FULL TITLE OF PROJECT

Models of care for the delivery of secondary fracture prevention after hip fracture: a health service cost, clinical outcomes and cost-effectiveness study within the South Central Region

AIMS AND OBJECTIVES

The aim of this project is to use a natural experimental study design to evaluate unplanned variation in the delivery of secondary fracture prevention services after hip fracture across hospitals in the South Central region. This study will use large administrative datasets (from primary and secondary care) to inform NHS managers and clinicians within the South Central region of the costs, cost-effectiveness and patient outcomes associated with different models of service delivery, identify barriers to change, and define which model of care is best. The specific aims are to:

1) Characterise the way hospitals in the South Central region have provided secondary fracture prevention services for hip fracture patients over the past decade
2) Identify the reasons why hospitals chose their specific model of service delivery and assess barriers to change
3) Establish the NHS costs and cost-effectiveness of different hospital models for delivery of secondary fracture prevention
4) Evaluate the impact that changes to the delivery of secondary fracture prevention have had on health outcomes by altering trends in hip re-fracture rates, NHS costs and life expectancy

The project will begin by characterising in detail the way each hospital in the region has provided secondary fracture prevention for hip fracture patients over the past decade. This information will be obtained through approaching health professionals involved in the care of hip fracture patients working in hospitals in the region. Qualitative research methods will be used to ascertain the reasons why hospitals have adopted their current models of care, and to identify barriers to changes in service delivery. A health economics analysis will enable us to establish the NHS costs and cost-effectiveness of each hospitals model of providing secondary fracture prevention within the region. Using a Natural Experimental design, interrupted time series analysis will evaluate the impact that changes to delivery of secondary fracture prevention have had on improving health outcomes.

BACKGROUND

The marked disparity in the delivery of secondary fracture prevention for hip fracture across the South Central region is of grave concern for not only clinicians and patients, but also commissioners. Given the substantial societal burden of hip fractures and the subsequent increased risk of fracture, understanding the causes and consequences of this disparity is a matter of urgent priority within the NHS.

Osteoporosis is a common bone disease affecting three million patients in the UK. The clinical and public health implications are substantial due to the mortality, morbidity and cost of medical care associated with osteoporotic fractures[1]. Of all the types of osteoporotic fracture, hip fractures are the most costly and a major public health problem due to an increasingly elderly population. Hip fractures usually occur as result of a low-impact falls in individuals with underlying bone fragility due to osteoporosis[2,3]. About 87,000 hip fractures occur annually in the UK, with a cost (including medical and social care) amounting to about £2.3 billion a year[1,3]. Length of stay accounts for the majority of overall hospital costs, estimated to be between £5,600 and £12,000 per case[1]. After discharge from hospital, the cost of complex home and institutional care for people who make a poor recovery is very high, with average additional costs for health and social aftercare of £25,000 in the first two years[1].

Importantly, patients experiencing hip fracture after low-impact trauma are at considerable risk for subsequent falls, osteoporotic fractures and premature death[4-6]. The risk of second hip fracture ranges from 2.3% to 10.6%, where the majority of second hip fractures occurred within a few years of the first hip fracture[7,8]. It has been estimated that 55.6% of hip fracture patients had at least 1 fall within 12-months, 11.8% sustained a fall related fracture, and 5% a fall related hip fracture[9]. Mortality during the first year after fracture ranges from 8.4% to 36%[4].

The onset of osteoporosis is asymptomatic and it is often only recognized after an older person falls and sustains a fracture. There have been widespread calls to improve the identification and treatment of hip fracture patients to reduce the risk of further falls, fractures and mortality[1,4,10]. The risk of further fracture can be reduced by up to half with bone protection therapy[1,11-13]. As most fractures result from a fall, interventions to reduce the risk of falls may be effective in preventing further such events, however direct evidence is lacking. Over the past decade guidance from a number of professional bodies has been published for the management of hip fracture patients (BOA Blue Book[1], SIGN[14], NICE[13,15]). NICE technology appraisal guidelines TA160/161[13] are related to the effectiveness of bone protection therapy and CG21 falls prevention[15]. In the UK, secondary prevention of fracture is underutilized and widely neglected[1]. As a consequence compliance with NICE publications TA161[13] and CG21[15] is low. Audits by the National Hip Fracture Database[16] and the Royal College of Physicians Audit[17] suggests the situation is improving, but still inadequate, such that prior to discharge only 66% of hip fracture patients were on bone protection medication and 81% received a falls assessment[16].

As almost half of all hip fracture patients have had a prior fracture[4], responding to the first fracture provides a golden opportunity to prevent the second. The BOA Blue Book[1] provided guidance on secondary prevention of fragility fractures. A comprehensive service should consist of osteoporosis assessment including a dual energy X-ray absorptiometry (DXA) scan to measure bone density if appropriate, treatment with bone protection therapy in osteoporosis patients, falls risk assessment and systems to improve adherence and persistence with therapy. Organising such services is challenging due to the multidisciplinary care patients require[3]. The 2011 NICE Hip Fracture Clinical Guidelines make specific recommendations regarding the treatment and multidisciplinary management of patients including liaison and integration of services. A Fracture Liaison Service (FLS) is the recommended model proposed by the Department of Health to organize secondary fracture prevention services[1] in a 'one-stop shop' setting delivered by a Nurse Specialist supported by a Lead Clinician ('Champion') in osteoporosis[18]. However, currently only 30% of hospitals in England have established a FLS[17]. A single model incorporating all components of secondary fracture prevention has not been mandated. Current practice is for various combinations of these components to be used within a hospital (and in some cases no components used).

The clinical effectiveness of coordinator-based models of care has been demonstrated, in terms of improving the uptake of appropriate osteoporosis management such as measuring bone density and the use of anti-resorptive drug therapy[4,10]. There is growing evidence of cost-effectiveness[19,20] and that they can provide cost-savings to the NHS[4,10,21]. Evidence is emerging on the ability of coordinator based systems to reduce the incidence of hip fractures. A review of the Glasgow Osteoporosis and Falls Strategy reported that hip fracture rates in the city had reduced by 7.3% over the decade compared to a 17% increase in fracture rates for the entire population of England over the same period[18,22]. These findings are consistent with observational data from the US by Dell and colleagues who reported a 37.2% reduction in hip fracture rates[23]. However, the strongest evidence on effectiveness has recently been provided by an Australian study that was designed as a prospective observational trial with a concurrent control group where, compared to standard care, targeted identification and management significantly reduced the risk of re-fracture by more than 80%[24].

