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THE KNOWLEDGE BROKERING ROLE OF MIDDLE LEVEL MANAGERS (MLMS) IN SERVICE INNOVATION: MANAGING THE TRANSLATION GAP IN PATIENT SAFETY FOR ELDERLY CARE

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SYNOPSIS

Title	The knowledge brokering role of middle level managers (MLMs) in service innovation: Managing the translation gap in patient safety for elderly care
Short title	The knowledge brokering role of middle level managers in service innovation
Chief Investigator	Professor Graeme Currie
Objectives	This study will: (i) Identify which MLMs act as knowledge brokers (e.g. junior or senior MLMs) (ii) Determine contribution of MLMs as knowledge brokers for service improvement (e.g. when they broker knowledge, what type, how, outcomes) (iii) Identify limiting or facilitating features of context for knowledge brokering by MLMs (e.g. involvement in research, policy coherence, culture, inter-organisational relationships, clinical-managerial relationships, organisational strategy/structure, individual and organisational development) (iv) Identify MLM attributes for knowledge brokering (e.g. role-based, personal, inter-personal relationships) (v) Identify prescriptions for improved knowledge brokering of patient safety evidence by MLMs.
Study Configuration	Multi-centre, across primary and secondary care, and social care / local authority.
Setting	Set in primary care, secondary care and social care / local authority, this study will recruit from the following sites: Nottingham University Hospitals NHS Trust, Nottinghamshire Healthcare NHS Trust, Sherwood Forest Hospitals NHS Foundation Trust, NHS Nottingham City, NHS Nottinghamshire County, Nottingham City Council and Nottinghamshire County Council.

Number of participants	150
Eligibility criteria	Participants will fall into at least 2 of the following categories: • Able to give consent • Over the age of majority • Employed as a middle level manager in elderly care, in one of the study sites • A producer, disseminator or auditor of patient safety knowledge linked to the Royal Society of Medicine, Patient Safety Research Programme, Health Foundation, NHS 3is, Care Quality Commission, Strategic Health Authority, Patients Association and other charitable campaign associations • Risk Committee member in one of the study sites • Pharmacist not employed by the NHS • Clinical director • Nurse manager • General Practitioner • Geriatrician • Psychiatrist • Allied Health Professional - E.g. Clinical Psychologist - Social Worker - Occupational Therapist - Physiotherapist
Description of interventions	A qualitative study, this research encompasses semi-structured interviews (including embedded social network analysis) and observation.
Duration of study	Overall: 27 months. Planned start date: 1 March 2011 Per participant: One interview, taking approximately 1.5 hours
Outcome measures	Qualitative analysis of results of study: no outcome measures as such, however, focus will be on: (i) identifying 'bottle necks' in brokering of patient safety knowledge through MLMs, including consequences of turnover of key knowledge brokers in the system; (ii) identifying service quality outcomes from effective

	knowledge brokering through the production of rich description of clinical outcomes where such data is available; (iii) collecting rich description of case context & process where MLMS brokered knowledge around patient safety to improve service quality to identify prescriptions for supporting effective knowledge brokering.

ABBREVIATIONS

AE	Adverse Event
AHP	Allied Health Professional
CI	Chief Investigator
CLAHRC NDL	Collaboration of Leadership in Applied Health Research and Care – Nottinghamshire, Derbyshire and Lincolnshire
CF	Consent Form
CRF	Case Report Form
DAP	Data Analysis Plan
DMC	Data Monitoring Committee
GCP	Good Clinical Practice
GP	General Practitioner
HCOP	Healthcare for Older People
ICF	Informed Consent Form
KBV	Knowledge Based View
MHRA	Medicines and Healthcare products Regulatory Agency
MLM	Middle Level Managers
NHCT	Nottinghamshire Health Care NHS Trust
NHS	National Health Service
NHS 3i	NHS Innovations
NUH	Nottingham University Hospitals NHS Trust
NICE	National Institute for Health and Clinical Effectiveness
NIHR	National Institute for Health Research
NPSA	National Patient Safety Agency
NRLS	National Reporting and Learning System
PAL	Patient Advice and Liaison
PCT	Primary Care Trust

P/GIS	Parent / Guardian Information Sheet
PI	Principal Investigator at a local centre
PIS	Participant Information Sheet
PPI	Patient and Public Involvement
QIPP	Quality, Improvement, Prevention and Productivity
RBV	Resource Based View
REC	Research Ethics Committee
RF	Research Fellow
R&D	Research and Development department
RQ	Research Question
SDO	Service Organisation and Delivery
SNA	Social Network Analysis
SUI	Serious Untoward Incident
WP	Work Package

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STUDY BACKGROUND INFORMATION AND RATIONALE

Our proposed study of knowledge brokering by middle level managers (MLMs), who hold responsibility for clinical service delivery, as well as management of human and knowledge resources, focuses upon the translation and utilisation of evidence for patient safety in the context of elderly care. Patient safety is a global concern, and particularly pertinent to elderly care (NPSA, 2009), through policy makers promoting the effective management of knowledge to ensure high quality healthcare delivery (Currie, Waring et al, 2008; Waring and Currie, 2009). We argue that MLMs are uniquely placed within organisations to broker the flows of exogenous and endogenous sources of knowledge necessary to improve patient safety. First, MLMs are able to broker exogenous knowledge 'downwards' from external producers and disseminators of evidence, such as NPSA safety alerts. Second, MLMs are able to broker endogenous knowledge 'upwards' from within the organisation, for example through incident reporting and investigation as in the NRLS (Waring, 2004; Waring and Currie, 2009; Waring and Bishop, 2010). Third, MLMs are uniquely positioned to fuse their understanding of local context (endogenous knowledge) with the more generic evidence base that constitutes exogenous knowledge, to ensure high quality service delivery that is patient safe. Finally, MLMs, that hold responsibility for clinical service delivery, span the boundary between managerial structures for brokering patient safety knowledge, such as risk committees, and frontline clinical practice. If the necessary antecedents for MLM knowledge brokering are in place, such as MLMs interaction with the external environment, then MLMs can effectively broker knowledge across organisations, as well as within organisations (Currie and Procter, 2005).

Our approach involves an examination of the process of knowledge brokering by MLMs to enhance patient safety. The key dimensions of the knowledge brokering process we analyse are:

- DIMENSION 1: The brokering of patient safety knowledge from external sources to inform service development within their local employing organisation;
- DIMENSION 2: The brokering of patient safety knowledge from internal sources to inform service development within their local employing organisation;

- DIMENSION 3: The fusing of external and internal knowledge, both within organisations, to ensure that service enhancement is aligned with global best practice, and simultaneously locally contextualised;
- DIMENSION 4: The brokering of patient safety knowledge across the constituent organisations of a local health and social care delivery system for service development.

Our proposed research will generate a deep understanding of the processes through which MLMs broker knowledge, grounded in the larger social context, and in doing so, develop a model for knowledge brokering to inform action. Our study is responds to 6 research questions:

RQ1. What expectations and perceptions do external regional and national producers/disseminators/auditors of patient safety knowledge have regarding the brokering of top-down knowledge ('safety alerts' broadly defined) through middle level managers and risk management structures to influence clinical practice?

RQ2. Which middle level managers are more likely to enact a knowledge brokering role within organisations and across the system, and why; e.g. more 'senior' or 'junior' middle level managers; more or less hybrid middle level managers; affiliated to certain more powerful professional groups, notably doctors etc.?

RQ3. What is the contribution of middle level managers towards brokering patient safety knowledge; e.g. when do they broker knowledge, what type, how, within or across organisations, and qualitative description of outcomes?

RQ4. How do expectations and perceptions of knowledge brokering patterns held by external national and regional producers/disseminators/auditors of patient safety knowledge diverge or converge from knowledge brokering patterns at local organisational or system levels?

RQ5. How do patterns of brokering associated with top down patient safety knowledge differ from knowledge brokering patterns associated with bottom up patient safety knowledge?

RQ6. What prescriptions can our analysis of knowledge brokering offer for policy and practice; e.g. how can middle level managers be enabled to broker patient safety knowledge more effectively?

