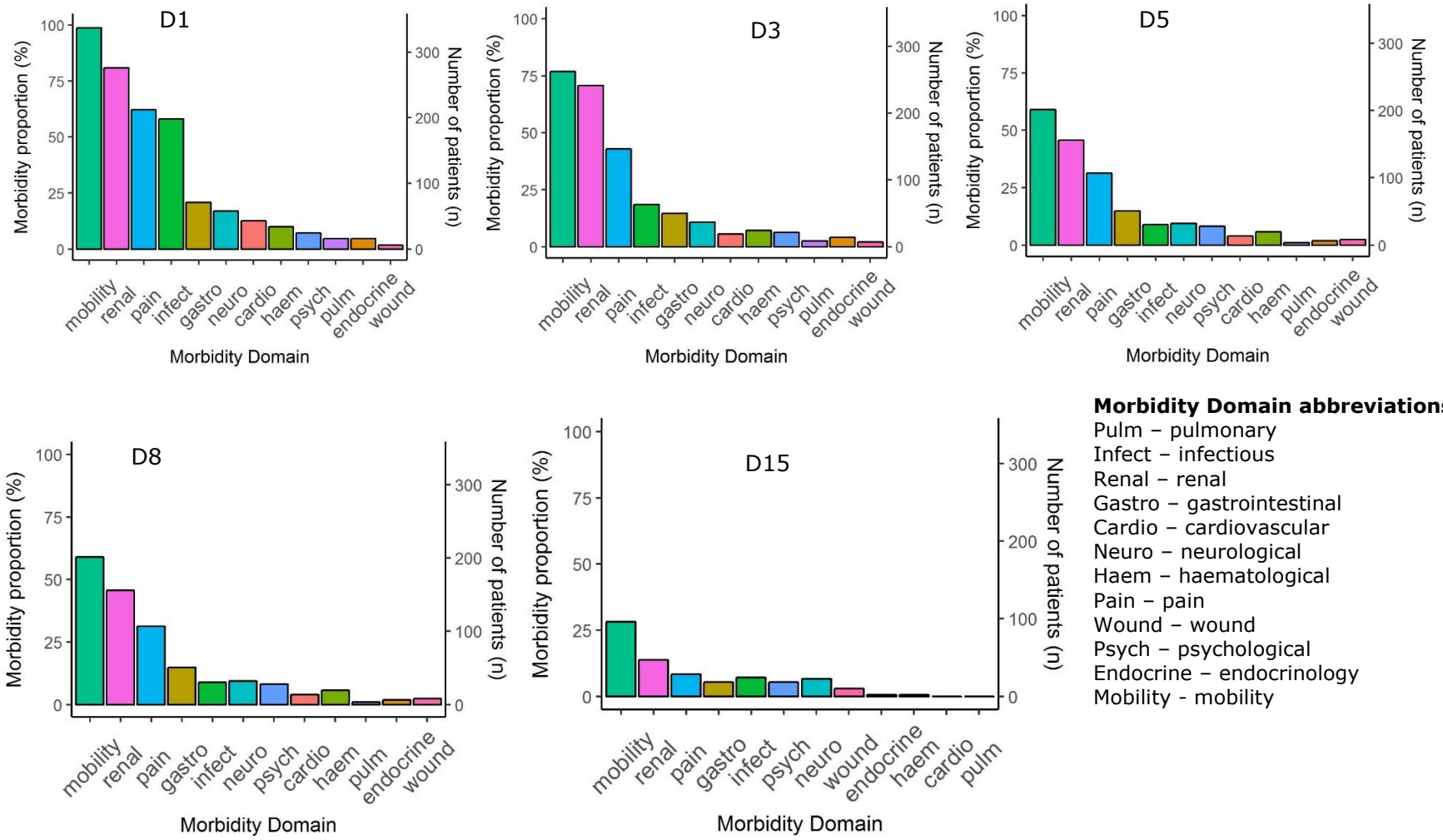
The total number of HF-POMS observed morbidity showed a gradual decrease from 1291, 892, 632, 358 and 132 for days 1,3,5,8, and 15 respectively. Five domains with very high prevalence at several time points were renal, assisted ambulation, pain and infectious. These were observed for nearly all the patients on certain days, ambulation assistance ranged from 98% – 58% present on days 1, 3 and 5, renal was 81%-46%, pain 62% -31% and infectious was 58%-9% during the same period. Moderately high morbidity levels were observed in the gastrointestinal, cardiovascular and neurological domains and low levels in the rest of the domains. High rates of inpatients without morbidities as defined by the HF-POMS were observed. This ranged from 19.45 % on day 5 to 38% and 58% on both days 8 and 15 respectively. By day 15, only 51 % of patients were discharged from hospital with 55% going to their own home. Table 26 and Figure 19 below summarise HF–POMS morbidity rates by postoperative day.

The increased serum creatinine levels as defined by the HF-POMS were observed in a very low number of participants (only 1%). This could have been due to the limited access to biochemistry results available for the study team. Furthermore, such blood tests are not a daily routine. In addition, although minor degrees of acute kidney injury are a risk factor for poorer outcome, it is asymptomatic and seem unlikely to be a cause for staying in acute care per se[207]. Table 34 is a summary of HF–POMS morbidity items present.

Table 26 Total Morbidity Present, n (%)

Morbidity Domain	D1 (n=341)	D3 (n=341)	D5 (n=329)	D8 (n=303)	D15 (n=167)
Pulmonary	16 (4.69)	9 (2.64)	3 (0.91)	3 (0.99)	0 (0.00)
Infectious	198 (58.06)	63 (18.48)	29 (8.81)	21 (6.93)	12 (7.19)
Renal	276 (80.94)	241 (70.67)	150 (45.59)	67 (22.11)	23 (13.77)
Gastrointestinal	71 (20.82)	51 (14.66)	49 (14.89)	24 (7.92)	9 (5.39)
Cardiovascular	43 (12.61)	19 (5.57)	13 (3.95)	7 (2.31)	0 (0.00)
Neurological	58 (17.01)	37 (10.85)	31 (9.42)	19 (6.27)	11 (6.59)
Haematological	34 (9.97)	24 (7.04)	19 (5.78)	1 (0.33)	1 (0.60)
Wound	6 (1.76)	7 (2.05)	8 (2.43)	3 (0.99)	5 (2.99)
Pain	212 (62.17)	146 (42.82)	103 (31.31)	70 (23.10)	14 (8.38)
Psychological	24 (7.04)	21 (6.16)	27 (8.20)	22 (7.26)	9 (5.39)
Endocrinology	16 (4.69)	14 (4.12)	6 (1.82)	4 (1.32)	1 (0.60)
Assisted Mobility	337 (98.83)	262 (76.83)	194 (58.97)	117 (38.61)	47 (28.14)
Discharged	0 (0.00)	0 (0.00)	12 (3.52)	38 (11.14)	174 (51.03)
Total Number of patients with morbidity	339 (99.41)	321 (94.13)	266 (80.85)	186 (61.39)	70 (41.91)
In hospital patients without morbidity as defined by the HF POMS	2 (0.59)	21 (6.16)	63 (19.45)	117 (38.61)	97 (58.08)

Figure 19 HF-POMS daily morbidity



Morbidity Domain abbreviations

Pulm – pulmonary
Infect – infectious
Renal – renal
Gastro – gastrointestinal
Cardio – cardiovascular
Neuro – neurological
Haem – haematological
Pain – pain
Wound – wound
Psych – psychological
Endocrine – endocrinology
Mobility - mobility

7.2.5 LOS predictive factors

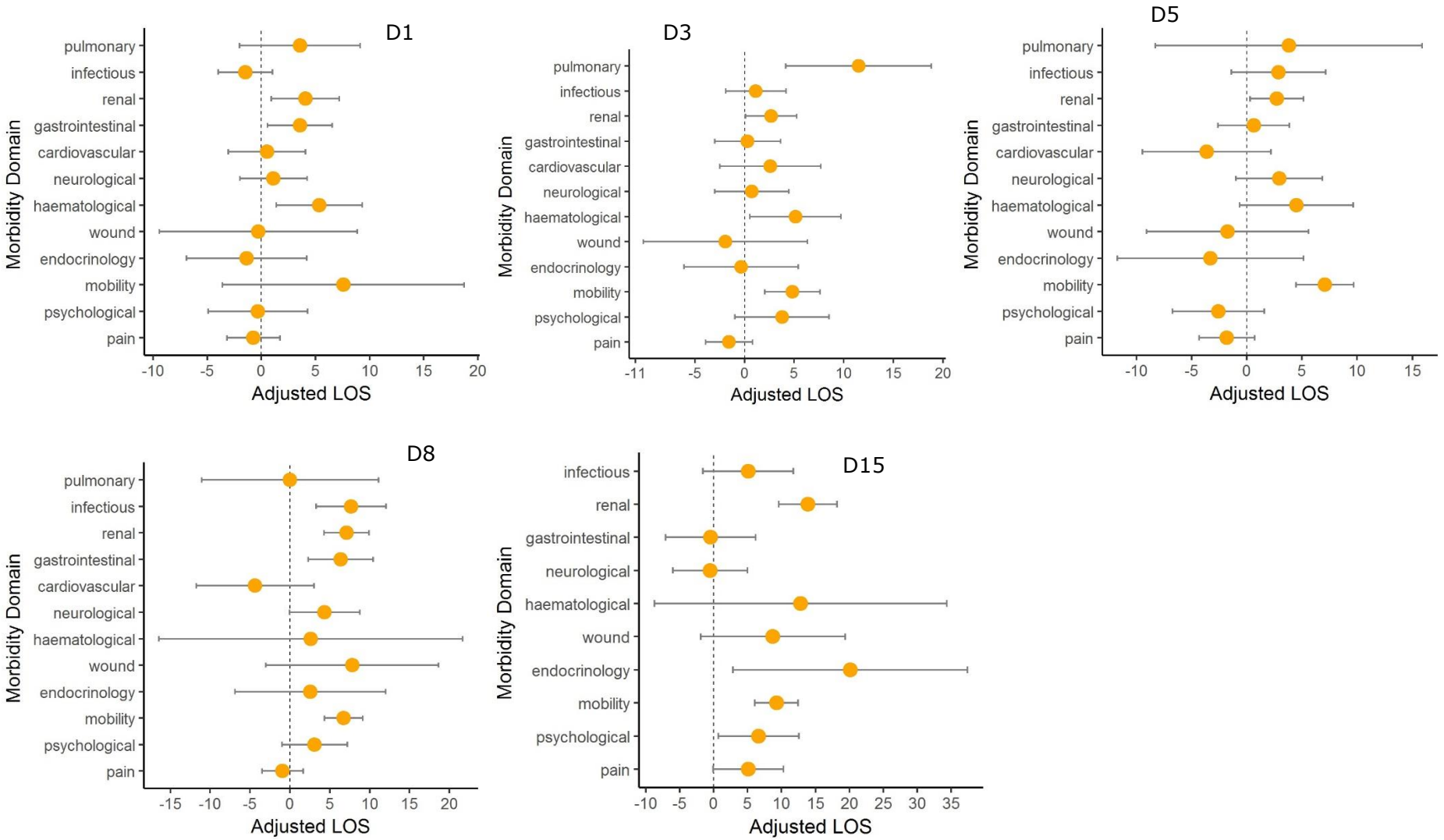
Presence of any morbidity on day 8 and 15 was associated with subsequent LOS of 3.08 days (95% CI 0.90 – 5.26, p= 0.005) and 15.81 days (95% CI 13.35 – 18.27, p = 0.001) respectively. Logistic regression was used to identify LOS independent predictive domains. Three morbidity domains (renal, gastrointestinal and haematological) on D1, four (pulmonary, renal, haematological and assisted ambulation) on D3 and two (renal and assisted ambulation) on D5 were independently associated with increased LOS. On D8 morbidity in the infectious, renal, gastrointestinal and assisted ambulation domains was observed to independently predict LOS by 7.68 days (95% CI; 3.29 - 12.06, p=0.001), 7.05 days (95% CI; 4.23-9.88, p=0.001), 6.18 days (95% CI; 1.99 - 10.30, p= 0.004), 6.66 days (95% CI 4.25 – 9.06, p = 0.001) respectively. On day 15 four domains (renal, psychological, endocrinology and assisted ambulation) were also associated with increased LOS. The renal domain was observed to be an independent predictor of LOS across all HF–POMS days and assisted ambulation in all other days except D1. Table 27 below is a summary of domains significantly influencing LOS by post-operative day and Figure 20 shows adjusted LOS by all HF-POMS domains per day.