Across the UK there is variation in the care pathway of the treatment and management of hip fracture patients and in the way secondary fracture prevention services are structured and organised. Even with a coordinator based system in place, the structure of services can vary between hospitals. For example, hospitals use different models of orthogeriatric care, where some hospitals now have specialised orthogeriatric wards, and in others patients are seen on the trauma ward. Some hospitals may only co-ordinate the care of hip-fracture patients whilst admitted as an inpatient, whilst others have ensured their osteoporosis service is integrated across primary care to monitor patient's adherence to bone protection therapy.

The South Central region covers a population of around 4 million people, with 11 hospitals treating fragility fractures. A recent service review undertaken by the Fracture Reduction in South Central

policy group (a group of health professionals involved in the delivery of osteoporosis services) has identified a wide variation in the way hospitals treat and manage hip fracture patients and provide and co-ordinate secondary fracture prevention services. The diversity of service delivery models will enable us to capture all aspects of secondary fracture prevention. Osteoporosis services provided to hip fracture patients can be characterised according to whether they are integrated across primary and secondary care, the support of Orthogeriatricians, Fracture Liaison Nurses, Falls Nurses, provision of DXA scanners, and rehabilitation on an acute ward or Geriatric Orthopaedic Rehabilitation Unit. Delivery of care has been changing over the past decade within each hospital, and services will continue to be re-configured. For example, a locum Orthogeriatrician was appointed at the John Radcliffe Hospital in 2009 and hospital reports suggest that in the following year mortality was reduced from 30% to 20% through a reduction in chest and urinary tract infections, but robust comparator analysis and cost-effectiveness has not been performed. At Southampton General Hospital, a fracture liaison nurse was appointed between 2005 to 2008 which was subsequently discontinued, and it remains unclear how this may have affected trends in re-fracture rates and mortality within the locality. The availability of large hospital and primary care datasets provide an excellent opportunity to determine the impact of these different models of care.

The aim of this study is to characterise the delivery of secondary fracture prevention services over the past decade across hospitals in the region. Using qualitative research methods we will identify the reasons why hospitals chose their specific model of service delivery and assess barriers to change. Using a Natural Experimental design[25] we will establish the cost-effectiveness of different models of care and the impact that changes to the delivery of care have had on altering trends in re-fracture rates, NHS costs and life expectancy.

The results of this study will inform NHS managers and health professionals as to which model of care is the most cost-effective, and describe the variation in the NHS costs and health outcomes associated with their current models of service delivery. The findings of the study will be actively disseminated to key stakeholders involved in the multidisciplinary care of hip fracture patients through engagement with NHS management, healthcare professionals (including members of rehabilitation teams), patients and the public. By establishing areas of good practice in service delivery that relate to improved health outcomes, but particularly by understanding drivers of cost-savings, decision making and barriers to change, this study will provide actionable findings that aim to remove unwarranted variation and improve the delivery of secondary fracture prevention services within the South Central region and will be translatable nationally to other hospitals across the country that treat hip fracture patients, guiding best practice across the whole NHS.

NEED

HEALTH NEED:
Hip fracture patients are at considerable risk for subsequent falls, osteoporotic fractures and death. Identification of osteoporosis and treatment with anti-resorptive therapy can halve the risk of further fracture. The involvement of an orthogeriatrician optimises a patient's pre-operative condition and ensures early identification and treatment of complications during their post-operative care, which may lower mortality risk. As most fractures result from a fall, evidence based falls interventions can also reduce the risk of fractures. Case finding of patients with a previous history of hip fracture, and targeting of secondary fracture prevention measures at high risk patient groups, can reduce the risk of further fractures.

The Fracture Reduction in South Central policY (FRISCY) network was established in 2009, consisting of a group of health professionals involved in the delivery of osteoporosis services and the care and management of hip fracture patients. The aim of the network is to improve the delivery of secondary fracture prevention services across the region. An initial review of secondary fracture prevention services currently provided by hospitals in the region identified variation in the way hospitals treat and manage hip fracture patients and provide and co-ordinate secondary fracture prevention services. Through collaboration with the FRISCY network, we aim to build on the existing

audit of current services, by characterising in detail delivery of secondary fracture prevention services across hospitals in the region over the past decade.

Variation in the delivery of secondary fracture prevention services between hospitals provides a natural experiment that will enable us to understand the cost-effectiveness of different models of service delivery. We will assess the impact that changes hospitals have made to the delivery of care over the past decade, such as introducing Fracture Liaison Nurses or establishing an Orthogeriatric Rehabilitation Unit, have had on altering trends in rates of re-fracture and mortality.

Through this study we will identify what worked well and what was less successful in delivery of secondary fracture prevention services over the past decade. The results of this study will inform both NHS managers and health professionals involved in the multidisciplinary care and management of hip fracture patients as to the hospital and non-hospital costs associated with these different models of care and their impact on health outcomes in terms of re-fracture rates and life expectancy.

EXPRESSED NEED FOR THE RESEARCH AND CAPACITY TO GENERATE NEW KNOWLEDGE

There is awareness amongst health professionals involved in the care of fragility fracture patients of variation between hospitals in the region in the way they currently deliver secondary fracture prevention services. In order to reduce variation in the delivery of healthcare, an audit of the costs and health outcomes associated with different service delivery models is required to provide information to NHS managers about which model of care is most cost-effective, capture potential savings arising from better management of this condition and to drive change in the delivery of care.

SUSTAINED INTEREST AND INTENT:

Osteoporosis currently affects over three million patients in the UK. Hip fracture is a major public health burden due to an increasingly elderly population. About 87,000 hip fractures occur annually in the UK, with a cost amounting to about £2.3 billion a year, and current projections suggest hip fracture incidence will rise to 91,500 in 2015 and 101,000 in 2020. The organizational and financial implications of hip fracture will remain formidable in the future. Understanding areas of good practice in the management of hip fracture patients, and improving delivery and uptake of secondary fracture prevention services, is key to driving change, understanding variation in service delivery, and standardising care.