<u>Translation of evidence about patient safety and quality</u>

While good at research and invention, the NHS is less successful at diffusing new ideas into service delivery – 'second translation gap' (HM Treasury (Cooksey Report), 2006; DH, 2007). A key issue therefore is how the NHS maximises its return on R&D investment. The translation of evidence into service change and practice is particularly crucial in the area of patient safety, where learning from safety events and clinical risks is recognised as integral to enhance patient safety (DH, 2000). It is widely recognised that there are various sources of knowledge and evidence around patient safety, such as informal communications, complaints, incident reports, safety alerts, bulletin and scientific research, yet research suggests that their influence and relevance to the clinical frontline remains problematic (Currie et al. 2008; Waring, 2004; 2005; Waring et al. 2010; Waring and Bishop, 2010). Crucial to the translation of patient safety evidence is the knowledge brokering role of clinical or hybrid middle level managers to move evidence into clinical practice.

The knowledge based view of strategy (KBV)

The knowledge-based view of the firm (Grant, 1996) is an innovation within the resource-based view (RBV) of the firm (Penrose, 1959; Wernerfelt, 1984; Barney, 1991). Underpinning the KBV is an assumption that knowledge is the key resource of any organisation and thus strategy should be concerned with the development, protection and transfer of knowledge (Henderson and Cockburn, 1994; Leibeskind, 1996). Grant (1996) argues that organisations exist because they are more efficient at integrating and applying specialized knowledge than markets. In many ways the KBV, with its emphasis on knowledge development and transfer, may be thought of as the link between the traditional static conceptualization of the RBV and more recent developments surrounding dynamic capabilities theory (see Teece, et al, 1997). As such, the KBV suggests a significant role for MLMs in the management of an organisation's knowledge. MLMs, given a set of knowledge resources, need to play an important brokering role in understanding the functionality of the knowledge (i.e. for what purposes knowledge may be used) and how they can match the knowledge to potential opportunities. In doing so knowledge brokers need to bridge multiple domains, learn about the knowledge resources within those domains, link that knowledge to new situations, and finally build new networks around the innovations that emerge from the process (Hargadon, 2002). We contend that the brokerage function is particularly important in a health services context because it is a knowledge rich environment, in which the knowledge is commonly complex and intangible in nature, and health care organisations face an austere financial climate

requiring managers to utilise knowledge as efficiently as possible to enhance service delivery and/or make efficiency gains: i.e. knowledge brokering responds to the need for Quality, Innovation, Productivity and Prevention (QIPP).

Strategic role of middle managers

Consistent with KBV, Floyd and Wooldridge (2000: xvi) state: "information flows and patterns of social influence that transform ideas and initiatives into new capabilities have their nexus at middle levels of management hierarchy…This is 'where the action is' in a capability-based view of strategy". MLMs act as 'knowledge engineers' (Nonaka and Takeuchi, 1995) or 'knowledge brokers', defined as those that: use their in-between vantage position to support innovation through connecting, recombining, and transferring to new contexts otherwise disconnected pools of ideas; i.e. they get the right knowledge into the right hands, at the right time (Hargadon and Sutton, 2000; Verona et al, 2006). Within our study, we use the term, 'middle level managers', deliberately to emphasise the following: Middle level managers may not have 'manager' as part of their title. They are located in the middle levels of the organisation, commonly within the clinical hierarchy, but have some responsibility for management of resource, including the knowledge resource associated with clinical service development and delivery. Consequently, the focus of our empirical investigation aligns with the need to examine the role of boundary spanners at the managerial-clinical interface, rather than focusing upon 'middle managers' that interact mainly with others within the managerial hierarchy. The operational details of our research design elaborate upon this further. With respect to healthcare organisations, Pappas and Wooldridge's (2002) study of a medium-sized hospital found that such MLMs are strategically positioned at the intersection of critical activities that facilitate organisational renewal. MLMs are well placed as brokers because they provide a unique 'linking pin' between operational and strategic contexts (Floyd and Wooldridge, 2000). In particular, where they have a relevant professional background, MLMs act as 'hybrid' managers (Currie and Brown, 2003; Currie and Procter, 2005) that bridge managerial and clinical contexts; i.e. some MLMs may be better placed than others to enact a strategic knowledge brokering role. However, MLMs may trade-off between organisational change and self-interest. MLM knowledge brokering may consequently impede translation of knowledge, as well as facilitate it (Guth and MacMillan, 1986; Wooldridge and Floyd, 1989). MLMs both filter (screen out) and funnel (draw in) innovation (Floyd and Wooldridge, 2000). A brokerage role, based upon their linking position, allows MLMs to mediate the flow

of resources or information between two other unconnected actors (Burt, 1992). The role of MLMs as knowledge brokers can be delineated into a number of roles: liaison, where they broker knowledge across different groups; representative, where the broker acts as a marginal sub-group to mediate actors within the same group; gatekeeper, where the broker screens knowledge to distribute within their own group; co-ordinator, where all the actors are in the same group; itinerant broker, where the broker mediates between actors in the same group, but where the broker is not part of this group (Fernandez and Gould, 1994). Some roles are more likely to realise brokerage advantages than others, dependent upon organisational context, and thus enhance organisational performance (Shi et al, 2009).

Knowledge brokering in healthcare

The strategic management literature resonates with literature about knowledge brokering in healthcare (Canadian Health Research Foundation, 2003; Clark and Kelly, 2005; Davies and Nutley, 2000; Denis et al, 2003; Dobbins et al, 2009; Hargadon, 1998; Hargadon and Sutton, 2000; Landry et al, 2001; Lomas, 2007; Martin, Currie et al, 2009; Pawlowski and Robey, 2004; SEHDSAHPM, 2005; Verona et al, 2006; Ward et al, 2009). The knowledge brokering healthcare literature is relatively normative, with a need for empirical evaluation of knowledge brokering at individual, group and organisational levels (Dobbins et al, 2009). However, the literature raises a number of issues that we follow through in our study. MLMs are more likely to broker knowledge 'downstream' but can link exploration with exploitation (Cillo, 2005); i.e. less likely to initiate innovation, but more likely to facilitate implementation through: building rapport with stakeholders; forging connections across producer and end-user domains; tailor interventions for end-users (Dobbins et al, 2009). Most of the healthcare literature focuses on external knowledge brokering (i.e. between research and practice) and suggests that health services are 'not very well organised' or 'not very receptive' to apply external evidence to service development' (Lomas, 2007). Meanwhile, internal knowledge brokers remain under-researched, yet crucial where evidence is 'complex'; i.e. not easily codified. Furthermore, the political dimension of knowledge brokering remains relatively unexplored, with a particular need to understand knowledge brokers' legitimacy claim to carry out their activity (Currie, Waring et al, 2008; Currie, White et al, 2009b; Martin, Currie et al, 2009), and also how others respond to brokerage activity; i.e. to shut it down where their interests are threatened (Shi et al, 2009). Brokers relate to different types of knowledge (Isabella, 1990; MacDonald, 1995).

The nature of knowledge impacts upon brokering patterns; e.g. professionally specialist or generalist (Currie et al, 2009); experiential or tacit knowledge embedded in practice (Gabbay and Le May, 2004); with different levels of MLM (senior MLMs or MLMs nearer the front line of service delivery), better able to broker different types of knowledge. To support knowledge brokering by MLMs requires face-to-face interaction over a long period to engender good relationships that encompass a high degree of trust between knowledge producers and end-users (Bowen et al, 2005; Dobbins et al, 2009; Landry et al, 2000). Involving MLMs earlier in research bridges a relevance gap (Starkey and Madan, 2001). Knowledge brokers possess superior interpersonal skills, and expertise from research and end-user domains (Dobbins et al, 2009). Knowledge brokering is facilitated by receptive contexts: where policy is coherent (Currie and Suhomlinova, 2006); where strategy is emergent, culture is supportive, managerial-clinical relations are effective, leadership is evident, inter-organisational networks are co-operative (Pettigrew et al, 1992); there exists organisational structure connecting MLMs laterally and externally, and organisational/individual development (Currie and Procter, 2005). Knowledge brokering is also influenced by turnover of personnel (i.e. we need to understand the dynamics of change in brokers); group affiliation, e.g. is peer-to-peer brokering more likely? (Shi et al, 2009).