Table 27 Summary of domains significantly influencing LOS by post-operative day

Postoperative Day	Morbidity Domain	Subsequent Adjusted LOS	P value	95% Confidence Intervals (CI)
1	Renal	4.07	0.011	0.02 – 7.22
	Gastrointestinal	3.56	0.020	0.57 – 6.55
	Haematological	5.35	0.008	1.40 – 9.31
3	Pulmonary	11.48	0.002	4.14 – 18.82
	Renal	2.71	0.043	0.08 – 5.26
	Haematological	5.13	0.028	0.55 – 9.71
	Assisted Mobility	4.82	0.001	2.02 – 7.62
5	Renal	2.70	0.029	0.28 – 5.13
	Assisted Mobility	7.07	0.001	4.47 – 9.68
8	Infectious	7.69	0.001	3.31 – 12.06
	Renal	7.10	0.001	4.28 – 9.91
	Gastrointestinal	6.37	0.002	2.28 – 10.46
	Assisted Mobility	6.73	0.001	4.33 – 9.12
15	Renal	13.90	0.001	9.58 - 18.22
	Psychological	6.65	0.030	0.72 – 12.58
	Endocrinology	20.12	0.023	2.84 – 37.39
	Assisted Mobility	9.26	0.001	6.09 – 12.43

LOS, length of stay

Figure 20 Adjusted LOS by morbidity domain per HF-POMS day



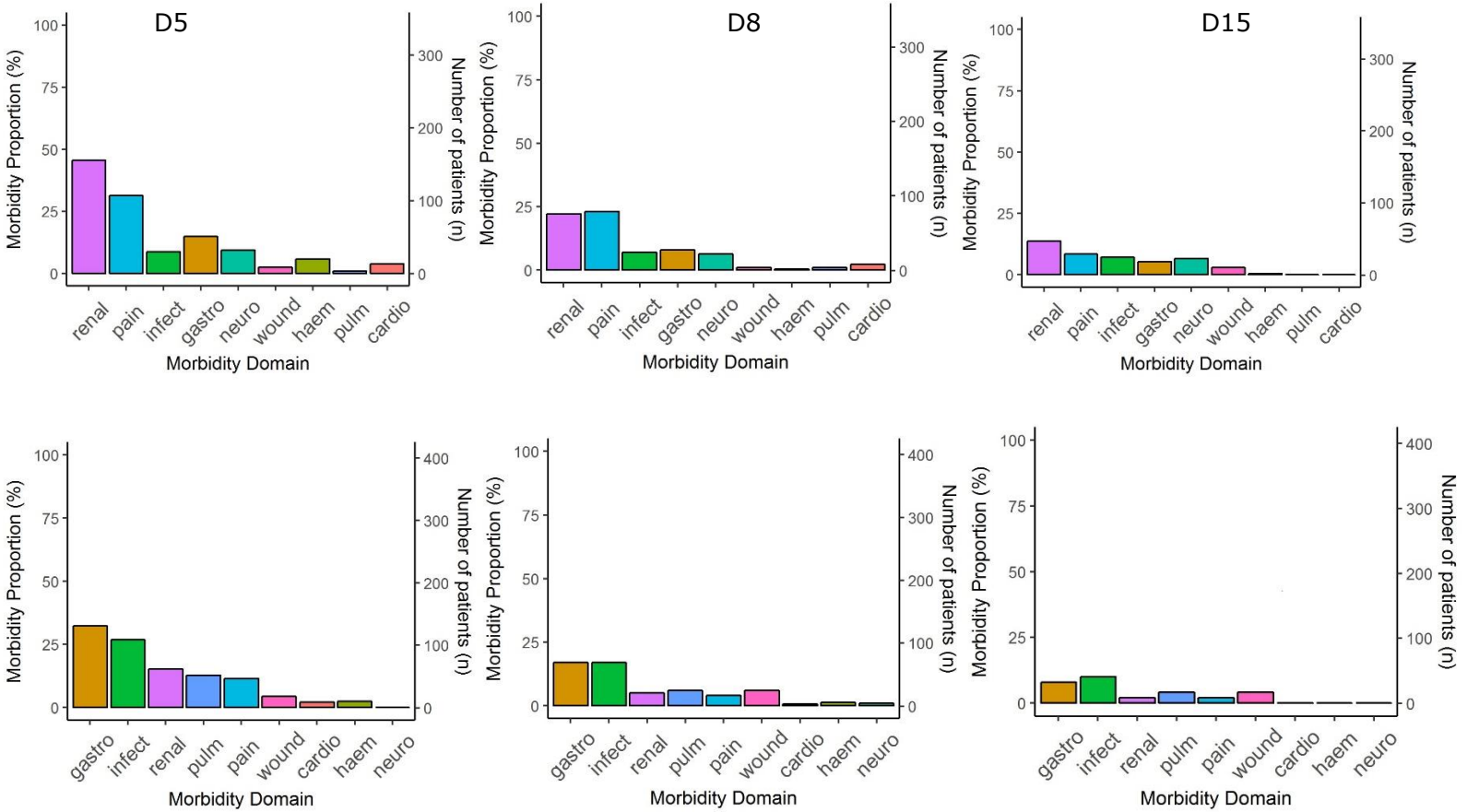
7.2.6 Morbidity Prevalence: Comparison between hip fracture patients and general surgery patients

Using data from Middlesex postoperative morbidity survey study [182], (Grocott's thesis Table 29 page 141), we compared the prevalence of common morbidity domains in our study population (after domain criteria definition modification for HF-POMS) to general surgery inpatients on postoperative days 5,8 and 15. The hip fracture population exhibited high renal (D5 – 150(45.59%), D8 – 67(22.11%), D15 – 23(13.77%) and pain (D5 -103(31.31%), D8 – 70(23.1%) and D15 – 14(8.38%) morbidities across all days and moderate levels in gastrointestinal, neurological and infections out of the total number of patients who were still inpatients on those individual days. While in general surgery gastrointestinal (D5 – 132(32.43%), D8 -68(22.74%), and D15 – 34(30.68%) and infectious (D5 – 109(26.70%), D8 – 68(22.74%), and D15 -42(37.84%) were the highest across all postoperative days with renal, pulmonary and pain domains moderately present. Variation in morbidity prevalence between the two cohorts were statistically significant ($p<0.05$) in almost all morbidity domains across the three postoperative days (Table 28). Figure 21 shows comparative proportions and patient numbers of those with HF-POMS and POMS defined morbidity out of the overall sample size. Table 36 is a comprehensive overview of the original POMS domains and criteria definitions and subsequent additional domains with respective criteria definitions for CPOMS and HF-POMS.

Table 28 Comparison of common POMS and HF-POMS domains prevalence between hip fracture patients (n=341) and general surgery patients (n= 439), the Middlesex postoperative survey study[182].

Domain	**D5**			**D8**			**D15**		
	Hip fracture	General surgery	p value	Hip fracture	General surgery	P value	Hip fracture	General surgery	P value
In patients	n=329	n=407	**0.013**	n=303	n=299	**<0.001**	n=167	n=111	**<0.001**
Pulmonary	3	52	**<0.001**	3	24	**0.001**	0	14	N/A
Infectious	29	109	**<0.001**	21	68	**<0.001**	12	42	**0.001**
Renal	150	62	**<0.001**	67	19	**<0.001**	23	8	**<0.001**
Gastrointestinal	49	132	**<0.001**	24	68	**<0.001**	9	34	**0.002**
Cardiovascular	13	9	0.140	7	2	**0.038**	0	1	N/A
Neurological	31	4	**<0.001**	19	3	**<0.001**	11	0	N/A
Haematological	19	10	**0.015**	1	4	0.283	1	1	0.858
Wound	8	18	0.176	3	26	**<0.001**	5	16	0.062
Pain	103	47	**<0.001**	70	16	**<0.001**	14	9	**0.009**
In hospital without defined morbidity	63	176	**<0.001**	117	161	**<0.001**	97	41	**<0.001**

Figure 21 Comparison of common HF-POMS (above) and POMS (below) domains prevalence between hip fracture patients (n=341) and general surgery patients (n= 439), the Middlesex postoperative survey study. [182]



Morbidity Domain abbreviations
Pulm – pulmonary
Infect – infectious
Renal – renal
Gastro – gastrointestinal
Cardio – cardiovascular
Neuro – neurological
Haem – haematological
Pain – pain
Wound – wound

7.2.7 Postoperative pain management

Pain score was measured using the numerical pain intensity scale 0 – 10 (0 – No pain, 5 – Moderate pain and 10 – Worst possible pain). However most patients had their pain recorded in their medical notes dichotomously as present or absent without a specific numerical scale value. Seven different types of opioids, parenteral and oral were observed – oral morphine most common, oxycodone, oxynorm, oxycontine, intravenous morphine, intravenous tramadol and an alfentinile infusion in one patient who was admitted to critical care unit.

Various doses were observed dependent on local prescribing practice and patient comorbidities and frailty. To standardise our analysis, all opioids doses were converted to dose equivalent to 10mg oral morphine using the Gloucestershire Joint Formulary guidelines[208]. We used Pearson's product-moment correlation to assess the association between the presence of pain and medication administration. A positive association was observed between pain and PRN (as required) opioids administration across all HF–POMS days. Correlation was moderately weak with the highest coefficient of 0.29 p = 0.001 on D1. Day 15 p >0.05 (Table 29).

Daily mean (SD) post-operative opioids (prn) administration in milligrams (mg) among all the patients was considerably low, 6.0 (10.6)mg, 3,0 (7.8)mg, 2.8 (7.7) mg, 1.4 (5.3) mg, and 0.5 (3.2) mg on D1, D3, D5, D8 and D15 respectively. Overall mean for all five postoperative days where data was collected was 12.8 (23.4) mg.

Some of the patients reported having pain but not asking the nurse for pain medication citing (i) staff are busy and not wanting to disturb them, (ii) not wanting to have any form of morphine, as they were afraid of getting confusion.

Table 29 Correlation between presence of pain and PRN opioid medication administration

Postoperative day	correlation	P value
D1	0.29	0.001
D3	0.20	0.001
D5	0.18	0.001
D8	0.14	0.006
D15	0.09	0.08

7.2.8 Mobility score

Three dimensional aspects of mobility were measured using a modified CAS [103] with a total score calculated per patient;

Table 30 Modified mobility score

Transfers (bed to chair and back)		Mobility (on level surfaces)		Stairs	
0	Unable to perform task	0	Unable to perform task	0	Unable to perform task
3	Attempts task but unsafe	3	Attempts task but unsafe	2	Attempts task but unsafe
8	Moderate help required (2 assist)	8	Moderate help required	5	Moderate help required
12	Minimal help required (1 assist)	12	Minimal help required	8	Minimal help required
15	Fully independent	15	Fully independent	10	Fully independent

Figure 22 below shows daily mobility scores. A gradual decrease in the proportion of patients with very low and low total mobility scores (>8 and 8 ≤ 16) respectively was observed.

LOS was negatively correlated with mobility score, showing that those with low total mobility scores had increased LOS (Table 31). Pain was also significantly negatively correlated with mobility score on D1, D3 and D5 showing that pain affect mobility immediately post operation reducing mobility (Table 32).