ORGANISATIONAL FOCUS CONSISTENT WITH SDO MISSION:

Set in the context of a natural experiment design, this study will use large administrative datasets (from primary and secondary care), to inform NHS managers and clinicians within the South Central region of the costs, cost-effectiveness and patient outcomes of their current models of service delivery. The study will also describe how changes hospitals have made to the delivery of secondary fracture prevention over the past decade, such as introduction of falls and fracture liaison nurses, have had on altering trends in rates of hip re-fracture and life expectancy. By using existing administrative data sources the study will not impact on NHS time. The aim of the study is to improve service delivery (a core aim of the HS&DR programme) of secondary fracture prevention services within the South Central region by informing NHS managers and health professionals as to which model of care is the most cost-effective, to describe the variation in the NHS costs and health outcomes associated with their current models of patient management, and to understand the drivers of decision making and barriers to change.

GENERALISABLE FINDINGS AND PROSPECTS FOR CHANGE:

The findings of the study will be actively disseminated to key stakeholders involved in the multidisciplinary care of hip fracture patients through engagement with NHS management, healthcare professionals, patients and the public. This will be facilitated through the involvement of an NHS manager as a named co-applicant to assist in dissemination of findings to NHS management across hospitals in the region through the major trauma network. The network consists of clinical and managerial representatives from both the Major Trauma Centres and Trauma Units. Whilst these

networks focus on major trauma they do bring together the people relevant to fragility fracture care. The NHS Buckinghamshire and Oxfordshire Cluster hold a Fragility Fracture Development and Implementation group with relevant local clinical and managerial colleagues, and the NHS manager will use this environment to share details and results of this study.

The findings from this study will be disseminated to health professionals through collaboration with the FRISCY network. This network includes clinicians from a wide range of disciplines including: Rheumatologists, GPs with a special interest in Osteoporosis, Trauma Surgeons, Fracture Liaison Nurses, Anaesthetists, Geriatricians, Orthro-geriatricians, Endocrinologists and Nurse Trauma Consultants.

Meaningful PPI representation will ensure the findings of the study are readily available and interpretable to the wider patient and public community. We aim to identify a panel of patients to provide patient representation on this study. We have identified a hip fracture patient who has agreed to provide patient representation for this study. The National Osteoporosis Society (NOS) are fully supportive of this study and have committed to assist in publicising the work and main findings, and in identifying further patient representation through volunteers in the local Oxford Support group.

Establishing areas of good practice in service delivery that relate to improved health outcomes, but particularly drivers of cost-savings, will lead to actionable findings that aim to remove unwarranted variation and improve the delivery of secondary fracture prevention services within the South Central region and guide best practice across the whole NHS.

METHODS

CONCEPTUAL FRAMEWORK:

A Natural Experimental Study to evaluate unplanned variation in secondary fracture prevention across all hospitals in the South Central region that treat hip fracture patients, to analyse the impact of different service delivery models on costs and health outcomes, and to determine the cost-effectiveness of the different models of care.

RESEARCH QUESTIONS:

1) Characterise the way hospitals in the South Central region have provided secondary fracture prevention services for hip fracture patients over the past decade
2) Identify the reasons why hospitals chose their specific model of service delivery and assess barriers to change
3) Establish the cost-effectiveness of different hospital models for delivery of secondary fracture prevention
4) Evaluate the impact that changes to the delivery of secondary fracture prevention have had on health outcomes by altering trends in hip re-fracture rates, NHS costs and life expectancy

STUDY SAMPLE:

This study will use two sources of routinely collected data from the UK General Practice Research Database and the English Hospital Episode Statistics database. Both are large national datasets that capture actual NHS patient activity within primary and secondary care settings, allowing us to contextualise changes and trends affecting all organisations during this period, as well as regional variation within South Central:

1) A cohort of hip fracture patients from the UK General Practice Research Database (GPRD) from 1999 to 2011 identified using READ/OXMIS codes. The GPRD comprises of computerised records of all clinical and referral events in both primary and secondary care in addition to comprehensive demographic information, medication prescription data, clinical events, specialist referrals, hospital admissions and their major outcomes, in a sample of 6.5 million patients from 433 contributing practices, chosen to be representative of the wider UK population. The GPRD dataset has been linked to data from the Hospital Episode Statistics (HES) database, which holds information on patients admitted to NHS hospitals in England, either as day cases or ordinary

admissions. We will obtain additional information on a subset of patients with data recorded in the HES database. To ensure we capture primary hip fractures, we will look at data from the preceding three years to ensure no prior hip fracture has been recorded, and data from HES will allow us to ascertain the side of surgery through the procedure codes (OPCS4).

2) A cohort of hip fracture patients treated at hospitals in the South Central region using English National Hospital Episode Statistics (HES) data linked to national mortality data from 1999 to 2011. The data come from a linked dataset of English national hospital episode statistics and data from death certification built by the team that developed and manages the Oxford record linkage study. The HES dataset includes records of all inpatient episodes undertaken in National Health Service (NHS) trusts in England, including acute hospitals. Information about deaths comes from death certificates held by the Office for National Statistics. This information includes the date of death and the causes of death, which were coded by the Office for National Statistics using the ninth and tenth revisions of the international classification of diseases (ICD-9 and ICD-10). A cohort of hip fracture patients (4260 patients per year in South Central) will be identified through OPCS4 operation codes and ICD diagnostic codes. The hospital provider code will allow identification of the 11 hospitals in the region.

PRIMARY OUTCOME: Second hip fracture

SECONDARY OUTCOMES: Mortality, non-hip fragility fracture, overall rate of hip fracture

OVERVIEW OF RESEARCH METHODS

The project will begin by characterizing in detail the way each hospital in the region has provided secondary fracture prevention for hip fracture patients over the past decade. This information will be obtained through approaching health professionals involved in the care of hip fracture patients working in hospitals in the region. Qualitative research methods will be used to ascertain the reasons why hospitals have adopted their current models of care, and to identify barriers to changes in service delivery. A health economics analysis will enable us to establish the cost-effectiveness of each hospitals model of providing secondary fracture within the region. Using a Natural Experimental design, interrupted time series analysis will evaluate the impact changes to the delivery of secondary fracture prevention has had on improving health outcomes.