Patient safety

Our proposed research fills a knowledge gap that is particularly timely given the initiatives announced in the Next Stage Review (specifically the need for locally driven innovation located nearer the front line of service delivery), the impending constraints on NHS expenditure, and the concerted efforts around innovation adoption orchestrated by the NIHR and others. Our proposed study examines knowledge brokering for innovation around patient safety in the area of elderly care across primary, acute and mental health services. Specifically, a recent review of the UK Patient Safety Research Portfolio (Dingwall, Waring et al. 2009; Waring et al. 2010) highlights the significant contribution to patient safety knowledge and evidence especially in the area of acute healthcare, but it also reveals a lack of attention to the area of primary and mental health services, and patient groups such as older people.

The study of knowledge brokering is difficult to operationalise. Nevertheless, a study of knowledge brokering is necessary, specifically as it relates to patient safety knowledge, as reported in *The Guardian*, 15 February 2010. The campaign group,

Action Against Medical Accidents, reported poor collaboration between managers and clinicians to ensure safety alerts resulted in changes in practice. Our proposed empirical study is located at the interface of managerial hierarchy and clinical practice, and is ideally positioned to respond to concerns raised. By empirically focusing upon organisational structures related to risk management, we can examine how managerial structures for brokering patient safety knowledge interact with middle level managers, who have clinical backgrounds, and that potentially broker patient safety knowledge into clinical practice. The report produced by Action Against Medical Accidents was narrowly focused upon 'safety alerts'. We focus our study upon 'safety alerts' in Work Package 1, but conceive of 'safety alerts' as broad: e.g. more than NPSA alerts, and including MHRA alerts, NICE guidelines, dissemination of lessons through bodies such as the Health Foundation and NHS East Midlands Quality Observatory, recommendations from bodies representing service users, such as the Patient Association and Patient Safety First Initiative.

Recognising that patient safety is a broad area, we have drawn upon secondary sources, including the NPSA's analysis of reported incidents, and exploratory conversations with clinicians to identify the following three patient safety issues as nationally and locally relevant: falls, medication, transition. In each case we note the existence of evidence passing 'vertically' between exogenous national actors and endogenous local service providers; as well as 'horizontally' between service departments and sectors, including primary, secondary and mental health services. Within this nexus of evidence we highlight the role of the MLM as brokering evidence into practice and to relevant stakeholders:

i. *Falls* remain a major and highly reported area of patient safety (NPSA, 2009). Many elderly people with falls report to ambulance services, but these are not fall prevention services, thus falls may re-occur. Falls can be prevented by multidisciplinary interventions, including strength and balance training (usually physiotherapy focused), home hazard assessment (usually occupational theory focused), diagnoses and medication, with effective multidisciplinary intervention dependent upon MLM knowledge brokering. We note the existence of both national (Patient Safety First) and local initiatives to promote patient safety around falls, such as the use of admission checklist of risk. Falls also exemplify the challenge of brokering across different professional perspectives; e.g. falls have the inherent tension of attempts to limit activity so as to prevent falls or to accept them as a consequence of allowing the patient

recover and lead a fuller life. Psychosocial knowledge regarding the patient's domestic circumstances can help mediate risk, but requires brokering in through MLMs.

ii. *Medication* related safety is a prominent area of concern (NPSA, 2009). Medication exemplifies the challenge of brokering across jurisdiction; e.g. GP or pharmacist in primary care may note a patient is failing to take their medication due to cognitive impairment (i.e. mental health problem), but fail to communicate this to the acute physician, that in turn, lacks access to mental health records. Such cognitive impairment is likely to impact upon the patient's take up of any further drug regimes, such as antibiotics to combat infection control.

iii. *Transition* provides a more generalised example of a knowledge management challenge connected to elderly care that brokering might mediate. In some cases elderly patients may be admitted to hospital 5-10 times on a year, have 3-4 spells in residential intermediate care, and have a raft of community services, such as community matrons. They may move from sector to sector frequently with each transition providing opportunity for a patient safety incident. Brokering of external knowledge from research providers and disseminators can guide best practice. Internal knowledge brokering may lead to solutions, which draw on external sources, but are contextualised to local practice, with psychosocial and clinical knowledge integrated to ensure service delivery is joined up across providers. As an elderly patient moves from sector to sector, information may be lost, decay, become distorted, misinterpreted, or repeated, as the patient moves through diagnosis, therapy, prognosis, with MLMs well positioned to effectively and efficiently broker knowledge, and mediate such challenges.

STUDY OBJECTIVES AND PURPOSE

PURPOSE

The healthcare literature about knowledge brokering is relatively normative (Dobbins et al, 2009), although there is some anecdotal evidence about the effectiveness of knowledge brokering in improving the quality and use of evidence in healthcare decision-making (Dobbins et al, 2009: Kitson et al, 1998; Lyons and Warner, 2005); i.e. knowledge brokering as a solution appears promising. Specifically, there is a need for a more critical, nuanced account of knowledge brokering in the NHS with a focus upon how MLMs support translation of evidence, e.g. MLMs in the NHS filter, as well as funnel innovation, as noted in a recent NHS Confederation report on the

Future of Leadership (2009), due to short-term targets, risk-aversion, and budget constraints. There is a need to render visible the context under which knowledge brokerage translates into organisational benefit (Shi et al, 2009).

We examine differences between MLMs (e.g. junior and senior MLMs) in brokering evidence across the healthcare system inclusive of commissioners and SHAs. Knowledge brokering literature focuses upon the research-practice link in healthcare (e.g. Dobbins et al, 2009), yet formal research interacts with other forms of knowledge. We consider how informal knowledge is brokered internally, whereby new ideas are created by rearranging knowledge already in use and by incorporating previously neglected information (Isabella, 1990; MacDonald, 1995). Finally, by assessing MLMs involvement in knowledge brokering over time, we consider the more generalised effect when MLMs are closely involved in R&D within healthcare organisations, including the consequences of turnover of key knowledge brokers.

A key issue is how the NHS maximises its return on R&D investment. While good at research and invention, the NHS is less successful at diffusing new ideas into service delivery – 'second translation gap' (Cooksey Report, 2006; DH, 2007). Crucial to this is the knowledge brokering role of general or clinical middle level managers (MLMs). MLMs need to get the right knowledge into the right hands, at the right time. We examine knowledge brokering of patient safety evidence in the care of elderly people at the level of the regional system, focusing upon issues shown to be important in national statistics (NPSA, 2009): 1) falls; 2) medication; and 3) transition across acute, primary care, mental health, local authority sectors. As a bottom line, cognisant of recent and past quality problems at for example, Mid-Staffordshire Hospitals Foundation Trust, Maidstone and Tunbridge Wells Trust, Bristol Royal Infirmary, and Harold Shipman, prescriptions around effective brokering of patient safety knowledge by MLMs prevent reputational damage and potentially save money for the NHS.

PRIMARY OBJECTIVE

- To identify which MLMs act as knowledge brokers (e.g. junior or senior MLMs).

SECONDARY OBJECTIVES

- To determine contribution of MLMs as knowledge brokers for service improvement (e.g. when they broker knowledge, what type, how, outcomes).

- To identify limiting or facilitating features of context for knowledge brokering by MLMs (e. g. involvement in research, policy coherence, culture, inter-organisational relationships, clinical-managerial relationships, organisational strategy/structure, individual and organisational development).
- To identify MLM attributes for knowledge brokering (e.g. role-based, personal, inter-personal relationships).
- To identify prescriptions for improved knowledge brokering of patient safety evidence by MLMs.