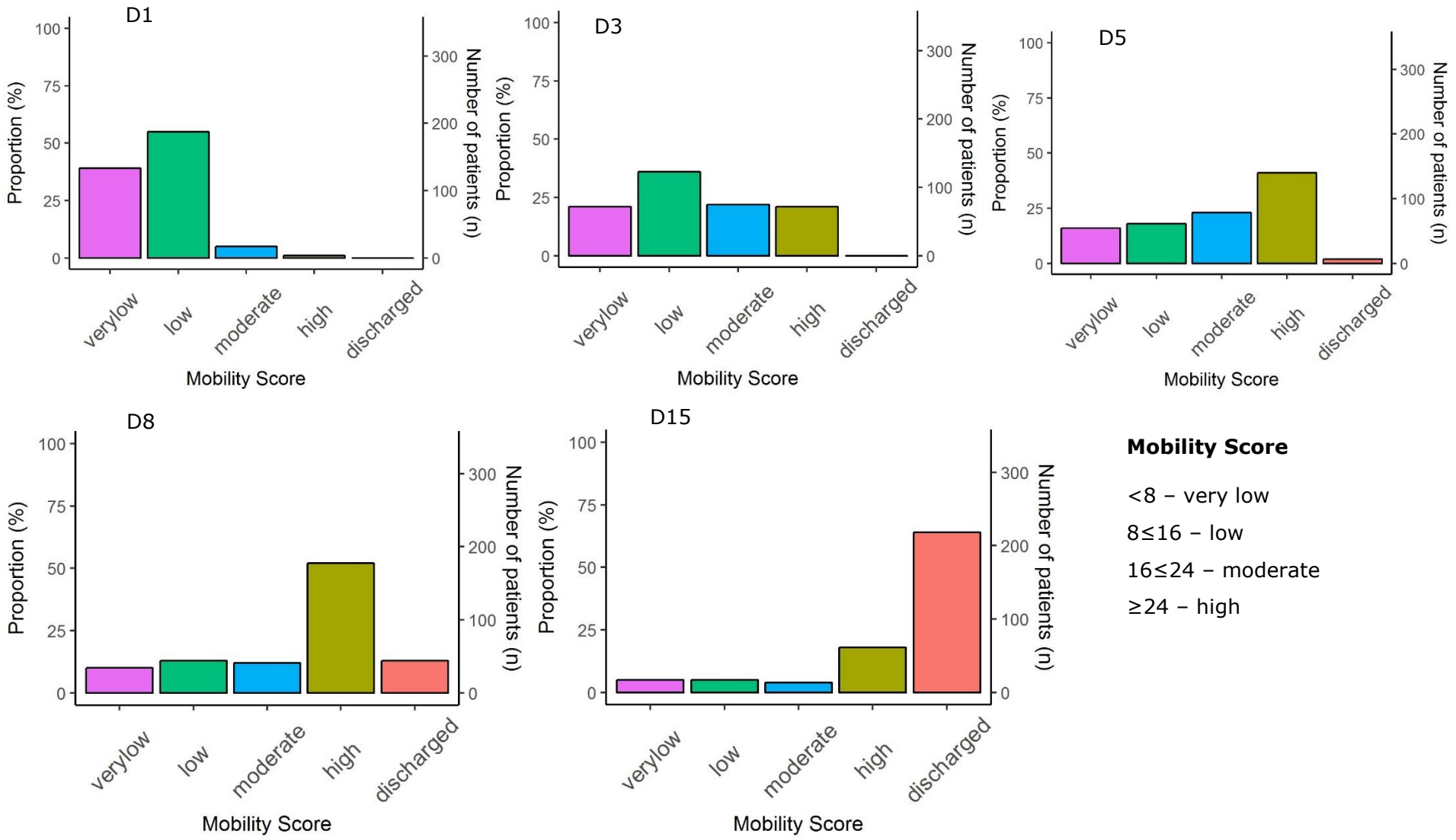
Table 31 Correlation between mobility score and LOS

Postoperative day	correlation	P value
D1	-0.179	0.001
D3	-0.272	0.001
D5	-0.431	0.001
D8	-0.560	0.001
D15	-0.735	0.001

Table 32 Correlation between pain and mobility score

Postoperative day	correlation	P value
D1	-0.131	0.02
D3	-0.123	0.02
D5	-0.094	0.08
D8	-0.083	0.12
D15	0.024	0.66

Figure 22 Mobility score per HF-POMS day



Mobility Score

<8 – very low

8≤16 – low

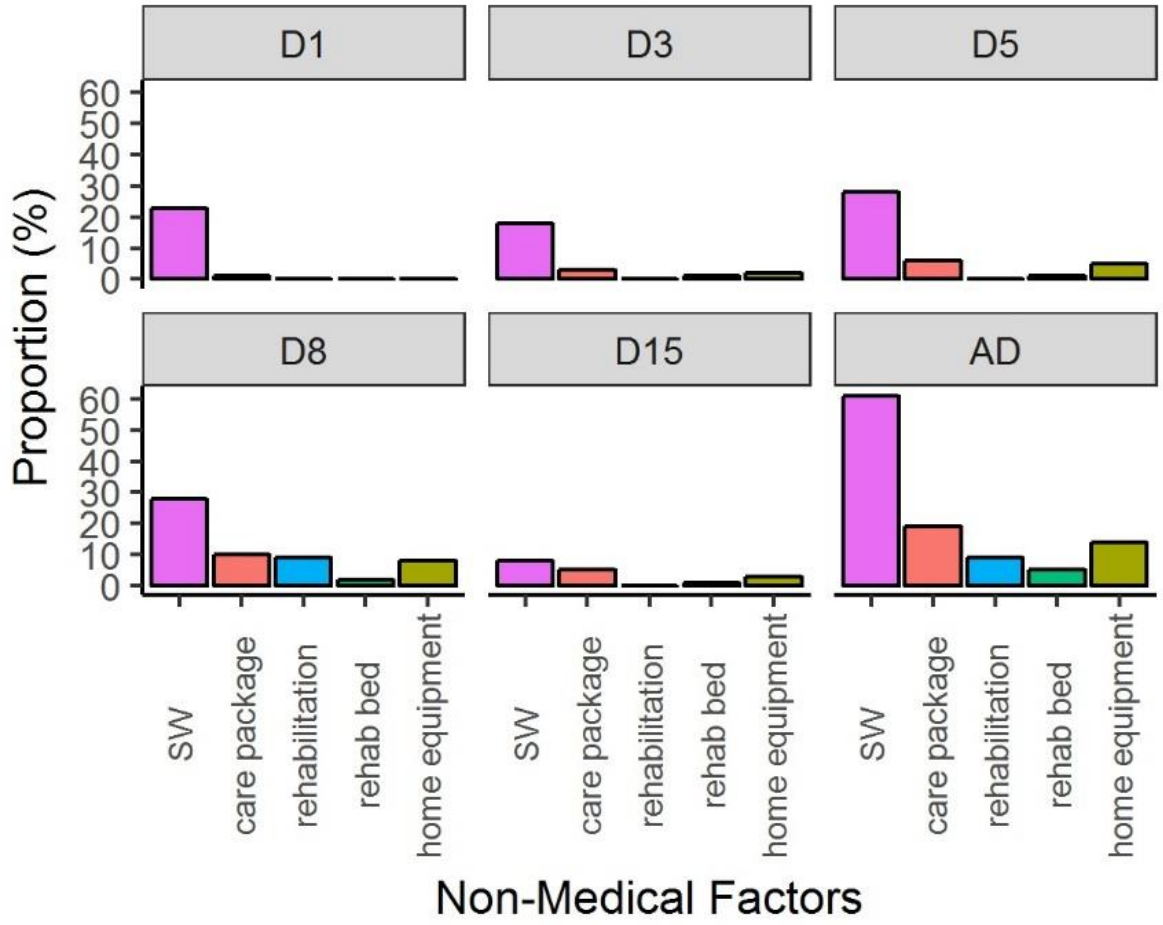
16≤24 – moderate

≥24 – high

7.2.9 Other reasons identified for staying in hospitals

Social reasons (safe guarding issues, package of care approval, awaiting social worker assessment/ social service assessment) awaiting equipment delivery at home, rehabilitation or awaiting rehabilitation bed, physiotherapy, awaiting repatriation to another hospital, awaiting for placement (nursing and or residential home) family issues and discharge planning. Figure 23 below show rates of these non-medical factors across all participants by HF-POMS day. Occupational therapy assessment and social worker assessment were seen across all days averaging 30% on D15, followed by awaiting care package, awaiting rehabilitation and home equipment averaging 10% each by D15.

Figure 23 Non-medical factors for staying in hospital



Abbreviations: SW social worker and OT assessment, rehab bed, awaiting rehabilitation bed, AD, all days, D, day.

7.3 Discussion

The main findings of this study on the development and validity of a postoperative morbidity tool in emergency hip fracture surgery is that, short term morbidity factors as defined by the HF-POMS are associated with length of hospitalisation and presence of certain morbidity domains on specific days can predict LOS. Studies that validated the unmodified POMS [150 151 160 161] in various surgeries have shown that individual POMS domains can predict LOS. The highest prediction in adjusted subsequent LOS of 20.1 days (95% CI; 2.85-37.40, p= 0.023) in our study was observed in the presence of endocrinology domain at day 15 - though the numbers of patients with this morbidity was low (20 (5.9%)), and the lowest prediction of 2.70 days (95% CI; 0.27-5.13, p=0.029) in the renal domain on day 5. We observed an overall in-hospital mortality rate of 2.4% in line with previous studies [3].

The HF-POMS tool has face validity, it has been developed solely from a homogenous emergency hip fracture patients and morbidity domains identified are commonly known hip fracture complications post-surgery [196] shown to influence LOS [209-211]. It has been developed using clearly defined morbidity criteria from validated tools. The recent National Hip Fracture Database report [11], reported the average LOS in acute orthopaedic wards in England as 15.3 days and overall LOS in acute hospital as 19.8 days. We observed an average LOS of 16.9 days similar to the national average.

An increase in NHFS was associated with subsequent increase in LOS by 1.98 days. One previous study [83] has shown that increasing NHFS is negatively correlated with eventual-return-to home r^2 =0.949, and with the percentage of those discharged back to their individual homes at the following post-operative days 7 (r^2 = 0.84), 14 (r^2 = 0.94) and 21 (r^2 = 0.96). Similarly increasing, ASA grade was associated with increased LOS.

7.3.1 POMS vs HF-POMS

Grocott and colleagues [150] found that orthopaedics patients were less likely to have POMS defined morbidity even though their total participant population included two-thirds orthopaedic patients. For similar domains in POMS, our study participants have exhibited a high presence of pain (9%-62%), renal (14%-81%) and infectious (7%-58%) categories. There are several reasons to be considered for these differences. First, all patients considered in our study are emergency admissions requiring urgent surgery compared to the other study where major elective surgery patients were enrolled. Patients admitted for elective surgery attend pre-op assessment a few days before surgery, ensuring that they are fit for surgery. Secondly, age difference. We recruited patients aged 70 years and above compared to 18 years and above. Elderly age has been associated with high risk of peri-operative morbidity, complications, mortality and increased LOS [162 212]. These two notions have also been observed by Howes and colleagues [151] in their study validating POMS in emergency laparotomy patients. Thirdly, in contrast to the POMS with nine morbidity categories, the HF–POMS has twelve morbidity domain

categories with, psychological, assisted ambulation and endocrinology domains added. Assisted ambulation and endocrinology domains are also available in the C-POMS. Fourth, in view of the fact that intravenous opioids are usually not the first preference for the treatment of pain, rather oral opioids are common choice in orthopaedic wards; the pain criteria definition was changed.