CHARACTERISING SECONDARY PREVENTION OF HIP FRACTURE ACROSS HOSPITALS IN SOUTH CENTRAL (*Work Stream 1*)

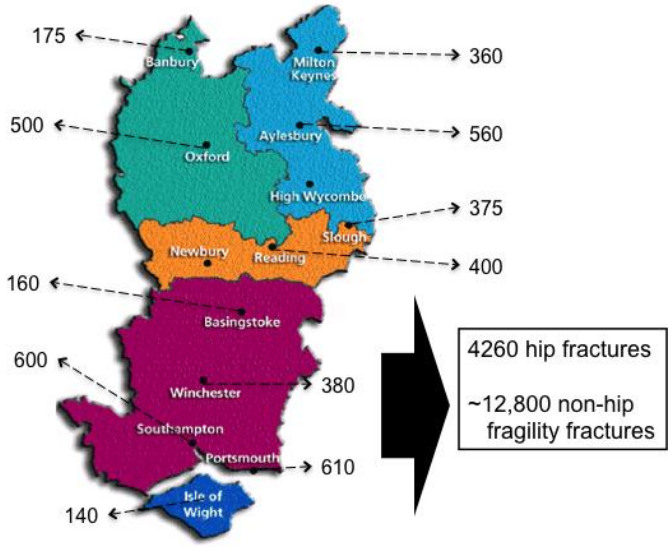
The first phase of this project is to comprehensively describe and explore the variation and disparity in secondary fracture prevention services offered to hip fracture patients across hospitals in the South Central region. Through the FRISCY network, we will approach health professionals involved in the frontline care of hip fracture patients working in hospitals in the South Central region. We will also contact the Human Resources departments for information on when staff were employed. Each of the 11 hospitals will be characterised in detail according to the way they currently deliver secondary fracture prevention services for hip fracture patients, and changes made to service delivery over the past decade. Characteristics and their date of implementation can include any of the following: Integration of falls and osteoporosis services across primary and secondary care, Orthogeriatricians, Fracture liaison Nurses, Falls Nurses, DXA scanners, Rehabilitation on acute ward or Geriatric Orthopaedic Rehabilitation Unit. Characteristics and date of implementation will be obtained from health professionals who will remain blinded to the study outcomes (re-fracture rates and mortality after the intervention) until the end of the study. In each hospital, a historical evolution of purchase and provision of services for hip fracture patients will be assembled to take account of wider changes such as vertical integration of services.

The study will be undertaken in each of the 11 acute NHS hospital trusts within the South Central region (**Figure 1**): Wexham Park Hospital (Slough), Royal Berkshire Hospital (Reading), Milton Keynes General Hospital, Stoke Mandeville Hospital (Aylesbury), North Hampshire Hospital (Basingstoke), Queen Alexandra Hospital (Portsmouth), Southampton General Hospital, Royal

Hampshire County Hospital (Winchester), St. Mary's Hospital (Isle of Wight), John Radcliffe Hospital (Oxford), Horton Hospital (Banbury).

Throughout the region, contrasts exist between hospitals according to the type of secondary fracture prevention service they had in place during the study observation period (1999 to 2011). Contrasts include: hospitals with no fracture prevention service over the entire observation period (Wexham Park and Horton); transient provision of a fracture liaison service (2005-8) with continuous orthogeriatric care since 2007 (Southampton); exclusive orthogeriatric care since 2007 without any fracture liaison service (Reading); a fracture liaison service (since 2008), orthogeriatric care (2009 onwards) and full fracture prevention service (from 2011) (Oxford). To provide greater clarity of the type of fracture liaison service two outlines are provided below (Oxford and Reading). Clinicians at each hospital were asked to briefly describe the major changes that have occurred to the care of hip fracture patients over the past decade and why these changes occurred.

Figure 1. Hospitals in the South Central region that treat hip fracture patients (annual number of hip fractures)



John Radcliffe hospital (Oxford)
Clinicians in the front line care of hip fracture patients became aware of the potential clinical benefits and accumulating evidence of the cost effectiveness of a Fracture Liaison Service so took it upon themselves to build a business case for the Primary Care Trust in order to introduce changes to the care of patients. The main change occurred in April 2007 when a Service Level Agreement (SLA) was reached between the Oxford Radcliffe Hospitals and Nuffield Orthopaedic Centre to provide a Fracture Liaison Service.

The service consists of an Osteoporosis & Fracture Liaison Clinical Nurse Specialist and a Specialist Practitioner - Osteoporosis Fracture Liaison Nurse Specialist who were appointed in May 2008. Their role was to co-ordinate the in-patient care of all incident hip fracture patients admitted to the hospital. The patient assessment consists of medical, lifestyle and dietary history, with a detailed osteoporosis risk screening, and referral as appropriate to the Metabolic Bone Clinic with a Bone Mineral Density (BMD) scan and to other specialist areas, such as the Falls Service. Locum orthogeriatricians were appointed in November 2009. They are based on the trauma ward to support the care of hip fracture patients. As of October 2011 further changes to the Fracture Prevention Service have been introduced, including out-patient trauma clinics case finding and assessment by the FLN, and follow up and monitoring of hip fracture patients at 3-months, and 1, 2, 3 and 5-years follow up.

In summary, there are three time points of interest: a) the appointment of Fracture Liaison Nurses in May 2008; b) appointment of orthogeriatricians in November 2009; c) Monitoring of patients in October 2011.

Royal Berkshire Hospital (Reading)
Looking back over the past decade the major change to the care of hip fracture patients has been the appointment of an Orthogeriatrician in August 2007. Prior to this a liaison service was in place that provided a session a week to Orthopaedics by one of the other Geriatricians. The Orthogeriatric Service at the hospital supports the inpatient care of hip fracture patients (and those elderly patients admitted with other fractures), but the service is not linked to fracture clinics or primary care so those not admitted do not have access to the service. There are currently no fracture liaison nurses or falls nurses at the hospital. Patients are seen by an Orthogeriatrician on the Trauma wards with the care of some transferring to a female Orthopaedic rehabilitation unit (GORU). Upon admission to hospital, all hip fracture patients receive a full osteoporosis assessment, including a DXA scan where appropriate, bone resorptive drugs and a falls assessment. A number of business cases have been put together to make a case for employing a FLN to support the care of all fragility fracture patients including hip fracture, but they have been rejected by the hospital and most recently the PCT.