STUDY DESIGN

Theoretically we take a dynamic knowledge based view (KBV) approach to strategic management to focus on knowledge brokering by MLMs. MLMs play an important, but under-researched role in knowledge brokering to strategically develop services. We focus on knowledge brokering of patient safety within the East Midlands (North) healthcare system focused on elderly care, but also delineate limiting or supporting features of organisational context across the research sites. Access to 6 fieldwork sites has been negotiated through the NIHR funded Collaborative for Leadership in Applied Health Research and Care - Nottinghamshire, Derbyshire, Lincolnshire (CLAHRC NDL): a mental health Trust - Nottinghamshire Healthcare NHS Trust (NHCT), acute Trusts - Nottingham University Hospitals Trust (NUH), Sherwood Forest Hospitals NHS Foundation Trust, PCTs - NHS Nottingham City, NHS Nottinghamshire County, NHS East Midlands, Nottingham City Council and Nottinghamshire County Council, who constitute end users of the proposed research, as well as empirical cases within the study. Our fieldwork will utilise a mixed methods approach: desk-based mapping of knowledge flows of patient safety evidence; semi-structured interviews to explain patterns of knowledge brokering and identify outcomes; social network analysis (SNA) incorporated in to semi structured interviews to identify patterns of knowledge brokering at local level; observation to examine knowledge brokering in-situ.

We will evaluate outcomes, both specific to and transferable beyond elderly care, and the range of patient safety issues we investigate (falls, medication, transition), to:

(i) Identify ‘bottle necks’ in brokering of patient safety knowledge through MLMs, including consequences of turnover of key knowledge brokers in the system.

(ii) Identify service quality outcomes from effective knowledge brokering through the production of rich description of clinical outcomes where such data is available.
(iii) Collect rich description of case context and process where MLMS brokered knowledge around patient safety to improve service quality to identify prescriptions for supporting effective knowledge brokering.

We will generate a deep understanding of the processes through which MLMs broker knowledge, which is grounded in the larger social context and so develop a model for knowledge brokering to inform action.

Methods

Work Package 1

A systematic literature review preceded the submission of this bid, and is continuing through the work of a PhD student working into the project (Verity Castledine). The literature review will be ongoing and iterative with data gathering and analysis.

As a starting point for our project, we will interview 20 external, national or regional level producers/disseminators/auditors of patient safety knowledge around falls, medication and transition. Indicatively, this sample encompasses policy, professional and service user stakeholders from the following organisations:

- Royal Society for Medicine (Geriatrics and Gerontology Section),
- Patient Safety Research Programme (now disbanded),
- Health Foundation,
- NHS 3Is,
- Care Quality Commission,
- Strategic Health Authority (e.g. the newly instituted East Midlands Quality Observatory).

To obtain the service user perspective, the Patients Association and other charitable campaigns, such as the Patient Safety First Initiative, will be approached and invited to participate in the interviews.

In the external stakeholders interviews, our aim is to elicit their expectations and perceptions of how knowledge is brokered, to identify a broad range of 'safety alert' evidence that is disseminated by these external stakeholders, to explore how this is

disseminated, and, to understand who brokers knowledge, both into the local organisation and onwards to clinical practice.

Work Package 2

In the second work package, we will carry out 45 interviews. These will examine knowledge brokering carried out by organisational middle level managers who are members of the standing risk management committee within a trust, who are tasked with brokering patient safety evidence produced or disseminated by external parties (e.g. in the form of 'safety alerts', broadly defined, or best practice guidelines) into clinical practice. Indicatively, such a committee is composed of: corporate risk manager, medical director, executive director for quality (commonly, a nurse), senior medical representative responsible for audit, senior nurse representative responsible for audit; i.e. 'senior' middle level managers, but that represent 'hybrids' between management and clinical practice.

Starting with the members of the standing risk management committee, through interviews (that encompass SNA to reduce time spent by middle level managers in participating in the research, and encourage better response rates to SNA), but also some observation of meetings, we can trace how and with whom these middle level managers interact, and broker patient safety knowledge to frontline clinical services. In so doing, we will follow up our initial interviews with others identified by standing committee members in the course of SNA or interviews. This is likely to reveal the role of less senior middle level managers in brokering top down knowledge to clinical services, and/or those outside the risk management structure; e.g. clinical directors, senior nurse managers, clinical leads, ward managers. In short, from the standing risk management committee, we will trace brokering of top-down knowledge by junior and senior middle level managers to the clinical frontline. This is likely to provide an illuminating counterpoint to the expectations and perceptions of those producing and disseminating external evidence that are interviewed in Work Package 1. 5 interviews will be carried out across the 5 NHS organisations (NHS Nottingham City, NHS Nottinghamshire County, Sherwood Forest Hospitals NHS Foundation Trust, Nottingham University Hospitals NHS Trust, Nottinghamshire Health Care NHS Trust) with risk committee members (i.e. 5 interviews in each), plus 5 interviews within each NHS organisation outside the committee, plus further 15 interviews outside NHS organisations. Total interviews = 65.

Work Package 3

In comparison to Work Package 2, our fieldwork in Work Package 3 focuses upon the brokering of bottom-up knowledge; e.g. learning from Serious Untoward Incidents (SUIs) related to falls, medication management or transition, or taking account of the service user perspective, responding to complaints raised by PALS. Again, we will carry out 65 interviews, As with Work Package 2, initially we interview middle level managers that are part of the organisational structure (to be identified in exploratory interviews in work package 2) designed to facilitate the brokering of patient safety knowledge to the clinical frontline. Following a SUI, commonly some type of appointed "risk management committee", "conference" or learning forum is put in place (although what it is called is varied; e.g. In Nottingham University Hospitals Trust, at directorate level, it is called a "governance committee"). Commonly, this might consist of: corporate risk manager, clinical director for the area, clinical governance lead for the area, patient safety lead for the area, ward or unit manager for the area, as well as frontline clinicians. The former are less senior middle level managers than Work Package 2, and participants are commonly located closer to clinical practice.

Our research design thus lends itself to comparative analysis of bottom-up versus top-down knowledge brokering, linked to which are the relative roles and effectiveness of senior versus junior middle level managers. Again, from risk management committee or other learning forums, through interviews (including SNA) but supplemented by some observation, we will trace brokering of knowledge between middle level managers, and then onto the clinical frontline, identifying those other middle level managers outside the risk management structure that broker patient safety knowledge; e.g. through clinical directorate meetings or local level team briefings. Similar to Work Package 2, this is likely to provide an illuminating counterpoint to the expectations and perceptions of those producing and disseminating external evidence that are interviewed in Work Package 1. We will carry out 5 interviews in each of the 5 NHS organisations (NHS Nottingham City, NHS Nottinghamshire County, Sherwood Forest Hospitals NHS Foundation Trust, Nottingham University Hospitals NHS Trust, Nottinghamshire Health Care NHS Trust) with appointed risk committee members or other decision-making forum members for SUI, plus 5 interviews within each NHS organisation outside these forums, plus further 15 interviews outside NHS organisations. Total interviews = 65.

Work Package 3 is consistent with studies by Currie and Waring (Currie et al, 2008; Waring and Currie, 2009), which emphasise the importance of bottom up learning around patient safety. As with Work Packages 1 and 2, which focus on top down knowledge brokering, for reasons of practicality and efficiency, the empirical design is relatively structured around learning and knowledge brokering from SUIs associated with elderly care falls, medication and transition, and the risk management structures tasked with addressing SUIs, but will also examine how complaints from service users through PALS are brokered into clinical practice through middle level managers.

As an indicative example of a need for effective bottom up knowledge brokering by middle level managers, within the Directorate for Healthcare for Older People (HCOP) at Nottingham University Hospitals Trust, there was a complaint about the care of a patient identified as being at high risk of falls. The response to the complaint was the introduction of cot sides to her bed and haloperidol, an antipsychotic medication. However, following this, she broke her arm falling out of bed to engage in social interaction with other patients. Following a "governance committee" meeting around such issues, far from uncommon in HCOP, visiting policy (a managerial decision) is being reviewed on the basis that one solution proposed to prevent such instances, by those close to care delivery, is a need for more frequent bedside attendance by extended family and others to give the patient the social interaction they crave. This would prevent patients trying to get out of bed for social interaction without the help of relevant healthcare staff. However, existing visiting arrangements suit professional work arrangements (e.g. ward rounds by consultants, delivering meals to patients), and more generally, ward managers in particular have exhibited defensiveness in response to what they perceive as a 'blame culture'. Thus, the problem remains of brokering knowledge from formal learning structures into clinical practice to overcome cultural and political barriers to the integration of clinical and psychosocial interventions.