7.3.2 Additional HF–POMS domains

Learning from peri-operative risk stratification tools which have evolved, redesigned and recalibrated for accuracy in specific surgical specialities the development and validation of a hip fracture specific POMS as already exemplified by the C-POMS [159] and suggested alternative POMS for paediatric surgery [150] is of clinical importance. There is also an important argument acknowledging that incidence and prevalence of certain morbidity fields being surgical specialty specific are accounted for by surgical site and nature of injury and/ or even underlying comorbidities. Gastrointestinal domain has been observed to be high in general abdominal surgery [149-151] [160] implying potential mobility and pain impact on hip fracture patients due to the fracture, surgical fixation and surgical process. The assisted ambulation domain was developed to account for this new or escalated postoperative requirement for mobility assistance with two people and a walking aid(s). Endocrine-metabolic complications in hip fracture population has previously been observed to have an effect on at least 35% of the patients [196] although lower rates were observed in this study.

The psychological domain has been included with a criterion definition as new or exacerbated postoperative anxiety affecting mobility and /or self-care (coping at home). The prevalence and ramifications of fear of falling causing anxiety after hip fracture surgery are well documented [193]. Two separate studies reported fear of falling ranging from 21%-85% [213] and 60% at four weeks and 47% at 12 weeks [214] after hip fracture. Delayed hospital discharge is impacted by lower odds of recovery among those with anxiety of falling as they restrict their activities in an effort to reduce the risk. Psychological aspects were associated with lower odds of recovery in patients with high function pre-fracture odds ratio 0.82 (95% CI 0.72 - 0.93) [214]. Furthermore, this could heavily influence the patient's quality of life in terms of physical health, mental health, and social and leisure pursuits accounting for low-moderate correlation among the HF–POMS domains and impact on discharge.

7.3.3 Pain management after hip fracture

Our study observed similar aspects to other studies that have assessed the impact of pain on outcome after hip fracture. One of the studies reported patients complaining of significantly higher pain scores at rest had prolonged hospital stay, were highly likely to miss or have shortened physiotherapy sessions, were less likely to ambulate past a bedside chair by postoperative D3 (OR 0.62, 95% CI 0.50 - 0.08, $p < 0.001$) and they took significantly longer to ambulate past a bedside chair as compared to patients with lower pain scores[215]. Another study [216] reported that at least 50% of patients with DHS and 80% of those with IMHS had moderate to

high pain scores at one to four days post operatively and a relatively high proportion of these patients had inadequate analgesia during physiotherapy sessions. We observed a negative correlation between pain and mobility scores supporting the assumption that poor pain management inhibits ambulation resulting in prolonged rehabilitation [215] [217] [218].

Moreover we observed an overall average of 12.8mg opioids administration across the five postoperative days in comparison to 12.2mg observed by Morrison and colleagues [215] over three postoperative days, which is considerably less than daily recommendation. Hip fracture guidelines [15] [19] and NHS standards recommend frequent assessment of pain both at rest and during activities, with routine formal charting of pain scores as routine practice. Although objective data are limited, clinical experience and our results showed limited application of the recommendations.

While consequences of poor pain management among the frail elderly after hip fracture surgery is clearly outlined in literature, certain attitudes and beliefs are still a barrier in the treatment of pain. Aspects outlined in other studies are what we also observed; staff are busy and they patients do not want to put undue burden on staff, pain is expected after such a major surgery and fears of developing opioids side effects [215].

7.3.4 Strengths and limitations of the study

Our inclusion criteria was 70 years and above which could limit generalising the results to patient below this age. A lower sample size of

341 participants was enrolled in this study, which could limit a direct comparison between the HF–POMS and the POMS. Low-moderate internal consistency was observed among the morbidity domains affecting its use a summary score. However the HF–POMS is a composition of 'causal indicators' as opposed to 'effect indicators' [219], reflecting that included domains and criteria items are manifestations of an underlying construct. In classic psychology scores using multiple items for measuring a construct of a disease such as depression, it is an inevitable assumption that item scores should collectively increase or decrease if the disease worsen or improve respectively. Under such circumstances, confirmation of unidemsionality through item response theory (IRT) measures and high internal consistency are required. Comparatively, tools determined by causal indicators such as HF–POMS were items taken together define the construct internal consistency could be considered irrelevant. The HF–POMS domains are a measure of multiple physiological systems, so there is an expected low-moderate correlation, where certain domains are considerably independent (e.g. Pain and Renal) and other times correlated (e.g. Wound and Infection). With due caution, the 12 domains of the HF–POMS may be summed up into a summary score reflecting the magnitude of postoperative morbidity after hip fracture.

Data for HF–POMS was collected from three national health institutional sites reflecting its potential for nationwide application and we have included patients with cognitive impairment, or inability to co-operate by gaining consent from the next of kin. This was deemed necessary for an

overall generalisability results as 35% of the elderly admitted with hip fracture present with some degree of cognitive impairment[38]. All research sites were acute care trusts and morbidity was measured during hospital stay, excluding LOS and complications observed at community and/ or rehabilitation units. In hospitals where rehabilitation units are attached to acute care 'super-spells' should be accounted for.

Through clinical experience, one could argue that daily application or the general use of the HF-POMS could also be limited by work pressures, increased workload and staff shortages within the current healthcare environment. Under such circumstances, prioritisation to apply the HF-POMS on patients identified pre-operatively as 'high risk' might be the best way forward.

Similarly to the POMS, the HF–POMS does not address non-medical aspects affecting prolonged hospital stay. Several non-morbidity factors have been identified keeping the patients in hospital [150 159]. In this study, we observed 29.9%, 34.31% and 12.6% of patients in hospital on days 5, 8 and 15 respectively needing social input in addition to other morbidities; however, 8.21% remained in hospital for social reasons only on D15. In one study [203], variation of LOS in hip fracture patients was due to Clinical Commissioning Group (CCG) which the patient came from (median LOS varied from 14.9 days to 23.4 days). CCGs vary in performance to aid discharged. The current health and social care-funding crisis across the UK local government authorities could be a key recipe in delaying discharges causing acute bed shortage.

7.4 Conclusions

Within old and frail hip fracture patients, the HF-POMS has identified infectious, renal, pain and assisted ambulation domains as highly prevalent after surgery. Post-surgical care in these patients presents exceptional clinical challenges and needs strategies to optimise patient care aiming early discharge. The HF-POMS provides a structured way to identify and quantify facilitating targeted treatment of morbidities could be part of early discharge planning to avoid prolonged hospital stay. Further research is required for national validation of the HF-POMS, which could also be used as a postoperative discharge summary tool and as an outcome measure in hip fracture clinical trials.

Table 33 Hip Fracture Postoperative Morbidity Score (HF-POMS): domains and criteria definition.

Morbidity type	Criteria definition
Pulmonary	Presence of one or more of the following: The patient developed a new requirement for oxygen or respiratory support;
Infectious	Presence of one or more of the following: Currently on IV antibiotics; Has had a temperature of >38®C in the last 24 hr; *Has a white cell count level requiring in hospital review or treatment;
Renal	Presence of one or more of the following: Presence of oliguria <500 mL/24hr; Increased serum creatinine (>30% from preoperative level); New urinary catheter in situ;
Gastrointestinal	Presence of one or more of the following: Unable to tolerate an enteral diet for any reason including nausea, vomiting, and abdominal distension (use of antiemetic); *Diarrhoea *New poor appetite causing poor oral intake
Cardiovascular	Presence of one or more of the following: Diagnostic tests or therapy within the last 24hr for any of the following: (1) new MI or ischemia, (2) hypotension (requiring fluid therapy >200mL/hr or pharmacological therapy), (3) *dizziness - significant postural hypotension on sitting or standing up (4) cardiac arrhythmia that requires treatment or further investigation, (5)

	pulmonary oedema, (6) thrombotic event (requiring anticoagulation).
Neurological	Presence of one or more of the following: New focal neurological deficit, confusion/ delirium, coma.
Haematology	Presence of one or more of the following: Requirements for any of the following within the last 24 hr: packed erythrocytes, platelets, fresh-frozen plasma, or cryoprecipitate.
Wound	Presence of one or more of the following: Wound dehiscence requiring surgical exploration or drainage of pus from the operation wound with or without isolation of organism; *Leaky wound requiring frequent dressing change
Pain	New and/or exacerbated postoperative pain significant enough to require any of the following: parenteral OR *oral opiates and/or continuing of additional analgesia; *pain limiting sitting up in bed or out on the chair.
*Endocrinology	*Difficult to control diabetes- hypoglycaemia or hyperglycaemia that requires specialist input
*Assisted Ambulation	Presence of one or more of the following: *A new or escalated postoperative requirement for mobility assistance with two people and a walking aids; *Fatigued quickly limiting mobility.
*Psychological	*A new or exacerbated postoperative anxiety affecting mobility and /or self-care (coping at home).

Abbreviations: WCC, white cell count, CRP, C-reactive protein, IV, intravenous, MI, myocardial infarction, * New domains and criteria definitions.

Table 34 HF – POMS Daily Morbidity items present

Morbidity Item	**D1**	**D3**	**D5**	**D8**	**D15**
Pulmonary					
New oxygen requirement or respiratory support	16	9	3	3	0
Infectious					
Currently on IV antibiotics	171	41	21	11	9
Has had a temperature of >38®C in the last 24 hr	19	0	5	6	2
Raised WCC	50	30	12	13	5
Renal					
Presence of oliguria <500ml/24 hr	13	3	0	0	0
Increased serum creatinine (> 30% from preoperative level)	0	4	0	1	0
New urinary catheter in situ	276	239	150	66	23
Gastrointestinal					
Unable to tolerate an enteral diet for any reason including nausea, vomiting and abdominal distension (use of antiemetic)	62	40	36	20	8
Diarrhoea	0	1	1	2	2
Reduced appetite	12	11	14	3	0
Cardiovascular					
New MI or ischemia	0	0	0	0	0
Hypotension (requiring fluid therapy > 200ml/hr or pharmacological therapy)	28	11	7	5	0
Atrial or ventricular arrhythmias	3	3	1	0	0
Pulmonary oedema	0	0	0	0	0
Thrombotic event (requiring anticoagulation)	0	0	0	0	0
Dizziness	13	6	7	2	0
Neurological					

New focal neurological deficit	0	0	0	0	0
Confusion/delirium	57	37	31	19	11
coma	1	1	0	0	0
Haematological					
Packed erythrocytes	34	24	19	0	1
platelets	0	0	0	0	0
Fresh-frozen plasma	0	0	0	0	0
cryoprecipitate	0	0	0	1	0
Wound					
Wound dehiscence requiring surgical exploration or drainage of pus from the operation wound with or without isolation of organism	0	1	1	1	3
Leaky wound	6	6	7	2	2
Pain					
Pain significant enough requiring parenteral opioids or regional anaesthesia	0	1	0	2	0
Oramoph	125	72	60	30	11
Pain limiting sitting out on the chair	197	128	92	58	11
Pain limiting sitting up in bed	71	35	0	10	4
Psychological					
Anxiety	24	21	27	22	9
Endocrinology					
On sliding scale	8	0	1	0	0
Uncontrolled blood sugars	12	14	5	4	1
Assisted Ambulation					
Mobility assistance	308	289	286	227	71
Fatigue	2	4	14	11	1

Abbreviations: MI, myocardial infarction, IV, intravenous, WCC, white cell count

Table 35 Rates (%) HF – POMS defined morbidity after surgery in patients with different NHFS[a] and in different ASA grades[b] defined morbidity risk categories.