The involvement of an Orthogeriatrician in the care of hip fracture patients has ensured that the majority of patients admitted with a hip fracture are now seen pre-operatively and the Orthogeriatrician attends the Trauma meetings. This allows the patient to get to theatre quicker and in a better condition by optimizing any pre-operative condition, such as pre-existing medical co-morbidity and acute conditions, ensuring those taking warfarin are identified, and assessing fitness for anaesthesia. Involving the Orthogeriatrician in post-operative care ensures early identification and treatment of complications such as chest-infections and MI. Rehabilitation goals are set with the Orthogeriatrician leading MDT meetings. Monitoring remains an issue as patients are not followed up post-operatively (apart from a postal survey to comply with the NHFD follow-ups at 1.4 and 12 months) to ensure they are adhering to bone resorptive drug therapy.

In summary, the one-time point of interest is the appointment of an orthogeriatrician in August 2007.

QUALITATIVE RESEARCH (*Work Stream 2*)
The aim of the qualitative study is to: a) ascertain the reasons why each hospital has adopted their current and most recent models of care; b) establish factors that facilitate or act as barriers to changes in service delivery; c) identify the elements of care of hip fracture patients that health professionals think are most effective.

Through the FRISCY network, we will approach key health professionals who specialise in Osteoporosis services involved in delivering secondary fracture prevention at the 11 hospitals in the South Central region. These will include consultant rheumatologists, geriatricians, members of rehabilitation teams, fracture liaison nurses and falls nurses. We will also identify NHS health service managers involved in the planning and commissioning of fracture services through managers in the major trauma network. Purposive sampling will be used to identify ‘key informants’ in each location and ‘snowball’ sampling techniques to identify subsequent interviewees. We expect to identify a total of up to 50 professionals, comprising one manager and two-three health professionals at each hospital. Professionals will be approached in writing and will be asked to provide their written, informed consent to take part. We expect that nearly all of the professionals approached will agree to be interviewed; the sample size of 50 interviewees will be sufficient for us to make comparisons between centres with different models of care as well as to make comparisons between professional groups (e.g. orthogeriatricians versus fracture liaison nurses).

We will conduct qualitative, one-to-one interviews with key stakeholders (such as NHS managers, clinicians, rehabilitation teams, nurses and GPs) to identify the reasons for any changes to service delivery models; to find out factors that facilitate or impede change in service delivery; and to find out what health professionals think are the most effective elements of their secondary fracture prevention

services. We will use the theoretical framework of Normalisation Process Theory (NPT) to help identify barriers to change within this context[26]. Face-to-face interviews will enable us to obtain candid information about the processes that led to different models of service provision and professionals' perceptions of those models.

The interviewer will use a structured 'topic guide' to ensure that similar questions are asked of all participants. Topic guides will be developed by the study team in collaboration with stakeholders that will include PPI. Although based around a topic guide, interviews will be flexible enough to allow the interviewer and participant to pursue additional lines of relevant discussion. The first 4-6 interviews will serve as pilot interviews after which the topic guide will be refined. Unless questions and topics change dramatically, then pilot interviews will remain part of the main dataset for analysis. With consent of participants, all interviews will be audio-recorded. Should some participants decline audio-recording then the interviewer will take notes instead.

Audio-recordings will be transcribed, anonymised and imported into the data analysis package Atlas ti. Data will be inductively coded ('indexed') and information transferred onto charts using the 'framework' approach to data organisation[27]. By charting the data in this way, data from professions and centres with different approaches will be compared and contrasted with one another. Analysis will be ongoing as the study progresses, with the qualitative lead double coding 20% of transcripts and working with the interviewer to develop a code list. This list will be refined as the study progresses. Once fully coded and displayed on charts, the data will be mapped and interpreted in light of existing literature and theory about service models, barriers to change and views about effective ingredients in fracture prevention. Through this, an account of the data, including illustrative quotations, will be developed. This will provide information that will help us to understand reasons for variation in models of service delivery that have the potential to affect patient outcome.

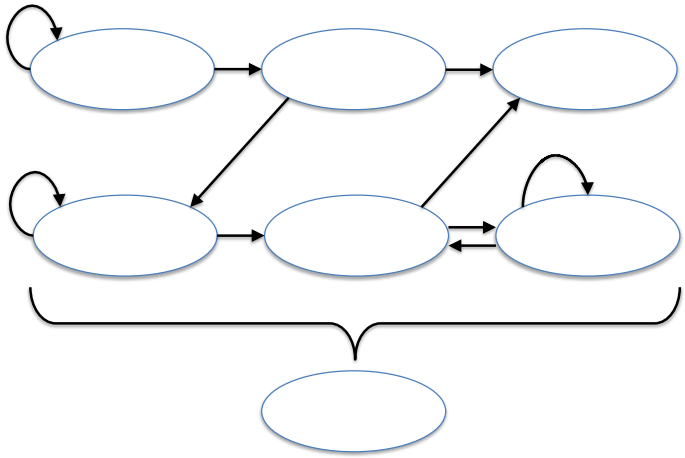
HEALTH ECONOMICS MODELLING (*Work Stream 3*)

NHS COSTS ASSOCIATED WITH HIP FRACTURES:
Data from HES and GPRD will be used to estimate the hospital and non-hospital costs associated with hip fracture in the year of fracture and subsequent years. Hospital costs will be derived by grouping each hospital episode into a Health Resource Group (HRG). HRGs are a method of classifying episodes with similar levels of resource consumption into the same group. National average costs for each HRG are published annually by the Department of Health[28]. The costs for several non-hospital categories will be derived from readily available national databases and will be multiplied by the respective use of NHS resources. Panel data regression analysis (e.g., fixed effects)[29-31] will be undertaken to estimate hospital and non-hospital costs conditional on patient characteristics (e.g., age, sex and area deprivation score) and co-morbidities (e.g., Charlson co-morbidity index, previous fractures). The aim is two-fold: 1) provide a set of life-time health cost-profiles that will be useful to NHS managers and researchers, and 2) inform the costs of the different stages of the Markov model described below.