A second indicative example, also evident above, emphasises that the medication solution, even if adhered to by cognitively impaired older patients, might be replaced with psychosocial intervention; i.e. the bio-medical model is inadequate. So, for example, as a result of "risk committee" meeting, where clinical and psychosocial evidence is brokered, HCOP has engaged in non-medication based management of patients; e.g. through a more preventative, non-medication approach for disturbed

behaviours, which has had a positive impact upon falls, medication management and transition. Middle level managers, specifically the clinical director and ward manager, played an important role in brokering knowledge between managerial hierarchy and clinical staff delivering care, in the development and implementation of preventative measures.

In Work Packages 2 and 3, we focus upon risk management committees or similar learning forums (in the case of bottom up knowledge brokering), since it is from these structures that patient safety clinical governance, interpretation/learning for service development, and diffusion of patient safety evidence come together. In essence, effective knowledge brokers are those that simultaneously contribute towards clinical governance, service development and diffusion of patient safety evidence. Effective knowledge brokers are unlikely to come from the ranks of corporate centre management (although the role of the corporate risk manager is of particular interest), but more from those middle level 'managers', who combine resource management responsibilities with clinical service development and delivery responsibilities. It is upon these 'middle level managers' that our empirical study will focus. From interviews with middle level managers within the risk management structures, we will snowball sample other relevant interviewees.

In the above, thus far, our empirical focus appears one of examining knowledge brokering within our five NHS case studies (Nottingham University Hospital, Sherwood Forest Hospitals NHS Foundation Trust, NHS Nottinghamshire County, NHS Nottingham City and Nottinghamshire Healthcare NHS Trust). However, our tracer issues of falls, medication and transition represent a health and social care wide system challenge, which requires brokering of knowledge between health and social care organisations. So, not only will we trace brokering of knowledge from the respective risk management structures to the clinical frontline, but we will trace the brokering of knowledge from one health care organisation to another, or between health and social care organisations or independent providers of clinical service (Nottingham City Council and Nottinghamshire County Council, as well as non-NHS pharmacists are encompassed within our study design). Thus, in Work Packages 2 and 3, we have allowed for 30 interviews with stakeholders outside NHS organisations. Through our interviews with NHS middle level managers, specifically the SNA component, we can identify other middle level managers, such as social care middle level managers (although the term, 'middle level managers', becomes

more loosely defined in the case of non-NHS pharmacists for example, that might broker medication knowledge), whom we will also seek to interview.

In total we carry out 150 interviews over the first 24 months of our 27 month project. We complement this with observations. Observations help the research team contextualise research findings, as detailed further below.

In work packages 2 and 3, our focus is on MLMs, although we will also interview relevant executive managers who can further illuminate the issue of knowledge brokering through MLMs. Focusing upon MLMs is relevant because, as detailed in background above, they represent vertical and horizontal 'linking pins' well placed to broker knowledge within and between organisations should wider features of context support this. Furthermore, (post-) New Public Management has engendered distributed or decentralised responsibility for service development in the NHS (Currie, Lockett et al, 2009). However, defining middle managers has proved challenging, resulting in a wide range of role holders being examined in studies to date within and beyond healthcare, which has stymied cumulative analysis of the role of middle managers. A major reason for this is that middle managers have typically occupied a large swathe of the managerial hierarchy, from those close to executive directors to those close to first line managers, and those who are dedicated general managers to those that discharge middle management responsibilities of resource management and control in the course of professional duties (Currie and Procter, 2005). Cognisant of this challenge, and that we seek to draw out lessons regarding who is best placed to broker knowledge, we use the term middle level managers (MLM) to focus upon a those, that hold resource and clinical management responsibility, brokering knowledge at middle levels of the organisation, as detailed above in sampling for WP (2) and (3) e.g. to emphasise, as well as clinical directors, nurse managers, this might include those providing leadership for their occupational group, such as, GPs (in primary care), geriatricians (in acute), psychiatrists (in mental health), AHPs (e.g. physiotherapists or pharmacists in acute, clinical psychologists in mental health, community occupational therapists in primary care, social workers in a local authority). We also need to consider those outside healthcare organisations: e.g. social care professionals (in local authorities) and non-NHS pharmacists; as potentially influential patient safety knowledge brokers in elderly care.

Our fieldwork associated with WP(2) and WP(3) encompasses mixed methods: social network analysis (SNA) embedded within interviews to identify patterns of knowledge brokering at the local level; semi-structured interviews to explain patterns of knowledge brokering and identify outcomes from knowledge brokering; observation to examine knowledge brokering in-situ.

Rationale for study design

SNA is particularly suited to the study of patterns of knowledge brokering in healthcare because it is inherently relational (Balkundi and Kilduff, 2006; Burt, 1992; Scott, 2000; Uhl-Bien, 2006). It will identify MLM knowledge brokers, their attributes and what they do. It is useful in identifying patterns of brokerage in terms of which actors are knowledge brokers (or more likely to be brokers) in a given network, and how knowledge and information flow between the brokered parties, namely the connection of brokerage ties. SNA also examines what benefits actors could get from the brokerage relationship, as well as how brokerage ties emerge, develop, evolve, or vanish. In investigating knowledge brokerage of MLMs, we look at how they leverage the expertise of others in an accurate and timely fashion, not just in terms of the structure of information flows, but also in terms of the properties of the relationships they have with others that allow them to respond to a current need or opportunity. Effective knowledge brokerage requires that key actors in the network are well connected both internally and externally, and are viewed as competent by their colleagues, so that other people turn to them for expertise and advice. Thus, data for SNA will be collected via a socio-metric questionnaire (embedded within interview), which will focus, among other items, on asking respondents some questions about work connections, as well as how accessible they are, and how much they value others' expertise. With respect to SNA, which is embedded in interviews in work packages 2 and 3, we utilise the framework and statistical analysis technique developed by Fernandez and Gould (2005), which they apply in conjunction with SNA, to identify brokering roles of middle level managers. This was effectively applied to examine knowledge brokering roles, which encompassed middle level managers in health and social care, in the recently submitted end of project report that was submitted to NIHR SDO: "Comparative evaluation of children's services networks; Overcoming professional, organisational and sector boundaries in Paediatric Nephrology, Child Protection and Cleft Lip and Palate Networks" SDO 08/1718/149 (Authors: Graeme Currie (Principal Investigator), Tina Starr, Leroy White, Robert Dingwall, Alan Watson, Paul Trueman).The categories

developed and described by Fernandez and Gould (*ibid*.) can be mapped onto more generic strategic roles for middle level managers, and the contingencies surrounding this, applied to the NHS by Currie and Procter (2005), based upon the work of Floyd and Wooldridge (2000), to produce transferable lessons beyond our empirical case. In short, SNA adds value through its application to identify knowledge brokering roles for middle level managers.

Semi-structured interviews have been chosen as they are a valuable tool in identifying context, outcomes of knowledge brokering, and prescriptions for more effective knowledge brokering. A semi-structured interview guide will be developed. The use of an interview guide allows for a less structured discussion, and results in richer data providing a greater understanding of import to the interviewee. The themes outlined in the schedules will be used to drive discussions forward while enabling comparable questions to be asked across all interviews, this allows for flexibility and for interviewer/informant to follow important topics or themes once in the interview, as flagged up by informant's previous comments. 110 interviews will be carried out in total.