	NHFS		**ASA grade**	
	≤4	>4	I/II	III/IV/V
Morbidity type	n=144	n=132	n=90	n=204
Pulmonary	2.90	4.35	1.36	5.10
Infectious	38.04	30.43	19.38	43.19
Renal	48.55	43.47	23.47	58.16
Gastrointestinal	17.39	20.65	12.24	25.51
Cardiovascular	11.23	9.42	5.78	14.63
Neurological	8.33	17.39*	4.42	21.43*
Haematological	10.14	8.33	4.42	14.97
Wound	1.81	1.45	2.04	5.10
Pain	41.30	34.42	24.15	50.68
Psychological	11.23	9.42	4.74	15.99
Endocrinology	3.62	3.62	0.68	5.44
Assisted Ambulation	51.81	47.82	29.93	69.39*

*P <0.05 for chi-square test of different between low and high-risk patient groups

[a]based on 276 of the total patients with NHFS, missing 65

[b]based on 294 of the total patients with ASA grade, missing 4

Table 36 Original POMS, CPOMS and HF-POMS: an overview

Morbidity Domain	Original and validated POMS	C-POMS	HF-POMS
Pulmonary	The patient developed a new requirement for oxygen or respiratory support	including nebulizer therapy or request for chest physiotherapy on or after D5; Pleural effusion requiring drainage	
Infectious	Currently on antibiotics and/or has had a temperature of >38$^{\circ C}$ in the last 24 hr	Has a white cell count/CRP level requiring in hospital review or treatment	Has a white cell count level requiring in hospital review or treatment
Renal	Presence of oliguria <500 mL/24 hr; increased serum creatinine (>30% from preoperative level); urinary catheter in situ.	Presence of decreased urine output requiring intervention (including IV frusemide); New urinary incontinence; Serum potassium abnormalities requiring treatment.	
Gastrointestinal	Unable to tolerate an enteral diet for any reason including nausea, vomiting, and abdominal distension (use of antiemetic).	The presence of a nasogastric tube; Diagnosis of a gastro intestinal bleed; Presence of diarrhoea	Diarrhoea; New poor appetite causing poor oral intake
cardiovascular	Diagnostic tests or therapy within the last 24 hr for any of the following: new myocardial infarction or ischemia, hypotension (requiring	hypotension (requiring fluid therapy >200mL/hr or pharmacological therapy, or omission of	dizziness - significant postural hypotension on sitting or standing up

	fluid therapy >200 mL/hr or pharmacological therapy), atrial or ventricular arrhythmias, cardiogenic pulmonary edema, thrombotic event (requiring anticoagulation)	pharmacological therapy; hypertension (pharmacological therapy or omission of pharmacological therapy)	
Neurological	New focal neurological deficit, confusion, delirium, or coma.	Lack of coordination; drowsy or slow to wake; poor swallow; blurred vision; sedated; changing loss of consciousness.	
Haematological	Requirement for any of the following within the last 24 hr: packed erythrocytes, platelets, fresh-frozen plasma, or cryoprecipitate.	Unthereapeutic INR requiring pharmacological therapy or omission of pharmacological therapy	
Wound	Wound dehiscence requiring surgical exploration or drainage of pus from the operation wound with or without isolation of organisms.	Presence of chest drains; Wound pain significant enough to require continuing or escalating analgesic intervention	Leaky wound requiring frequent dressing change
Pain	New postoperative pain significant enough to require parenteral opioids or regional analgesia.	Postoperative pain significant enough to require parenteral opioids and/or continuing or additional analgesia.	New and/or exacerbated postoperative pain significant enough to require any of the following: parenteral OR *oral opioids and/or continuing of additional analgesia; pain limiting sitting up in bed or out on the chair

Endocrinology	New or additional requirements for blood sugar management	Difficult to control diabetes-hypoglycaemia or hyperglycaemia that requires specialist input
Assisted ambulation	A new or escalated postoperative requirement for mobility assistance	Presence of one or more of the following: A new or escalated postoperative requirement for mobility assistance with two people and a walking aids; Fatigued quickly limiting mobility.
Review	Remaining in hospital for further review, investigations, and or procedure	
Psychological		A new or exacerbated postoperative anxiety affecting mobility and /or self-care (coping at home).

CHAPTER 8

Conclusion and implications for practice and research

8.1 Introduction

This final chapter brings together all the overall findings observed from the present study. Firstly, a summary of the main findings will be outlined followed by clinical implications, and finally suggested further research and conclusion will close this chapter.

8.2 Summary of the main findings

8.2.1 Risk stratification tools

Current study findings show that broadly, perioperative care (pre-, intra- and post-operative) hugely influences outcome after fragility hip fracture. National hip fracture guidelines [15 19] and other hip fracture care organisation [10-12] are intended to ensure expected quality systematic standardised care management of this patient population across regions and nations where applicable. However, local and regional aspects sometimes differ, which could explain some of the differences in care among health care institutes.

The systematic literature review conducted on the currently used risk stratification tools in hip fracture patients, outlined various tools available. The key function of risk stratification process is to identify patients at high risk of mortality and morbidity allowing provision of adequate clinical care at every stage of the patient's journey. Some tools have been developed in general surgery and then adapted and/ or modified specifically to the hip fracture patient population [30 52 76 128], while some have been developed and validated solely in hip fracture patients [51]. Most commonly used tools

were, ASA, CCI, E-PASS,NHFS and POSSUM/Orthopaedic POSSUM. ASA, CCI and NHFS are pre-operative tools, easy to use, readily available using routine data, with no special tests required, while E-PASS and POSSUM would require intra-operative data to obtain a total score.

Among all the tools, we observed that the NHFS was widely validated internationally [67] [142] and nationally with both acceptable discrimination and good fit/calibration, and was developed specifically for a hip fracture population, easy to use and readily available in comparison to other tools.

Moreover, new risk-scoring tools are progressively developed in an effort to enhance precision, sensitivity and discrimination for the future. All current and future scoring tools require regular recalibration, evaluation and comparison to ensure they are fit for purpose. During the course of this study the Surgical Outcome Risk Tool (SORT)[52] was developed by Protopapa and colleagues. The tool was developed from 16 788 patients across all surgical specialties with an acceptable discrimination and calibration. A comparative recalibration for the NHFS and SORT was performed using UK national hip fracture data [107]. Both tools showed good discrimination abilities, however the NHFS showed good fit and SORT was of poor fit [111].

8.2.2 Postoperative morbidity

Postoperative morbidity is more prevalent than mortality and it significantly affects LOS, in-turn influencing resource utilisation; hence, it has been proposed as a better outcome measure. The POMS was

developed in patients from all surgical specialties [149] and mostly validated in general surgery [150 151 160 161]. Due to variations in injury type and surgical procedures, patients across individual surgical specialties and elective are more likely to exhibit complications associated with that particular illness/disease. C-POMS was developed and validated for elective cardiac patients [159]. We aimed to assess the public (patients, patients' relatives and healthcare professionals') perceptions on factors influencing LOS and develop and validate a hip fracture postoperative morbidity survey tool (HF-POMS).

8.2.3 Public Perception on factors affecting LOS

A qualitative method was employed to identify stakeholders' perceptions on factors they consider imperative on delaying discharge. Five main themes and four sub themes were identified; medical reasons (preoperative comorbidities and postoperative complication), social reasons, psychological reasons, age and frailty, and recovery process (mobility and rehabilitation). Medical reasons identified included all major HF-POMS domains. The results of the present study support results from previous studies [188 193 199 200 202], which reported similar observations. While healthcare professionals broadly identified all aspects, detailing medical factors and consequences of prolonged social care assessment on bed availability, relatives and patients were concerned more about functional outcomes, and how well individual patients will cope at home once discharged.

8.2.4 Development of HF-POMS

We hypothesised that emergency hip fracture patients undergoing surgery will exhibit high morbidity rates in certain domains due to the nature of the fracture and surgical trauma. Data for tool development were collected from 341 participants enrolled in the study from April 2015 until end of July 2016. Routine data were collected on D1, D3, D5, D8 and D15 in line with similar previous tool development studies [149 150 159]. An additional 19 items were identified that met the inclusion criteria. A 12-domain HF–POMS tool was developed. New domain criteria for domains such as pain were adapted to include oral opioids, which are recommended for pain management for this patient population rather than intravenous opioids. Assisted ambulation, endocrinology and psychological domains were new additional domains. Psychological domain considers the ramifications of fear of falling causing anxiety in patients, consequently prolonged rehabilitation due to restricted activities due to fear of falling.

Clinical application of the HF–POMS tool in hip fracture patients showed an association with LOS on days 8 and 15. Specific domains independently predicted LOS on specific days. Construct validity of the HF–POMS tool showed that patients with high ASA physical grade and high NHFS had higher morbidity presentation compared to those with low scores. The current tool could be applied to hip fracture patients post-operatively as a discharge tool/score.

8.3 Clinical implication and future research

Currently there is no agreed standardised risk stratification tool in use in hip fracture. We observe that the NHFS could be the best tool of choice currently. The National Hip Fracture Database (NHFD) uses the CEU 17 as a risk score. No previous studies have been done to compare CEU 17 and the NHFS; however, in our recent personal communication with one lead othor-geriatrician in the UK, they have recently completed a study (awaiting publication) comparing the two risk scoring tools. Furthermore, we observed that SORT has good discrimination comparable to the NHFS, but poor fit.

A key recommendation from our observations is the need to emphasise routine and appropriate use of the currently available risk stratification tools. If not used they will not benefit the patients. If applied correctly, current tools could act as a guide for future more accurate tools either through recalibration or risk score variable modification. There is no 'super' risk stratification tool in existence, however better use of current tools is important for both the clinicians (in identifying the level of care required by the individual patient) and the patients (improved outcome with targeted care where required). Development and validation of a new risk scoring tools is a process requiring time and resources, which could be mitigated by better use or the (modification, evaluation and recalibration) of available widely validated tools.

Further research to compare and evaluate these three tools in national data should be considered to identify the best tool for use. Standardising risk scoring would be advantageous across all health care institutes or NHS trusts to enhance quality care and for auditing regional patient risk presentation variations.

All hip fracture clinical tools in use are purposed to provide relevant specific information to clinicians and to patients and their relatives. Provision of adequate information to patients and their relatives (regular update from healthcare professional) about prognosis and the recovery progress during hospital stay is an important aspect of daily care provision (a key aspect of quality care provision). This helps in addressing any concerns patients might have and encourage patient participation in their care and potentially early discharge.

The HF-POMS has demonstrated its similarity to the original POMS in identifying morbidity of a type and severity. Additional domains are necessary to account for all morbidity aspects in this patient population different form the original POMS. There was a varied difference in morbidity domains with high prevalence between general surgery (gastrointestinal, infectious, wound, and pulmonary) and hip fracture patients (mobility, renal, pain, and infectious). Therefore, using the original POMS might not be the best to quantify morbidity after hip fracture surgery. HF–POMS is easy to use, readily available, and uses routine data. While it can be used in its current form, further validation is

required. Its domain aspects are important for not just policy makers, commissioning groups and clinical decision-making, but also contains outcome measures relevant to patients and their families. Again, we advocate routine use of the HF-POMS as an early morbidity detection tool from D5 onwards, audit tool, resource utilisation modelling tool and discharge criterion tool, regionally and nationally for its validity.

8.4 Conclusion

This project has expounded on the impact of current clinical peri-operative care on patients with fragility hip fractures. Identifying those at high risk of poor prognosis and/or intra and postoperative complications remains an ongoing challenge. Appropriate risk stratification hip fracture tools needs to be continuously validated and recalibrated for accuracy and precision. Similarly, the HF–POMS tool require further clinical research application to validate its clinical utility aspects in hip fracture patients. It has all the domains required and criteria definition to capture morbidity for this specialty patient population. Non-medical domains must be considered to enhance a complete picture of healthcare resource utilisation by patients exhibiting zero morbidity according to HF-POMS criteria.

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10. APPENDICES

Appendix 1

Summary of currently used risk scoring tools in hip fracture patients

American Society of Anaesthesiologists Score (ASA) [49]. It describes the fitness for surgery of an individual patient.