COST-EFFECTIVENESS OF MODELS OF CARE:
A disease specific Markov model[32] will be developed to evaluate the costs, (quality-adjusted) life expectancy and cost-effectiveness of the different hospital models of care for secondary fracture prevention. Patients reside in one of a finite number of health states and make transitions between those states over time. The Markov health states will be defined according to good practice modelling guidelines[33,34]. These will reflect the relevant states of health associated with hip fractures (e.g. primary hip fracture, secondary hip fracture, death) and the impact of the models of care (e.g. bone protection therapy, discharge method (home or care home)). Figure 2 shows an example of the possible structure of the Markov model. The specification of the health states will be informed by the analysis of the HES/GPRD datasets, targeted literature searches, but in particular from discussion with clinical experts. Transition probabilities will determine the probability of remaining in a particular state or transiting into another. These will be informed by survival analyses of the HES-mortality linked dataset and relevant targeted literature searches. As part of these searches, we will be looking at referrals to

nursing homes or home care following primary hip fracture and, complemented with the HES/GPRD data, help determine their impact on the likelihood of subsequent hip fractures. Relative effectiveness measures will be applied to the transition probabilities to model the impact of the different models of care. The choice of cycle length will be determined by the timing of events concerning the natural history of patients with hip fracture. The structure of the Markov model, the data used, and any simplifying assumptions made during its construction will also be checked with clinical experts.

Figure 2. Possible Markov model structure



Costs and utility scores will be assigned to each health state. Costs associated with hip fractures will be obtained from the HES and GPRD datasets as described above. Costs associated with the different models of care will be obtained from the hospitals. NHS resource use associated with the treatment pathway of hip fracture patients will be identified and valued using appropriate data sources. Utility scores provide the weights required to calculate the Quality-adjusted Life Years (QALYs) of the different models of care under evaluation[35]. These scores express the quality of life associated with a health state on a scale from 0 (dead) to 1 (perfect health). We will search the literature for data sources on utility scores and consider their synthesis to inform the different health states being modelled. The impact of the different models of care will be modelled by multiplying their relative effect by the transition probabilities between health states associated with the baseline model of care. Once the Markov model is built, we will simulate the transition of a cohort of hip fracture patients through the health states over time, to estimate expected costs and outcomes. All costs and effects will be discounted beyond the first year of simulation using recommended discount rates. Probabilistic sensitivity analysis will be used to propagate parameter uncertainty and quantify it in the resulting pairs of costs and effects[36]. Cost and effect results will be reported as means with 95% credible intervals. Incremental cost-effectiveness ratios (ICERs) for the different models of care will be calculated by dividing the difference in costs by the difference in effects and will be depicted on the cost-effectiveness plane[37]. Cost-effectiveness acceptability curves will also be used to represent the decision uncertainty[38]. These show the probability that a model of care is cost-effective for given values of the amount that the decision maker is willing to pay for an additional unit of outcome. The value of information approach will be used to identify key model inputs for which there would be gain from reducing uncertainty by collecting more data in a subsequent study[39].

The Markov model will be evaluated following the recommendations from modeling guidelines[33,34]. Face validity will be performed by checking whether its assumptions, structure and results are reliable, sensible and can be explained intuitively. Internal validation will be performed by undertaking sensitivity analyses using extreme or null values of parameter inputs to assess whether the results are reasonable. Further validation will entail comparing model outputs with data used to inform it. External validation will be performed by comparing the results of our model with those from other independent models that have addressed similar questions.

NATURAL EXPERIMENT TO EVALUATE CHANGES TO DELIVERY OF SECONDARY FRACTURE PREVENTION (*Work Stream 4*)

A Natural Experimental study design[25] will be used to evaluate the impact that changes hospitals in the region have made to the way they deliver secondary fracture prevention services for hip fracture patients, have had on a range of health outcomes. The hospital will be the unit of analysis and each of the 11 hospitals in the South Central region will be analysed individually.

The primary exposure ('intervention') is the change a hospital has made to delivery of secondary fracture prevention. The intervention and date it occurs will be different for each hospital in the region. For example, at the Royal Berkshire Hospital in Reading the change (intervention) occurred in August 2007 with the appointment of an orthogeriatrician. A natural experimental design is a valid methodological approach to evaluate the impact of a range of events, policies and interventions which are not under the control of researchers, but which are amenable to research which uses the variation in exposure that they generate to analyze their impact on health outcomes[25]. The model will incorporate a 'lag time' from the intervention date to allow time for it to take effect.

A non-exposed ('control') group will provide an indication of what would have happened in the absence of the intervention (known as a counterfactual) matched on the index date. Within the South Central region there are two hospitals that have not provided secondary fracture (Wexham Park Hospital and Horton Hospital, Oxfordshire) that will provide control groups. We will also use the overall trend in outcomes across all hospitals in the South Central region as a control comparison.

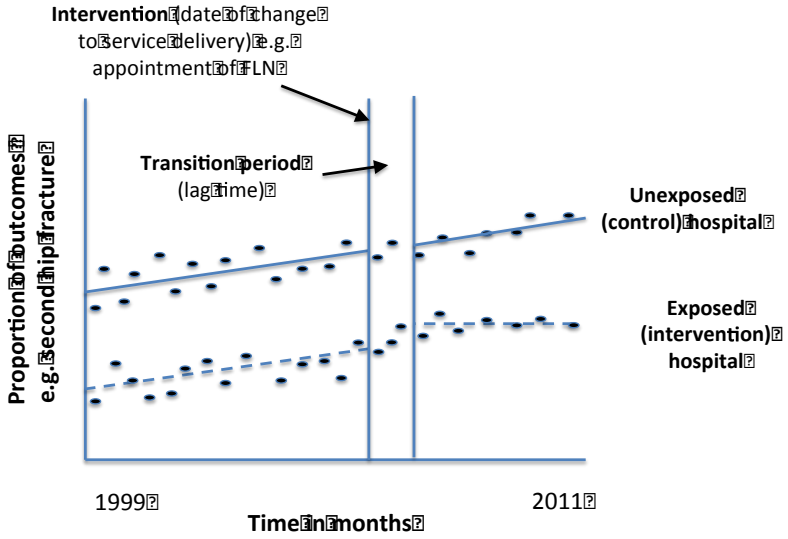
Each hospital will be analysed using an interrupted times series design[40,41], using repeated measures before and after the intervention to control for secular changes. Using this design, each hospital acts as its own control. In interrupted times series studies, sample size calculations are related to the estimation of the number of observations or time points at which data will be collected[40]. According to the quality criteria of Ramsey et al, at least 10 pre- and 10 post-data points would be needed to reach at least 80% power to detect a change (if the autocorrelation is >0.4)[42]. Our outcomes will be estimated at monthly intervals and, as autocorrelation is unknown, we will allow at least 2 years either side of the date of interest (24 pre and 24 post-data points).