Knowledge brokering is a situated activity (Currie and Kerrin, 2004; Martin, Currie et al, 2009). Consequently, observation will allow researchers to develop a contextualised understanding of knowledge brokering activity by MLMs. 'Pure' observation of knowledge brokering is however, impractical as we trace it through clinical encounters: i.e. it is intrusive and inefficient way of observing knowledge brokering. Consequently, we will undertake observation in structured settings, most obviously risk management structures, but potentially also within other relevant local level meetings; e.g. ward or clinical directorate meetings, local team briefings in our 'provider' sites (Nottingham University Hospitals NHS Trust, Nottinghamshire Healthcare NHS Trust, Sherwood Forest Hospital NHS Foundation Trust). Specifically, we will observe 3 standing risk management committees in Work Package 2 (3 observations of 2 hour meetings of each of the standing risk management committees in our NHS study sites. Total hours observation = 18), and 3 appointed risk management committees or other learning forums in Work Package 3 (3 observations of 2 hour meetings of each of the appointed risk management committees in our NHS study sites. Total hours observation = 18), plus observation of other local level meetings (e.g. clinical directorate meetings as learning from SUIs

work their way into the operational management hierarchy) deemed relevant in Work Packages 2 and 3 (Total = 18 hours), over the same period of time.

Data analysis, integrating the Work Packages 1-3 and integrating qualitative interviews and SNA.

Work Packages 1-3 are carried out in sequence, with analysis of each carried out following completion of fieldwork in each respective work package. Analysis will use relevant software for qualitative data, dependent upon the experience of the RF recruited; e.g. in the past, we have recruited students with experience of N-Vivo, a software package often valued for organising emergent analysis as a sequence of Work Packages are completed. Guided by Currie and Waring, and based upon the literature review and emergent empirical themes, the RF will code interview and observation data within each Work Package. Using the data organised through the software package, following completion of Work Packages 1-3, the RF will engage in comparative analysis across the Work Packages, which is more qualitative and less structured in nature; e.g. to compare expectations/perceptions of knowledge brokering by external producers/disseminators/auditors of patient safety knowledge with our empirical cases (comparing Work Package 1 with Work Packages 2 and 3); to compare top down and bottom up patterns of knowledge brokering (comparing Work Packages 2 and 3). The RF will utilise SNA data to contribute to both within and across Work Package analysis, with SNA diagrams and statistical analysis produced through the UCINET software package.

STUDY CONFIGURATION

This is a multi-centre study involving the participation of different MLMs and related professional groups. The study uses qualitative methodologies, encompassing interview, observation and social network analysis (SNA) techniques.

WORK PACKAGE	**RESEARCH QUESTION**	**RESEARCH ACTIVITY**	**TIMING (MONTHS)**
Ethics and R&D			Upfront
Literature review	To further detail RQ(1)-RQ(5)	Deskwork	Upfront and ongoing/iterative with data collection and analysis

WP(1) Key research producers, disseminators, auditors of best practice	RQ(1), RQ(2), RQ(5)	20 national level interviews Social Network Analysis	1-4 gather 5-7 analyse
WP(2) MLMs & executive managers within elderly care regional level healthcare system focussed on external knowledge brokering	RQ(2)-RQ(5)	65 interviews Observation Social Network Analysis embedded in interviews Secondary data collection	7-12 gather 13-15 analyse
WP(3) MLMs & executive managers within elderly care regional level healthcare system focussed on internal knowledge brokering	RQ(2)-RQ(5)	65 interviews Observation Social Network Analysis embedded in interviews Secondary data collection	16-21 gather 22-24 analyse
WP(4)	All	Write up	25-27

STUDY MANAGEMENT

The Chief Investigator has overall responsibility for the study and shall oversee all study management.

On a day-to-day basis, the study will be carried out by a RF, who will be supervised by and accountable to the chief investigator (professorial scale) and wider study team. The study team will meet on a regular basis to review progress and deal with governance and ethical issues.

Data collected will be in the form of field notes and audio-recordings; no personal information will be collected. Study data will be transcribed verbatim. Original audio recordings will be destroyed after 7 years. They will be anonymised and archived with the research data as source data. Anonymised transcripts will be kept, in accordance with University of Warwick research code of conduct guidelines, for seven years post last publication and then reviewed for destruction. All files will be stored on a password protected computer. All paper files will be stored in a locked cabinet, within a locked office.

A Scientific Advisory Board (SAB) will provide high level governance of the research (design, findings, dissemination) and consist of research producers and end users. A number of high level executives from national (e.g. Simone Jordane, Executive Director, NHS 3Is), regional (e.g. Michael Hewitt, R&D Director, NHS East Midlands), and local NHS organisations (e.g. Andrea Ward, Clinical Director, MHSOP, NHCT; Amanda Sullivan, Executive Director Quality, NHS Nottinghamshire), including an experienced user in the region (Ossie Newell, MBE, stroke rehabilitation and elderly care, Nottingham) and a professor from HEI (Ken Starkey, Professor of Organisational Learning, Nottingham University Business School), have agreed to sit on the SAB. The SAB will meet 4 times over the course of the research.

DURATION OF THE STUDY AND PARTICIPANT INVOLVEMENT

Participant involvement will cease following the termination of their interview.

End of the Study

The end of the study will be when all data has been collected and analysed, and the final report written. This is expected to occur by June 30th 2013.

SELECTION AND WITHDRAWAL OF PARTICIPANTS

Recruitment

Participants will be recruited from the study sites (NHS Nottinghamshire County, NHS Nottingham City, Nottinghamshire Healthcare NHS Trust, Nottingham University Hospitals NHS Trust, Sherwood Forest Hospitals NHS Foundation Trust, NHS East Midlands, Nottingham City Council and Nottinghamshire County Council), the Royal Society of Medicine, Patient Safety Research Programme, Health Foundation, NHS

3is, Care Quality Commission, Strategic Health Authority, Patients Association and other charitable campaign associations, and other Allied Health Care professionals.

The initial approach to participate in the study will come from a member of the research team. The research team will inform the participant of all aspects pertaining to participation in the study. It will be explained to the potential participant that that entry into the study is entirely voluntary and that their employment status will not be affected by their decision. It will also be explained that they can withdraw at any time but attempts will be made to avoid this occurrence. In the event of their withdrawal it will be explained that their data collected so far cannot be erased and we will seek consent to use the data in the final analyses where appropriate.

Inclusion criteria

Participants will fall into at least 2 of the following categories:

- Able to give consent
- Over the age of majority
- Employed as a middle level manager in elderly care, in one of the study sites
- A producer, disseminator or auditor of patient safety knowledge linked to the Royal Society of Medicine, Patient Safety Research Programme, Health Foundation, NHS 3is, Care Quality Commission, Strategic Health Authority, Patients Association and other charitable campaign associations
- Risk Committee member in one of the NHS study sites
- Pharmacist not employed by the NHS
- Clinical director
- Nurse manager
- General Practitioner
- Geriatrician
- Psychiatrist
- Allied Health Professional
    - E.g. Clinical Psychologist
    - Social Worker
    - Occupational Therapist
    - Physiotherapist

Exclusion criteria

- Minors (under 18 years);
- Capability to give informed consent (includes availability of legally acceptable surrogate).

Expected duration of participant participation

Study participants will be participating for the length of the interview. Upon conclusion of the interview, the participant's involvement in the study will be over.

Participant Withdrawal

Participants may be withdrawn from the study either at their own request or at the discretion of the Investigator. The participants will be made aware that this will not affect their future employment. Participants will be made aware (via the information sheet and consent form) that should they withdraw the data collected to date cannot be erased and may still be used in the final analysis.

Informed consent

All participants will provide written informed consent. The Consent Form will be signed and dated by the participant before they enter the study. The Investigator will explain the details of the study and provide a Participant Information Sheet, ensuring that the participant has sufficient time to consider participating or not. The Investigator will answer any questions that the participant has concerning study participation.

Informed consent will be collected from each participant before they undergo any interventions related to the study. One copy of this will be kept by the participant, and one will be kept by the Investigator.

Informed consent for the observational aspects of this study will be collected from each participant verbally before commencement of the meeting or other learning forum being observed. Any participant may withdraw their consent at any time during an observed meeting, and the Investigator will leave the meeting at that point.

Should there be any subsequent amendment to the final protocol, which might affect a participant's participation in the study, continuing consent will be obtained using an amended Consent Form which will be signed by the participant.

STUDY REGIMEN

Work package 1: Interviews with external producers and disseminators of patient safety knowledge

Participants will be identified

[Opportunities for observation will be identified throughout the following process, but are likely to focus on risk management committees and other learning forums]

↓

Participants will be contacted by post. An invitation letter, PIS and CF will be sent

↓

Postal invitation will be followed up after approximately 10 days, by phone or email

↓

RF will arrange interviews

↓

Before the interview commences, the RF will give the participant another copy of the PIS and ask if they have any questions; after answering any questions, the RF will ask the participant to sign the CF.