ASA grade	
I	A normal healthy patient
II	Patient with mild systemic disease
III	Severe systemic disease but not incapacitating
IV	Severe systemic incapacitating disease that is a constant threat to life
V	Moribund, not expected to survive 24 h with or without the operation

Nottingham Hip Fracture (NHFS) [51]

Variable	**Value**	**Score**
Age	<66	0
	66-85	3
	≥86	4
Sex	Male	1
Admission Hb	≤10g dl^{-1}	1
MMST	≤6 out of 10	1
Living in an institution	Yes	1
Number of Co-morbidities	≥2	1
Malignancy	Yes	1

Charlson Comorbidity Index (CCI) [50]

This is a method of classifying comorbidity to predict short- term and long-term mortality. It is based on assigning weights roughly equal to the 1-year relative risk of death for each condition

Score: 1	**2**	**3**	**6**
Myocardial Infarction	Hemiplegia	Moderate or severe liver disease (e.g., cirrhosis with ascites)	Metastatic solid tumour
Congestive Heart Failure	Moderate or severe renal disease		Acquired immune deficiency syndrome (AIDS)
Peripheral Vascular disease	Diabetes with end organ damage		
Cerebrovascular disease	Any malignancy		
Dementia			
Chronic pulmonary disease			
Connective tissue disease			
Ulcer disease			
Mild liver disease			
Diabetes			

Physiological and Operative Severity Score for the enUmeration of Mortality and Morbidity (POSSUM)[128]

POSSUM Physiological Variables

Score	1	2	4	8
Age(years)	<60	61-70	>71	-
Cardiac Signs	Normal	Cardiac drugs or steroids	Oedema Warfarin	Jugular venous pressure
CXR	Normal	-	Borderline cardiomegaly	Cardiomegaly
Respiratory signs	Normal	SOB exertion	SOB stairs	SOB rest
CXR	Normal	Mild COAD	Moderate COAD	Any other change
Systolic BP, mm Hg	110-130	131-171 100-109	>171 90-99	<80
Pulse beats/min	50-88	81-100 40-49	101-120	>121 <39
Coma score	15	12-14	8-11	<8
Urea nitrogen (mmo/l)	<7.5	7.6-10	10.1-15	>15.1
Sodium (mEq/l)	>136	131-135	126-130	<125
Potassium (mEq/l)	3.5-5	3.2-3.4 5.1-5.3	2.9-3.1 5.4-5.9	<2.8 >6
Haemoglobin (g/dl)	13-15	11.5-12.9 16.1-17	10-11.4 17.1-18	<9.9 >18.1
WCC ($X10^{12}$/l)	4-10	10.1-20 3.1-3.9	>20.1 <3	-
ECG	Normal	-	AF (60-90)	Any other change

POSSUM surgical variables

Score	1	2	4	8
Operative magnitude	minor	intermediate	major	major+
No of operations within 30 days	1		2	>2
Blood loss per operation (ml)	<100	101-500	501-999	>1000
Peritoneal contamination	No	serous	Local pus	Free bowel content, pus or blood
Presence of malignancy	No	Primary cancer only	Node metastases	Distant metastases
Timing of operation	Elective		Emergency, resuscitation possible, operation <24 h	Emergency, immediate operation < 2 h

AF, arterial fibrillation; COAD, chronic obstructive airway disease; CXR, chest e-ray; BP, blood pressure; ECG, electrocardiogram; JVP, jugular venous pressure; SOB, shortness of breath, WCC, white cell count.

Equations for Estimation of Physiologic Ability and Surgical Stress (E-PASS) scores: preoperative risk score (PRS), surgical stress score (SSS), and comprehensive risk score (CRS). [105]

1. PRS =-0.068 + 0.00345X_1 + 0.322X_2 + 0.205X_3 + 0.153X_4 + 0.148X_5 + 0.0666X_6 X_1: age; X_2: presence (1) or absence (0) of severe heart disease; X_3: presence (1) or absence (0) of severe pulmonary disease; X_4: presence (1) or absence (0) of diabetes mellitus; X_5: performance status index (0–4); X_6: American Society of Anesthesiologists physiological status classification (1–5) Severe heart disease is defined as heart failure of New York Heart Association Class III or IV, or severe arrhythmia requiring mechanical support. Severe pulmonary disease is defined as any condition with a % VC less than 60% and/or a $FEV_{1.0\%}$ less than 50%. Diabetes mellitus is defined according to the WHO criteria. Performance status index is defined by the Japanese Society for Cancer Therapy.
2.SSS = -0.342 + 0.0139X_1 + 0.092X_2 + 0.352X_3 X_1: blood loss/body weight (g/kg); X_2: operation time (h); X_3: extent of skin incision (0, minor incision for laparoscopic or thoracoscopic surgery including scope-assisted surgery; 1, laparotomy or thoracotomy alone; 2, both laparotomy and thoracotomy)
3. CRS = -0.328 + 0.936 (PRS) + 0.976 (SSS)

VC, vital capacity; FEV, forced expiratory volume

Surgical Outcome Risk Scoring Tool [52]

Variables	Coefficient
ASA-PS grade	
III	1.411
IV	2·388
V	4·081
Urgency of Surgery	
Expedited	1.236
Urgent	1·657
Immediate	2.452
Specialty	
High risk (gastrointestinal, thoracic or vascular)	0·712
Severity of Surgery	
Xmajor/complex	0.381
Cancer	0·667
Age (years)	
65-79	0.777
≥ 80	1.591

ASA-PS, American Society of Anesthesiologists Physical Status; Xmajor, extra major. SORT Risk score = (ASA − PS III × 1.411) + (ASA − PS IV × 2.388) + (ASA − PS V × 4.081) + (urgency 'expedited' × 1.236) + (urgency 'urgent' × 1.657) + (urgency 'immediate' × 2.452) + (high-risk specialty × 0.712) + (severity 'Xmajor complex' × 0.381) + (cancer × 0.667) + (age 65–79 years × 0.777) + (age ≥ 80 years × 1.591)

Appendix 2 Search Strategy for hip fracture risk stratification tools.

We developed search terms based on medical subject headings (MeSH), free text words and words in the title or abstract. We combined search terms of patient population (hip fracture patients) with risk stratification tools and outcome assessment. The MeSH terms used included combinations of the terms: hip fracture, risk adjustment/risk stratification, and surgical procedures, also applied with special characters ($, *). Example of online search terms is given below.

#1 (hip fractur*) or (hip fragility) or (hip surger*) or (femoral fractur*) or (femoral surger*) or (fracture neck of femur).

#2 (effect*) or (consequence*) or (result*) or (impact*) or (benefit*) or (outcome*) or (risk*) or (predict*) or (tool*)

#3 (care*) or (manag*) or (optimis*) or (complicat*) or (morbidity) or (mortality) or (death*).

#4 (peri-operat*) or (perioperat*) or (pre-operat*) or (preoperat*) or (peroperat*) or (before operat*) or (before surger*) or (peri-surger*) or (presurger*) or (during operat*) or (during surger*) or (intra-operat*) or (intraoperat*) or (post-op*) or (post surger*) or (after surger*) or (after adj operat*).

#1 AND #2 AND #3 AND #4 (combining all searches with AND). The following key words were also searched separately in all databases: ASA, CCI, E-PASS, NHFS, MMES and POSSUM.

Appendix 3

Framework for assessing internal validity of articles dealing with prognosis [62].

Sample of patients

Inclusion criteria defined

Sample section explained

adequate description of diagnostic criteria

clinical and demographic characteristics fully described

representative

assembled at common (usually early) point in course of disease

complete (all eligible patients included)

Follow up of patient

Sufficiently long

outcomes

Objective

unbiased (for example, assessment blinded to prognostic information)

Fully defined

appropriate

known for all or high proportion of patients

Prognostic Variables

Fully defined, including details of measurements methods if relevant

Available for all or high proportion of patients

Analysis

Continuous predictor variable analysed appropriately

Statistical adjustments for all important prognostic factors

Appendix 4 identified risk stratification tools

- ASA = American Society of Anaesthesiologist
- Barthel Index
- BMI = Body Mass Index
- CAS = Cumulative Ambulation Score
- CCS = Clinical Classification Software
- CDT = Clock Drawing Task
- CCI = Charlson Cmmorbidity Index
- Cignitive- FIM
- DHP = Discharge of Hip Fracture Patients Score
- Donati Score
- E-PASS = Estimation of Physiology Ability and Surgical Stree Scoring
- Goldman Index
- Iezzoni
- MMSE = Mini-Mental State Examination Screen
- NMS = New Mobility Score
- NHFS = Nottingham Hip Fracture Score
- POSSUM = Physiological and Operative Severity Score for enUmeration of Moratality and morbidity
- P-POSSUM = Portsmouth Physiological and Operative Severity Score for enUmeration of Moratality and morbidity
- O-POSSUM = Orthopeadic Physiological and Operative Severity Score for enUmeration of Moratality and morbidity

- SPMSQ = Short Portable Mental Status Questionnaire
- SORT =Surgical Outcome Risk Tool
- RD = Risk model for Delirium
- RISK-VAS = Visual Analogue Scale for Risk
- FRAMO Index = Fracture and Mortality Index

Appendix 5 Ethical, R&D approvals and study documents

NHS
Health Research Authority

NRES Committee East Midlands - Northampton
Royal Standard Place
Nottingham
NG1 6FS

Telephone: 0115 8839521

29 January 2015

Dr Iain Moppett
Associate Professor/Honorary Consultant
University of Nottingham and Nottingham University Hospitals NHS trust
Anaesthesia
Queen's Medical Centre
Nottingham
NG7 2UH

Dear Dr Moppett

Study title:	**Morbidity outcomes associated with length of hospital stay in hip fracture patients (MOHF): public perception.**
REC reference:	**15/EM/0054**
Protocol number:	**14113**
IRAS project ID:	**167614**

Thank you for your letter of . I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 21 January 2015

Documents received

The documents received were as follows:

Approved documents

The final list of approved documentation for the study is therefore as follows:

Document	*Version*	*Date*
Copies of advertisement materials for research participants [Clinical study area poster]	1.0	03 December 2012
Covering letter on headed paper		26 January 2015
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only)		
IRAS Checklist XML [Checklist_26012015]		26 January 2015
Letter from sponsor		17 December 2014
Non-validated questionnaire [Patient stuy interview questions and questinnaire]	1.0	03 December 2014

Non-validated questionnaire [Healthcare professionals and Patient relatives/carers study interview questions and questionnaire]	1.0	03 December 2014
Participant consent form [Patient Consent Form]	2.0	26 January 2015
Participant consent form [Healthcare Professionals Consent Form]	2.0	26 January 2015
Participant consent form [Patient Relatives/Carers Consent Form]	2.0	26 January 2015
Participant information sheet (PIS) [Patient Participant Information Sheet]	2.0	26 January 2015
Participant information sheet (PIS) [Healthcare Professionals (Staff) Participant Information Sheet]	2.0	26 January 2015
Participant information sheet (PIS) [Relatives/Carers Participant Information Sheet]	2.0	26 January 2015
REC Application Form [REC_Form_12012015]		12 January 2015
Research protocol or project proposal		03 December 2014
Summary CV for Chief Investigator (CI)		
Summary CV for student		
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Protocol Synopsis]	1.0	03 December 2014

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

15/EM/0054 **Please quote this number on all correspondence**

Yours sincerely

V Strutt

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E-mail: NRESCommittee.EastMidlands-Northampton@nhs.net

Copy to: *Takawira Marufu*
MS Angela Shone
Dr Maria Koufali, Nottingham University Hospitals

Nottingham University Hospitals NHS
NHS Trust

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Research & Innovation
Nottingham Health Science Partners
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28th July 2015

Dr Iain K Moppett
Academic Department of Anaesthesia
C Floor East Block
Nottingham University Hospitals NHS Trust
Derby Road
Nottingham
NG7 2UH

Dear Dr Iain K Moppett

Short Title / Acronym	Morbidity outcomes following hip fracture / MOHF
CSP Number	
R&I REF	15AN001
Long Title	Morbidity outcomes associated with length of hospital stay in hip fracture patients (MOHF): public perception.
PROJECT MILESTONES	
Recruitment Target	156
Date of Valid Submission	13/04/2015
Recruitment End Date	28/02/2016

The R&I Department have considered the following documents submitted on 22/07/15 and there is no objection from the NUH R&I Office to the implementation of this amendment. The documents reviewed are detailed below:

Participant consent form [Consultee] 1.0 02 June 2015
Participant information sheet (PIS) [Consultee] 1.0 02 June 2015
Research protocol or project proposal 2.0 02 June 2015

The amendment may therefore be implemented immediately at this site under the conditions of the existing NHS Permission.