A cohort of primary hip fracture patients will be identified for each hospital in the region using the HES data linked to National Statistics mortality data. Data on outcomes are measured at equally spaced intervals over the time period of interest (1999 through to 2011). Outcomes of interest will include the monthly proportions of second hip fractures (primary outcome) and deaths and other non-hip fragility fractures (secondary outcomes). Using the interrupted times series approach, we estimate the trend in the rates of outcome prior to the intervention, and after the intervention, and test for changes pre- and post- intervention in a) the overall (absolute rate) of outcome, and b) the slope of the trend in rates of outcome (see Figure 3). Analyses will control for case-mix including adjustment for the following confounding variables: age, gender, area deprivation, Charlson co-morbidity index.

Segmented linear regression models will be used to estimate the monthly proportions of outcomes. Controlling for baseline level and trend, the models estimate changes in levels and trends of rates after the change in service delivery. The regression model includes terms to estimate the pre-existing level for each rate in the first month of the observation period (intercept), trend in the rate before the intervention was introduced, change in level of the rate after the intervention, and change in trend after intervention. For hospitals where there is more than one intervention (change to service delivery), the models will include additional covariates of the second intervention and time since second intervention[43]. The models can also cope in situations when the intervention takes time to affect the outcome (lag times), and in this situation we will consider taking that time period out of the analysis[44]. For each time series model we will include an extensive pre-intervention period to control for biases in level and trend at baseline. Cox proportional hazards regression modeling will be used to obtain incidence rates for outcomes of time to second hip fracture and mortality. Analyses will be repeated on two separate cohorts of primary hip fracture patients – a pre-intervention cohort and post-intervention cohort. Analyses will be adjusted for potential confounding variables including age, sex, area

deprivation score and Charlson co-morbidity index. Patients are censored on date of the outcome of interest, date of death, date of loss to follow up, or end of study period.

Figure 3. Hypothetical example of interrupted times series analysis



NATURAL EXPERIMENT TO EVALUATE THE EFFECT OF NATIONAL GUIDELINES

Using an interrupted time series approach we will examine the effect national guidelines have had on altering trends in re-fracture rates and life expectancy. The primary exposure of interest (intervention) is the date national guidelines were issued which include: *a)* British Orthopaedic Association (BOA) Blue Book (Sept 2007)[1]; *b)* NICE Technology Appraisal 161 (Oct 2008)[13]; *c)* NICE Technology Appraisal 87 (Jan 2005)[45]; *d)* NICE Clinical Guideline 21 (Nov 2004)[15].

The dataset we will use for this analysis is from the GPRD using a cohort of all primary hip fracture patients in England. The advantage of using the GPRD database is that it allows us to control for a wider range of potential confounding variables, such as medication use and co-morbidities. Additional outcomes can also be included such as the proportions of patients taking bone strengthening drugs (bisphosphonates), and other types of non-hip fragility fractures recorded in a primary care setting. Methods of analysis are the same as those described earlier.

RESEARCH OUTPUTS:

Throughout all stages of this project, we will engage with key stakeholders including NHS managers, healthcare professionals, patients and the public for interpretation, dissemination and direct communication of the main findings. This will be facilitated through involvement of an NHS manager as a co-applicant, collaboration with the FRISCY network, support of the National Osteoporosis Society, and PPI representation. Through the qualitative component of this grant, we will listen to the views of health professionals and NHS managers as to the perceived barriers to changing service delivery, and use this knowledge to modify the way we present the results of the main findings of the study to key stakeholders. Findings will be fed back to stakeholders at individual hospitals, published in peer-reviewed journals and at national conferences. Study progress will be regularly fed back to members of the FRISCY network at their half yearly meetings. A final and full research report detailing all the work undertaken and supporting technical appendices, an abstract and an executive summary will be provided at the end of the study. A set of PowerPoint slides will be provided presenting the main findings from the research for use of members of the research team and others in disseminating research findings to the NHS.

CONTRIBUTION TO COLLECTIVE RESEARCH EFFORT AND RESEARCH UTILISATION

This project adheres to the aims of the NIHR Health Services & Delivery Research programme by focusing on the research needs of NHS managers and building capacity amongst those who manage, organise and deliver services to use research to improve the organisation and delivery of secondary fracture prevention services after hip fracture.

Within the South Central region it has been established that there is considerable variation in the way hospitals treat and manage hip fracture patients and provide and co-ordinate secondary fracture prevention services. There is a research need to inform NHS management and health professionals involved in the care of hip fracture patients as to why this variation exists, the impact it has on health outcomes, associated costs to the NHS and which models of care are more cost-effective. The recent publication of the NHS Atlas of Variation has highlighted the importance of addressing and reducing unwarranted variations in healthcare activity and expenditure.

Through this project we aim to characterise the way hospitals in the South Central region have provided secondary fracture prevention services over the past decade, to establish the cost-effectiveness of the different models for delivery of secondary fracture prevention services, and evaluate the impact that changes to the delivery of care (e.g. appointment of orthogeriatrician) have made on altering trends in rates of second hip fracture, NHS costs and life expectancy.

Throughout this project we will engage with all important stakeholders including NHS management, Healthcare professionals, patients and the public. An NHS manager involved in the delivery of Trauma and Specialist surgery at the Oxford Radcliffe Hospitals NHS trust is a named co-applicant on this grant who will assist in interpreting the data and dissemination of findings to NHS management across hospitals in the region through the major trauma network.

Through collaboration with the FRISCY network we will present and disseminate the results of the study to healthcare professionals working in hospitals across the South Central region who are involved in the multidisciplinary care of hip fracture patients with a special interest in improving secondary fracture prevention services. The clinical lead for the FRISCY network is a named co-applicant on this grant and we will seek support from health professionals in the network to characterise delivery of secondary fracture prevention across hospitals in the region over the past decade, and for interpretation of the main findings.