↓

Subject to consent, the RF will commence the interview and SNA. The interview will be audio recorded.

↓

Data will be transcribed and stored according to methods outlined above.

↓

Data analysis will commence.

Work package 2: interviews, SNA and observation with MLMs

Participants will be identified

[Opportunities for observation will be identified throughout the following process, but are likely to focus on risk management committees and other learning forums]

↓

Participants will be contacted by post/email. An invitation letter, PIS and CF will be sent

↓

Postal/email invitation will be followed up after approximately 10 days, by telephone or email

↓

RF will arrange interviews

↓

Before the interview commences, the RF will give the participant another copy of the PIS and ask if they have any questions; after answering any questions, the RF will ask the participant to sign the CF.

↓

Subject to consent, the RF will commence the interview and SNA. The interview will be audio recorded.

↓

Data will be transcribed and stored according to methods outlined above.

↓

Data analysis will commence.

↓

Further participants will be identified from the SNA form.

↓

Participants will be contacted by post. An invitation letter, PIS and CF will be sent

↓

Postal invitation will be followed up after approximately 10 days, by telephone or email

↓

RF will arrange interviews

↓

Before the interview commences, the RF will give the participant another copy of the PIS and ask if they have any questions; after answering any questions, the RF will ask the participant to sign the CF.

↓

Subject to consent, the RF will commence the interview and SNA. The interview will be audio recorded.

↓

Data will be transcribed and stored according to methods outlined above.

↓

Data analysis will commence.

Work package 3: Interviews, SNA and observations relating to knowledge brokering for SUIs.

Participants will be identified

[Opportunities for observation will be identified throughout the following process, but are likely to focus on risk management committees and other learning forums]

↓

Participants will be contacted by post. An invitation letter, PIS and CF will be sent

↓

Postal invitation will be followed up after approximately 10 days, by telephone or email

↓

RF will arrange interviews

↓

Before the interview commences, the RF will give the participant another copy of the PIS and ask if they have any questions; after answering any questions, the RF will ask the participant to sign the CF.

↓

Subject to consent, the RF will commence the interview and SNA. The interview will be audio recorded.

↓ ↓

Data will be transcribed and stored according to methods outlined above.

↓

Data analysis will commence.

Further participants will be identified from the SNA form.

↓

Participants will be contacted by post. An invitation letter, PIS and CF will be sent

↓

Postal invitation will be followed up after approximately 10 days, by telephone or email

↓

RF will arrange interviews

↓

Before the interview commences, the RF will give the participant another copy of the PIS and ask if they have any questions; after answering any questions, the RF will ask the participant to sign the CF.

↓

Subject to consent, the RF will commence the interview and SNA. The interview will be audio recorded.

↓

Data will be transcribed and stored according to methods outlined above.

↓

Data analysis will commence.

Plan of investigation

Prior to the start of the study, REC and R&D approvals will be sought, to minimise any delay to the study. Over the duration of the study there will be three Patient Public Involvement/Steering Advisory Board meetings at months 3, 15 and 26.

WP1 Months 1-7: Interviews with research producers & disseminators, including SNA & data analysis. To be discussed with PPI sub-group & SAB (scheduled for month 3). This activity links to RQ(1) & RQ(2).

WP2 Months 7-15: Interviews including SNA with MLMs and executive managers within elderly care regional level healthcare system focussed on external knowledge brokering. To be discussed with PPI sub-group & SAB (scheduled for month 15)

WP3 Months 16-24: Interviews including SNA with MLMs and executive managers within elderly care regional level healthcare system focussed on internal knowledge brokering.

WP4 Months 25-27: Final report writing, national dissemination event to academics & applied researchers, other national regional & local dissemination, including CLAHRC organised workshops. Following discussion with PPI sub-group & SAB (scheduled for month 26) production of end of research programme report to SDO (month 27).

Compliance

Since there are no clinical or pharmaceutical interventions, compliance is not a relevant issue for this study.

Criteria for terminating the study

Owing to the nature of the study, there are no procedures for premature termination.

ADVERSE EVENTS

The occurrence of adverse as a result of participation within this study is not expected and no adverse event data will be collected.

ETHICAL AND REGULATORY ASPECTS

The nature of the study and the issues on which it focuses means that interviews are unlikely to cover sensitive or difficult areas. Nevertheless, researchers will use their judgement in the conduct of interviews and seek to ensure that interviewees are comfortable at all times.

Whilst the ethical issues faced in policy−oriented, qualitative research are not of the same order as those facing research involving clinical interventions, this is not to say that they can be brushed aside. The ethical and design issues that are of particular importance in this kind of research relate to the need to recognize the ways in which the social relationships relating to the phenomena being studied may impact on the research process, by impeding some participants from fully expressing their views while encouraging others to do so.

A key issue is that participants in this research will be asked to comment frankly on something which may be a core part of their work, as this relates to the actions of other individuals and organisations involved. From the point of view of us as researchers, of good research practice, and of the participants themselves, it is

clearly important that those involved are as frank as possible, so that we might get a clear picture of the what has helped or hindered knowledge brokering activities. If some respondents are franker than others, we may get a very skewed view of this, and of the role of different factors and individuals in the process. This quandary is amplified by the fact that there may well be entrenched power relationships within the groups of individuals being studied, with certain parties exerting considerably more influence than others, which may make those less influential parties more reluctant to be frank.

Awareness of this ethical issue is in itself one thing that will help us to address it. When discussing the research with participants at the recruitment stage, we will emphasize that the views of all involved are equally important, and that we will make every effort to use what they tell us in a non−attributable way. Good research practice in interviewing will also be important, and will be assisted by the experience of those who will conduct the research.

ETHICS COMMITTEE AND REGULATORY APPROVALS

The study will not be initiated before the protocol, consent forms and participant information sheets have received approval / favourable opinion from the Research Ethics Committee (REC), and the respective National Health Service (NHS) Research and Development (R&D) department. Should a protocol amendment be made that requires REC approval, the changes in the protocol will not be instituted until the amendment and revised informed consent forms and participant information sheets have been reviewed and received approval / favourable opinion from the REC and R&D departments. A protocol amendment intended to eliminate an apparent immediate hazard to participants may be implemented immediately providing that the REC are notified as soon as possible and an approval is requested. Minor protocol amendments only for logistical or administrative changes may be implemented immediately; and the REC will be informed.

The study will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, 1996; the principles of Good Clinical Practice, and the Department of Health Research Governance Framework for Health and Social care, 2005.

INFORMED CONSENT AND PARTICIPANT INFORMATION

The process for obtaining participant informed consent or assent and parent / guardian informed consent will be in accordance with the REC guidance, and GCP and any other regulatory requirements that might be introduced. The investigator or their nominee and the participant or other legally authorised representative shall both sign and date the Consent Form before the person can participate in the study.

The participant will receive a copy of the signed and dated forms and the original will be retained in the Study records.

The decision regarding participation in the study is entirely voluntary. The investigator or their nominee shall emphasize to them that consent regarding study participation may be withdrawn at any time without penalty or affecting their employment or loss of benefits to which the participant is otherwise entitled. No study-specific interventions will be done before informed consent has been obtained.

The investigator will inform the participant of any relevant information that becomes available during the course of the study, and will discuss with them, whether they wish to continue with the study. If applicable they will be asked to sign revised consent forms.

If the Consent Form is amended during the study, the investigator shall follow all applicable regulatory requirements pertaining to approval of the amended Consent Form by the REC and use of the amended form (including for ongoing participants).

RECORDS

Case Report Forms

Each participant will be assigned a study identity code number, for use on CRFs, other study documents and the electronic database. The documents and database will also use their initials (first and last names separated by a hyphen or a middle name initial when available) and date of birth (dd/mm/yy).

CRFs will be treated as confidential documents and held securely in accordance with regulations. The investigator will make a separate confidential record of the participant's name, date of birth and Participant Study Number, to permit

identification of all participants enrolled in the study, in case additional follow-up is required.