We are here for you

Nottingham University Hospitals NHS
NHS Trust

Please note that you may only implement changes that were described in the documents listed above.

Yours sincerely,

Dr Brian Thomson / Dr Maria Koufali
Director of R&D / Deputy Director Research and Innovation

We are here for you

RESEARCH & INNOVATION

University Hospitals of Leicester NHS
NHS Trust

DIRECTORATE OF RESEARCH & INNOVATION

Director: **Professor Nigel Brunskill**

Assistant Director: **Dr David Hetmanski**

Head of Research Operations: **Carolyn Maloney**

Direct Dial: (0116) 258 8351
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Research & Innovation Office
Leicester General Hospital
Gwendolen Road
Leicester
LE5 4PW

18/11/2015

Dr Farah Ahmed
University Hospitals of Leicester
Anaesthetic Department
Leicester Royal Infirmary
Infirmary Square
Leicester
LE1 5 WW

Dear Dr Farah Ahmed

Ref: **UHL 11437**
Title: **Morbidity outcomes associated with length of hospital stay in hip fracture patients (MOHF): public perception.**
Project Status: **Project Approved**
End Date: **31/05/2016**

Date of Valid Application: 17/11/2015
Days remaining to recruit first patient: 69 Days

I am pleased to confirm that with effect from the date of this letter, the above study has Trust Research & Development permission to commence at University Hospitals of Leicester NHS Trust. The research must be conducted in line with the Protocol and fulfil any contractual obligations agreed between UHL & the Sponsor. If you identify any issues during the course of your research that are likely to affect these obligations you must contact the R&D Office.

In order for the UHL Trust to comply with targets set by the Department of Health through the 'Plan for Growth', there is an expectation that the first patient will be recruited within 70 days of receipt of a Valid Application. The date that a Valid application was received is detailed above, along with the days remaining to recruit your first patient. **It is essential that you notify the UHL Data Management Team as soon as you have recruited your first patient to the study either by email to RIData@uhl-tr.nhs.uk or by phone 0116 258 4573.**

If we have not heard from you within the specified time period we will contact you not only to collect the data, but also to record any issues that may have arisen to prevent you from achieving this target. It is essential that you get in touch with us if there is likely to be a problem in achieving this target so that we can discuss potential solutions. The Trust is contractually obliged to meet the 70 day target and if an adequate reason acceptable to the NIHR has not been submitted to explain the issues preventing the recruitment of your first participant, the Trust will be financially penalised.

In addition, we are required to publish the Title, REC Reference number, local target recruitment and actual recruitment as well as 70 days data for this study on a quarterly basis on the UHL public accessed website.

All documents received by this office have been reviewed and form part of the approval. The documents received and approved are as follows:

Document Name	Version	Date
Patient study interview questions and questionnaires	V1.0	03/12/2014
Healthcare professionals and patient relatives/carers study interview questions and questionnaire	V1.0	03/12/2014
Patient consent form	V2.0	26/01/2015
Healthcare professionals consent form	V2.0	26/01/2015
Patient relatives/carers consent form	V2.0	26/01/2015
Patient information sheet	V2.0	26/01/2015
Healthcare Professionals information sheet	V2.0	26/01/2015
Relative/Carers information sheet	V2.0	26/01/2015
REC Favourable Opinion	Study Approval	29/01/2015

Non-Substantial Amendment 1 02/02/2015

Document Name	Version	Date
REC Favourable Opinion	NSA 1	03/02/2015
Notice of Minor Amendment	NSA 1	02/02/2015
Poster	V2.0	02/02/2015

SA 1

Document Name	Version	Date
REC Favourable Opinion	SA 1	21/07/2015
Notice of Substantial Amendment	V1	02/06/2015
Consultee consent form	V1.0	02/06/2015
Consultee information sheet	V1.0	02/06/2015
Protocol	V2.0	02/06/2015
MCA 1 Form	N/A	N/A

Please be aware that any changes to these documents after approval may constitute an amendment. The process of approval for amendments should be followed. Failure to do so may invalidate the approval of the study at this trust.
PLEASE NOTE: Takawira Marufu has not been approved to work on the study at this time as a research passport was not received in order to process a letter of access.

Undertaking research in the NHS comes with a range of regulatory responsibilities. Please ensure that you and your research team are familiar with, and understand the roles and responsibilities both collectively and individually.

Documents listing the roles and responsibilities for all individuals involved in research can be found on the R&I pages of the Public Website. It is important that you familiarise yourself with the Standard Operating Procedures, Policies and all other relevant documents which can be located by visiting www.leicestershospitals.nhs.uk/aboutus/education-and-research

The R&I Office is keen to support and facilitate research where ever possible. If you have any questions regarding this or other research you wish to undertake in the Trust, please contact this office. Our contact details are provided on the attached sheet.

We wish you every success with your research.

Yours sincerely

Carolyn Maloney

Carolyn Maloney
Head of Research Operations

Encs: .R&I Office Contact Information

Version 16. 03/06/2015

The University of Nottingham

Nottingham University Hospitals NHS
NHS Trust

Division of Anaesthesia and Intensive Care
University of Nottingham
Queen's Medical Centre
Nottingham NG7 2UH

CONSENT FORM
PATIENT
Final version 2.0 26 January 2015

Title of Study: Morbidity outcomes associated with length of hospital stay in hip fracture patients (MOHF): public perception.

REC ref: 15/EM/0054

Name of Researcher: Dr Iain Moppett

Name of Participant: **Please initial box**

1. I confirm that I have read and understand the information sheet version number 2.0 dated 26/01/2015 for the above study and have had the opportunity to ask questions. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my medical care or legal rights being affected. I understand that should I withdraw then the information collected so far cannot be erased and that this information may still be used in the project analysis. ☐

3. I understand that relevant sections of my medical notes and data collected in the study may be looked at by authorised individuals from the University of Nottingham, the research group and regulatory authorities where it is relevant to my taking part in this study. I give permission for these individuals to have access to these records and to collect, store, analyse and publish information obtained from my participation in this study. I understand that my personal details will be kept confidential. ☐

4. I understand that the interview will be recorded and that anonymous direct quotes from the interview may be used in the study reports. ☐

5. I understand that confusion or delirium is common after a broken hip. I give permission for study relevant information to be collected even if I develop confusion or delirium. ☐

6. I agree to take part in the above study. ☐

Name of Participant	Date	Signature
Name of Person taking consent	Date	Signature

3 copies: 1 for participant, 1 for the project notes and 1 for the medical notes

MOHF Consent Form Final Version 2.0 26 January 2015

The University of Nottingham

Nottingham University Hospitals NHS
NHS Trust

Division of Anaesthesia and Intensive Care
University of Nottingham
Queen's Medical Centre
Nottingham NG7 2UH

CONSENT FORM
HEALTHCARE PROFESSIONALS
Final version 2.0 26 January 2015

Title of Study: Morbidity outcomes associated with length of hospital stay in hip fracture patients (MOHF): public perception.

REC ref: 15/EM/0054

Name of Researcher: Dr Iain Moppett

Name of Participant: **Please initial box**

1. I confirm that I have read and understand the information sheet version number 2.0 dated 26/01/2015 for the above study and have had the opportunity to ask questions. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without legal rights being affected. I understand that should I withdraw then the information collected so far cannot be erased and that this information may still be used in the project analysis. ☐

3. I understand that the data collected in the study may be looked at by authorised individuals from the University of Nottingham, the research group and regulatory authorities where it is relevant to my taking part in this study. I give permission for these individuals to have access to these records and to collect, store, analyse and publish information obtained from my participation in this study. I understand that my personal details will be kept confidential. ☐

4. I understand that the interview will be recorded and that anonymous direct quotes from the interview may be used in the study reports. ☐

5. I agree to take part in the above study. ☐

Name of Participant	Date	Signature
Name of Person taking consent	Date	Signature

2 copies: 1 for participant and 1 for the project notes

The University of Nottingham

Nottingham University Hospitals NHS
NHS Trust
Division of Anaesthesia and Intensive Care
University of Nottingham
Queen's Medical Centre
Nottingham NG7 2UH

CONSENT FORM
PATIENT RELATIVES/CARERS
Final version 2.0 26 January 2015

Title of Study: Morbidity outcomes associated with length of hospital stay in hip fracture patients (MOHF): public perception.

REC ref: 15/EM/0054

Name of Researcher: Dr Iain Moppett

Name of Participant: **Please initial box**

1. I confirm that I have read and understand the information sheet version number 2.0 dated 26/01/2015 for the above study and have had the opportunity to ask questions. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my legal rights being affected. I understand that should I withdraw then the information collected so far cannot be erased and that this information may still be used in the project analysis. ☐

3. I understand that the data collected in the study may be looked at by authorised individuals from the University of Nottingham, the research group and regulatory authorities where it is relevant to my taking part in this study. I give permission for these individuals to have access to these records and to collect, store, analyse and publish information obtained from my participation in this study. I understand that my personal details will be kept confidential. ☐

4. I understand that the interview will be recorded and that anonymous direct quotes from the interview may be used in the study reports. ☐

5. I agree to take part in the above study. ☐

Name of Participant	Date	Signature
Name of Person taking consent	Date	Signature

2 copies: 1 for participant and 1 for the project notes

The University of Nottingham

MOHF
Rec: 15/EM/0054; UoN: 14113

Morbidity outcomes associated with length of hospital stay in hip fracture patients (MOHF): public perception.

CASE REPORT FORM – PART 1

18th May 2015

Short title:	Morbidity outcomes following hip fracture.
Acronym:	MOHF
NRES reference:	**15/EM/0054**
Trial Sponsor:	University of Nottingham
Funding Source:	The Sir Jules Thorn Charitable Trust

The University of Nottingham

MOHF
Rec: 15/EM/0054; UoN: 14113

SCREENING

Participant ID: ***MOHF**_nnn_II_YY* *e.g. IV_123_AB_34*	Race: White Black or Black British Asian or Asian British Mixed Chinese Other_____
Date of birth: *Dd/mm/yyyy* Hospital number K:	
Gender: Male / Female	
Date and time of admission: *Dd/mm/yyyy* *Hh:mm*	Date and time of surgery (start): *Dd/mm/yyyy* *Hh:mm*
Fracture type: Intracapsular undisplaced Intracapsular displaced Extracapsular undisplaced Extracapsular displaced Trochanteric	Operation: Hemiarthroplasty - cemented Hemiarthroplasty – uncemented DHS IMHS Other_____
Admitted from: Home – independent Warden controlled Residential care Nursing care	Surgical estimate of blood loss:
Investigator signature:	Source data: Patient notes / other

The University of Nottingham

MOHF
Rec: 15/EM/0054; UoN: 14113

INCLUSION / EXCLUSION / CONSENT

Participant ID: ***MOHF**_nnn_II_YY* *Date of birth:* *Dd/mm/yyyy* *Hospital number K:*	
Date and time of assessment: *Dd/mm/yyyy* *Hh:mm*	
Inclusion: o Primary fracture of the hip planned for surgery o Acute admission to the trust o Aged 70 and above o Able to give own consent All correct?	
Exclusion: o Terminal Stage of any illness o On-Going participation in another clinical Trial No exclusions?	
Date and time of consent: *Dd/mm/yyyy* *Hh:mm*	Creatinine level (cr) on admission .....
Peri-operative Risk Score: *NHFS* *ASA* *NCEOPD* *Other Specify*	Pre-fracture/preadmission mobility status
Previous Medical History of Fracture: Y/N Other: 1. 2. 3. 4. 5.	Prescribed medications on admission:
Investigator signature:	Source data: Patient notes / other