We recognise the importance of meaningful PPI Involvement and have worked collaboratively with the PPI Officer at the NIHR RDS South Central to identify individuals to become involved. We have identified, through the RDS, a lay person with broad experience of writing plain English summaries to review and amend our lay summary. We have taken these comments on board and amended our summary accordingly. We are keen to involve not only patients, but carers of people who have experienced a hip fracture. We appreciate their perspective will be slightly different, especially as up to 50% of people with hip fractures have evidence of cognitive impairment and therefore we consider this to be vital to bring a broad level of understanding. The National Osteoporosis Society have signaled they are keen to support our research by helping to identify a carer to join the steering group and to help disseminate the findings of this research. PPI will help to improve the scientific quality through informing the study design, interpretation and dissemination of the findings.

We have identified a person who has experienced a hip fracture and, with the support of the RDS PPI Officer, they been given information on how they can be involved, the type of support available to them and ascertained if they require any further support, such as training, to help in this role. Using the INVOLVE guidance, we have identified a variety of resources to help them in this role and have offered payment for both time and expenses. They have been invited to a meeting with some of the members of the steering group, the PI and the PPI Officer to help introduce them to the team and to welcome them into the project. They are willing to be involved in the steering committee. A carer is still to be identified, but once they have been found, they will be invited to join this meeting. Through

the involvement of a hip fracture patient and carer, we will listen to their ideas regarding interpretation and dissemination of findings. It is important to us that the findings of this study are readily available and interpretable by not only health professionals and NHS management, but also the wider patient and public community.

We shall disseminate the findings of the study in peer-reviewed journals, at national and international conferences, and inform learned societies in osteoporosis (National Osteoporosis Society, Arthritis Research UK), rheumatology (British Society for Rheumatology), geriatrics (British Society of Geriatrics) and orthopaedics (British Orthopaedic Association) of what we have learnt regarding both clinical and cost-effectiveness in the delivery of secondary fracture prevention services across the South Central region.

The project will be conducted within the research infrastructure of the Oxford NIHR Musculoskeletal Biomedical Research Unit (BRU) which has been successful in receiving renewed funding for five years from April 2012. A key theme is to improve outcomes of patients presenting with osteoporotic fractures. This study fits well within the broad work in the department at the Oxford NIHR Musculoskeletal BRU in improving the care of the trauma patient and will build on the research infrastructure already in place.

APPROVAL BY ETHICS COMMITTEES

In order to conduct a service evaluation (work stream 1) we will obtain R&D approval for the 11 hospitals from each NHS Trust, for example the Oxford Radcliffe Hospitals NHS Trust. To conduct qualitative interviews with NHS staff (work stream 2) we will obtain necessary permissions from the University of Oxford's Research Ethics Committee and local R&D offices; research solely with NHS professionals as participants no longer routinely requires NHS REC approval. A study protocol will be submitted to the ISAC (Independent Scientific Advisory Committee) for approval to use and publish GPRD data (work streams 3 and 4). NHS REC approval is not required for the use of anonymised routinely collected datasets such as HES and GPRD.

PROJECT MANAGEMENT

Joint applicants from different institutions will communicate through regular (3-monthly) project steering group meetings to be held in Oxford. A dedicated part-time project manager will be appointed to assist with the day-to-day running of the project. A project advisory group will be established with an independent chair that will meet on a 6-monthly basis.

PUBLIC USERS / PUBLIC INVOLVEMENT

We recognize the importance of meaningful PPI Involvement and have worked collaboratively with the PPI Officer at the NIHR RDS South Central to identify individuals to become involved. We have identified, through the RDS, a lay person with broad experience of writing plain English summaries and invited her to review and amend our lay summary. After reviewing this she commented that she felt the research appeared to be very worthwhile, with a great potential benefit to many patients. She suggested that it might be useful to amend the summary slightly as she was concerned that the consequence of dying as a result of a fall-related fracture needs to be treated with sensitivity and this should be reflected in the patient information leaflet given to participants. We have taken these comments on board and amended our summary accordingly. The final patient information leaflet will also reflect these comments once it has been drafted by our lay contributors.

We are keen to involve not only patients, but carers of people who have experienced a hip fracture. We appreciate their perspective will be slightly different, especially as up to 50% of people with hip fractures have evidence of cognitive impairment, and therefore we consider this to be vital to bring a broad level of understanding. PPI will help to improve the scientific quality through informing the study design, interpretation and dissemination of the findings. The National Osteoporosis Society have signaled they are keen to support our research by helping to identify a carer to join the steering group and to help disseminate the findings of this research. As the research develops other areas of

collaboration may become apparent. We anticipate that PPI in this project will be part of a fluid process.

We have identified a person who has experienced a hip fracture and, with the support of the RDS PPI Officer, they have been given information on how they can be involved, the type of support available to them and ascertained if they require any further support, such as training, to help in this role. Using the INVOLVE guidance, we have identified a variety of resources to help them in this role and have offered payment for both time and expenses. They have been invited to a meeting with some of the members of the steering group, the PI and the PPI Officer to help introduce them to the team and to welcome them into the project. They are willing to be involved in the steering committee. A carer is still to be identified, but once they have been found, they will be invited to join this meeting. An advert for a carer has been drafted and placed in key clinical areas within the hip fracture clinics, as well as via the National Osteoporosis Society.

In the later stages of this project we will conduct a service user forum, comprising of 8 to 10 individuals that have experienced a hip fracture together with carers. The forums will be conducted twice in order to discuss the top 3-5 models of service delivery. Sessions will be organised and facilitated by a research nurse (recruited from within the FRISCY network) that will take place at least 1 month apart to allow reflection time for services users. At the first forum session, patients and carers will be provided with a plain English description of the top 3-5 service models, sent out in advance, along with information on patient and public involvement in research. In the sessions the research nurse facilitator will foster discussion about the different service delivery models and using consensus techniques will capture service users views about the acceptability of these models in practice. Views will be linked to service users own individual experiences that they will be encouraged to share with others. The group discussion will be recorded on flip-charts and in notes by a scribe who will be present.

At the end of the first meeting, the group's views will be collated and drafted into a brief report that will be sent out to group members after the meeting. One month later the service user forum will be reconvened in order to refine the group members perspective and to work together to produce a report on the acceptability of different models. The report will be posted back to them and applicant feedback will be collected. Each meeting will last around 2 and a half hours, and include a comfort break, refreshments and chance for discussion. Patients and carers will be recruited through the National Osteoporosis Society, and letters of invitation will be sent out to patients identified from the hospitals. Service users will be reimbursed for their time and expenses. In order to recruit service users from hospitals we will obtain agreement from local R&D officers.

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