CRFs shall be restricted to those personnel approved by the Chief or local Investigator and recorded as such in the study records.'

All paper forms shall be filled in using black ballpoint pen. Errors shall be lined out but not obliterated by using correction fluid and the correction inserted, initialled and dated.

The Chief or local Investigator shall sign a declaration ensuring accuracy of data recorded in the CRF.

Source documents

Source documents shall be filed at the investigator's site and may include but are not limited to, consent forms, study records, field notes, interview transcriptions and audio records. A CRF may also completely serve as its own source data. Only study staff shall have access to study documentation other than the regulatory requirements listed below.

Direct access to source data / documents

The CRF and all source documents shall made be available at all times for review by the Chief Investigator, Sponsor's designee and inspection by relevant regulatory authorities.

DATA PROTECTION

All study staff and investigators will endeavour to protect the rights of the study's participants to privacy and informed consent, and will adhere to the Data Protection Act, 1998. The CRF will only collect the minimum required information for the purposes of the trial. CRFs will be held securely, in a locked room, or locked cupboard or cabinet. Access to the information will be limited to the research team and any relevant regulatory authorities (see above). Computer held data including the study database will be held securely and password protected. All data will be stored on a secure server, not on the hard-drives of individual computers. Access to the files will be restricted by user identifiers and passwords.

QUALITY ASSURANCE and AUDIT

INSURANCE AND INDEMNITY

Insurance and indemnity for clinical study participants and study staff is covered within the NHS Indemnity Arrangements for clinical negligence claims in the NHS, issued under cover of HSG (96)48. There are no special compensation arrangements, but study participants may have recourse through the NHS complaints procedures.

The University of Warwick has taken out an insurance policy to provide indemnity in the event of a successful litigious claim for proven non-negligent harm. >> CHECK THIS WITH MARCUS

STUDY CONDUCT

Study conduct will be subject to systems audit for inclusion of essential documents; permissions to conduct the study; CVs of study staff and training received; local document control procedures; consent procedures and recruitment logs; adherence to procedures defined in the protocol (e.g. inclusion / exclusion criteria, timeliness of visits); accountability of study materials.

STUDY DATA

Monitoring of study data shall include confirmation of informed consent; source data verification; data storage and data transfer procedures; local quality control checks and procedures, back-up and disaster recovery of any local databases and validation of data manipulation. The principal investigator, or where required, a nominated designee of the Sponsor, shall carry out monitoring of study data as an ongoing activity.

Entries on CRFs will be verified by inspection against the source data. A sample of CRFs (10% or as per the study risk assessment) will be checked on a regular basis for verification of all entries made. In addition the subsequent capture of the data on the study database will be checked. Where corrections are required these will carry a full audit trail and justification.

Study data and evidence of monitoring and systems audits will be made available for inspection by the REC as required.

RECORD RETENTION AND ARCHIVING

In compliance with the ICH/GCP guidelines, regulations and in accordance with the University of Warwick Code of Research Conduct and Research Ethics, the Chief or local Principal Investigator will maintain all records and documents regarding the conduct of the study. These will be retained for at least 7 years or for longer if required. If the responsible investigator is no longer able to maintain the study records, a second person will be nominated to take over this responsibility.

The study documents held by the Chief Investigator on behalf of the Sponsor shall be finally archived at secure archive facilities at the University of Warwick. This archive shall include all study databases and associated meta-data encryption codes.

DISCONTINUATION OF THE TRIAL BY THE SPONSOR

The Sponsor reserves the right to discontinue this study at any time for failure to meet expected enrolment goals, for safety or any other administrative reasons. The Sponsor shall take advice as appropriate in making this decision.

STATEMENT OF CONFIDENTIALITY

Individual participant medical or personal information obtained as a result of this study are considered confidential and disclosure to third parties is prohibited with the exceptions noted above.

Participant confidentiality will be further ensured by utilising identification code numbers to correspond to treatment data in the computer files.

Data generated as a result of this study will be available for inspection on request by the participating physicians, the University of Warwick representatives, the REC, local R&D Departments and the regulatory authorities.

PUBLICATION AND DISSEMINATION POLICY

Study results will be published and disseminated in a variety of ways. A report of the study will be produced, including an executive summary which will be distributed to

healthcare participants and other interested parties, who may also request a copy of the full report.

Peer-reviewed publications in academic outlets will be pursued, as will outputs in practitioner-oriented publications. Results will be presented at conferences. NIHR SDO will be informed beforehand of any publications. All data will be anonymised and will not refer to any participant or organisation by name.

USER AND PUBLIC INVOLVEMENT

Alignment with CLAHRC NDL activity is central to our engagement plans as follows:

1. Existing PPI mechanisms (POPULOS) within CLAHRC NDL, as part of the CLAHRC NDL's engagement, synthesis and dissemination theme will be used to obtain the input of patients and carers through a PPI sub-group dedicated to our proposed study. The PPI sub-group will comment upon research design, comment on ongoing findings, and facilitate dissemination (Academic lead: Professor Justine Schneider, University of Nottingham). The PPI sub-group will meet separately with the research team 3 times, immediately prior to each SAB meeting above, on the basis that such structural arrangements engender greater participation and patient and public 'voice'. A representative from PPI sub-group will participate in SAB meetings (Ossie Newell CBE, a longstanding regional and nationally recognised PPI lead for elderly care).
2. The CLAHRC NDL model of translating research into practice is one heavily reliant upon knowledge brokering through "Diffusion Fellows"; i.e. senior clinicians and managers working with applied researchers and implementation educators to accelerate the diffusion of evidence into practice. We have identified a Diffusion Fellow within CLAHRC NDL from one of our fieldwork sites to work with the research team around knowledge brokering in patient safety, specifically to diffuse formative lessons throughout the life of the study.

Beyond the involvement of end-users of the research as outlined above, we will disseminate at specific events linked to the proposed research. Dissemination will take place towards the end of the study and will leverage CLAHRC NDL structures and processes designed to ensure that research makes a difference to practice. CLAHRC NDL will offer: 3 'situated learning' workshops (for 20 participants on each

occasion), which subject to local demand, will be opened up beyond NHS East Midlands. Additionally there will be a half day national event tailored for the academic or applied health research community on completion of research. Finally, we will link into existing local, regional and national structures and processes for dissemination as relevant. To ensure further national dissemination, the research team will seek to present findings at: SDO Network events; annual HSRN/SDO Conference; annual NHS Confederation Conference. Finally, the research team will engage in collective research efforts facilitated by the SDO Network. Dissemination of formative lessons as the research progresses through the channels above, and feeding into the six-monthly interim and final reports for NIHR SDO. Most obviously, in focusing our empirical work upon organisational level risk management structures, we are likely to engage important NHS stakeholders in our research. We will feedback our research findings locally within our empirical sites. More generally, we will target learning, and invite attendance at our dissemination event, and disseminate executive summaries of our research, focused upon knowledge brokers revealed within our study; e.g. target learning at clinical directors, clinical governance leads or practice development leads in elderly services, or at corporate level, the risk manager or medical director.

STUDY FINANCES

Funding source

This study is funded by NIHR SDO Programme (2011-2013, £301, 178)

Participant stipends and payments

Participants will not be paid to participate in the study.

SIGNATURE PAGES

Signatories to Protocol:

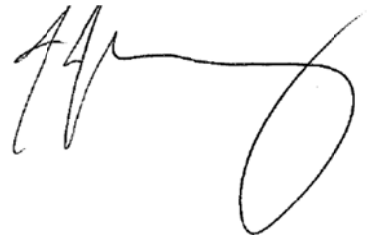
Chief Investigator: (name) Graeme Currie

Signature:

Date: 06/01/2011

Co- investigator: (name) Justin Waring

Signature:



Date: 06/01/2011

Co- investigator: (name) John Gladman

Signature:

Date: 06/01/2011

Co- investigator: (name) Andy Lockett

Signature:

Date: 06/01/2011

Co- investigator: (name) Leroy White

Signature:

Date: 06/01/2011

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