The University of Nottingham

MOHF
REC: 15/EM/0054; UoN: 14113

Morbidity outcomes associated with length of hospital stay in hip fracture patients (MOHF)

CASE REPORT FORM – PART 2

18th May 2015

Short title:	Morbidity outcomes following Hip Fracture
Acronym:	MOHF
NRES reference:	**15/EM/0054**
Trial Sponsor:	University of Nottingham
Funding Source:	The Sir Jules Thorn Charitable Trust

The University of Nottingham

MOHF
REC: 15/EM/0054; UoN: 14113

POST-OP DAY

Participant ID: ***MOHF**_nnn_II_YY* D.O.B: __/__/____ Hosp No. K:	Date: *Dd/mm/yyyy*
Reasons for patient hospital stay:	

Morbidity	***Criteria***	***Source Data***	
Pulmonary	The patient has developed a new requirement for oxygen or respiratory support (e.g. mechanical ventilation or CPAP)	☐	
Infectious	Currently on antibiotics Has/ had a temperature of >38°C in the last 24 hr: Raised WCC	☐ ☐ ☐	
Renal	Presence of oliguria <500ml/24 hr Increased serum creatinine (>30% from preoperative level) Urinary catheter in situ for non-surgical reasons	☐ ☐ ☐	
Gastrointestinal	Unable to tolerate an enteral diet for any reason including nausea, vomiting, and abdominal distension (use of antiemetic) Recurrent aspiration	☐ ☐	
Cardiovascular	Diagnostic tests or therapy within the last 24 hr for any of the following: (1) new myocardial infarction or ischemia (2) hypotension (requiring fluid therapy >200 ml/hr or pharmacological therapy) (3) atrial or ventricular arrhythmias, (4) cardiogenic pulmonary edema, (5) thrombotic event (requiring anticoagulation) (6) Raised Blood pressure requiring pharmacological therapy	☐ ☐ ☐ ☐ ☐ ☐	
Neurological	New focal neurological deficit Confusion/Delirium Coma Worsening of pre-existing cognitive disorder	☐ ☐ ☐	
Haematology	Requirement for any of the following within the last 24 hr (1) packed erythrocytes, (2) platelets, (3) fresh-frozen plasma, (4) cryoprecipitate	☐ ☐ ☐ ☐	
Wound	Wound dehiscence requiring surgical exploration Drainage of pus from the operation wound with or without isolation of organisms High risk of pressure sore (require 2 hourly position turns)	☐ ☐	
Pain	New postoperative pain significant enough to require (1) Parenteral opioids or regional analgesia (amount .....mg) (2) Oramoph (Amount .....mg) (3) Pain score using numeric visual analogue scale At rest .....; on movement	☐ ☐ ☐	

	(4) Pain limits sitting up in bed (5) Pain limits sitting out on the chair (6) Pain limit walking	☐ ☐ ☐	
Psychological	Anxiety ☐ Depression ☐ Apathy ☐		
Mobility	Rehabilitation ☐ Physiotherapy ☐		
Social	Awaiting: Social worker/Occupational Therapy assessment ☐ Care package ☐ Home equipment ☐ Family (specify)		
Other specify:			
Patient's reasons why they are still in hospital: Family/carers/friends:			
Mobility Score: *Complete Mobility score sheet*			
Investigator signature:			

The University of Nottingham

MOHF
REC: 15/EM/0054; UoN: 14113

DISCHARGE

Participant ID: ***MOHF**_nnn_II_YY* D.O.B: __/__/____ Hosp No. K:	Date of discharge: *Dd/mm/yyyy*

Discharge destination:

- Own home ☐
- Warden controlled ☐
- F20 ☐
- Residential care ☐
- Nursing home ☐
- Died ☐

Investigator signature:

Mobility Score

Transfers (bed to chair and back)	
0	Unable to perform task
3	Attempts task but unsafe
8	Moderate help required (2 assist)
12	Minimal help required (1 assist)
15	Fully independent

Mobility (on level surfaces)	
0	Unable to perform task
3	Attempts task but unsafe
8	Moderate help required
12	Minimal help required
15	Fully independent

Stairs	
0	Unable to perform task
2	Attempts task but unsafe
5	Moderate help required
8	Minimal help required
10	Fully independent

Date	Transfers	Mobility	Stairs	Total

Investigator signature:

The University of Nottingham

MOHF

Morbidity outcomes associated with length of hospital stay in hip fracture patients (MOHF): public perception.

Patient Study Interview Questions and Questionnaire

03 December 2014

Short title:	Morbidity outcomes following hip fracture.
Acronym:	MOHF
SPONSOR reference:	**14113**
NRES reference:	**15/EM/0054**
Trial Sponsor:	University of Nottingham
Funding Source:	The Sir Jules Thorn Charitable Trust

The University of Nottingham

MOHF

Part 1

Participant ID: ***MOHF**_nnn_II_YY* *e.g. IV_123_AB_34*	
Date of birth: *Dd/mm/yyyy* Hospital number (S):	
Participant Group	Patient
Investigator signature:	

Interview Questions:

1. In your opinion/experience why do patients stay in hospital after hip fracture surgery?
    - Medical reasons
    - Mobility reasons
    - Social reasons

2. From reasons you have given above which of these do you feel are not important
    - What makes you say that?

3. Are there any other issues that you would like to highlight that have not been covered above?

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Part 2

Below is a list of reasons that current research has outlined as associated with lengthy hospital stay after hip fracture surgery. There is a scale beside each statement. This scale is numbered 1 to 5. Please place an X in the box which you feel best describes how important the statement is in relation to hospital stay and complications after hip fracture surgery.

These numbers correspond to a response as below:

1 – Strongly agree
2 – Agree
3 – Neither agree or disagree
4 – Disagree
5 – Strongly disagree

Statement	1	2	3	4	5
You have developed a new breathing problem requiring oxygen or breathing support	☐	☐	☐	☐	☐
You have one or more of the following: • You are on antibiotic treatment • You had a raised temperature of more than 38°C in the last 24 hours.	☐ ☐	☐ ☐	☐ ☐	☐ ☐	☐ ☐
You have a urinary catheter in situ other than for operation reasons	☐	☐	☐	☐	☐
You are unable to tolerate oral food intake for any reason including nausea, vomiting, and abdominal distension.	☐	☐	☐	☐	☐
You had a heart disease test or therapy within the last 24 hours for any of the following reasons: • New heart attack • Low blood pressure or high blood pressure • Life threatening Irregular heart beat • Blood clot requiring anticoagulation	☐ ☐ ☐ ☐	☐ ☐ ☐ ☐	☐ ☐ ☐ ☐	☐ ☐ ☐ ☐	☐ ☐ ☐ ☐
Change in your conscious level you develop confusion You develop delirium You become unconscious	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐
You had any blood product transfusion requirement within the last 24 hours	☐	☐	☐	☐	☐
Your wound is leaking/opening requiring returning to theatre or drainage of pus.	☐	☐	☐	☐	☐
You have pain after hip operation significant enough to need strong pain killers through a drip or additional painkillers.	☐	☐	☐	☐	☐
You have new or additional requirements for blood sugar management	☐	☐	☐	☐	☐
You develop an increased level of help with mobility	☐	☐	☐	☐	☐

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MOHF

You feel anxious	☐ ☐ ☐ ☐ ☐
You feel depressed	☐ ☐ ☐ ☐ ☐
You are waiting for equipment delivery/installation at home	☐ ☐ ☐ ☐ ☐
You remain in hospital for social reasons such as awaiting package for care.	☐ ☐ ☐ ☐ ☐

Patient Participant Information Sheet

Final version 2.0 26 January 2015

Title of Study: Morbidity outcomes associated with length of hospital stay in hip fracture patients (MOHF): public perception.

Name of Researcher: Dr Iain Moppett

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 research team members 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. This study is part of a PhD student research project.

What is the purpose of the study?

Patients who have broken their hip are at significant risk of problems and some face a long hospital stay after their operation. We do not fully understand the reasons which might be considered important or are of concern to patients and their relatives/carers, for keeping patients in hospital after hip fracture surgery, but if we can find out, it will help to design, and give, the best treatment and care during the patient's time in hospital.

Why have I been invited to take part?

You have broken your hip. We would like to speak to 20 participants in the first part of the study. These can be patients, carers or healthcare professionals. After this we would like to involve a further 450 patients with broken hips in a follow up study to validate the Hip Fracture Postoperative Survey (HF-POMS) tool for use in recording reasons (factors) keeping patients in hospital after hip fracture surgery.

What will happen to me if I take part?

The study will take place during your hospital stay.
The study is in two stages, **Stage 1** interviews and completion of a questionnaire and **stage 2** follow up during hospital stay. If you take part in stage 1 you will automatically be included in stage 2.

Stage1: We will record an interview with you before or after hip surgery where we will be asking you for reasons about patients stay in hospital after hip fracture. You will also be requested to complete a short questionnaire. The questionnaire has a list of the reasons which are already known to keep patients in hospital after hip fracture surgery, you will be asked to scale these reasons in order stating which is of most concern to you or the ones which are important to you. This is done only once.

The interview will take 45 to 60 minutes.
If you have not been included for interviews, we will only follow you up during your hospital stay as below.
Stage 2: We will visit you on days 1,3,5,8 and, if you are still in hospital, day 15 to look in your medical notes and charts to see what the doctors looking after you have said are the reasons why you are still in hospital.

You may or may not develop confusion or delirium which is common after a broken hip. We will continue follow up and collect relevant research information on the specified days even when you develop confusion or delirium as this could be one of the reasons delaying your discharge.

There will be no follow up required after hospital discharge.

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 consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. This would not affect your legal rights.

Expenses and payments

Participants will not be paid to take part in this study.

What are the possible disadvantages and risks of taking part?

This is an observational study which means that we are just watching what happens to you. The study does not involve any interventions; there are no risks in taking part. There might be some inconveniences during interview or questionnaire completion time. We will work around your regular hospital

care, and visits, to organise your interviews and follow up, to minimise any inconvenience to you.

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 to improve the care we deliver to patients with broken hips in the future.

What happens when the research study stops?

When the study stops, we will publish what we have found even if it is negative. We may use quotes, but these will be anonymous.

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 Patient Advice and Liaison Service (PALS): QMC Campus 0800 183 0204.

Will my taking part in the study be kept confidential?

We will follow ethical and legal practice and all information about you will be handled in confidence.

If you join the study, some parts of your medical records and the data collected for the study will be looked at by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

All information which is collected about you during the course of the research will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database. Any information about you which leaves the hospital will have your name and address removed (anonymised) and a unique code will be used so that you cannot be recognised from it.

Your personal data (name, address, hospital number and date of birth) will be kept for 3 years after the end of the study. The Principle Investigator and other designated researcher are the only people who will be able to link your personal information to your research data. All other data (research data) will be kept securely for 7 years. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team will have access to your personal data.

What will happen if I don't want to carry on with the study?

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw then the information collected so far cannot be erased and this information may still be used in the project analysis.

Involvement of the General Practitioner/Family doctor (GP)

The involvement of your GP is not required.

What will happen to the results of the research study?

We hope to publish the results of this study in scientific and medical journals. If you are interested in obtaining a copy of the published results, please inquire from the study coordinating office at the University of Nottingham (details below) as to how you may do this.

Who is organising and funding the research?

This research is being organised by the University of Nottingham and is being funded by The Sir Jules Thorn Charitable Trust.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the East Midlands – Northampton Research Ethics Committee.

Further information and contact details

Contacts for further information

You may contact: Dr Iain Moppett

By phone: 0115 924 9924 Ext. 61195

By email: iain.moppett@nottingham.ac.uk

By post: University Department of Anaesthesia
C Floor, East Block
Queen's Medical Centre
Derby Road
Nottingham
NG7 2UH

Thank you for taking the time to read this information sheet and agreeing to take part in this study. You will be given a copy of this information sheet and a signed consent form to keep.