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The detection and management of pain in patients with dementia in acute care settings

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Aims and Objectives

The aim of this study is to identify how pain is currently detected and managed for patients with dementia in acute care settings and to assess the feasibility of introducing decision support tools to assist with the process.

The study will address the following research questions:

1. How are clinicians detecting, managing and documenting pain in people with dementia in acute care settings?
2. What is the clinical utility of existing tools to assist with the detection and management of pain in people with dementia in acute care settings?
3. How acceptable and feasible would it be to introduce decision support tools into acute care settings?
4. What is the role of carers in supporting the detection of pain in people with dementia in acute care settings?

The study has the following research objectives:

1. To identify the evidence base for existing tools that focus on the detection and management of pain in patients with dementia.
2. To explore current processes for the detection and management of pain in patients with dementia across acute care settings.
3. To develop decision support tools that could be used to assist with the process of pain detection and management in patients with dementia.
4. To assess the feasibility of using the decision tools in acute care settings to assist with the detection and management of pain in patients with dementia in acute care settings.
5. To provide strategies for incorporating carers' expertise into the detection and management of pain in people with dementia in acute care settings.
6. To provide data to inform the development of a randomised trial of decision tools to improve pain management, if they are assessed as feasible.

Background

'Dementia' is a broad term, comprising a number of chronic neurodegenerative syndromes, including Alzheimer's disease, vascular dementia and frontotemporal dementia[1]. These syndromes are associated with multiple changes in the brain, causing deterioration in cognitive performance as well as changes in behaviour, personality and communicative functioning[2 3]. Increasing age is a key risk factor for developing dementia and it is estimated that 1 in 14 people over 65 years have a diagnosis of dementia, increasing to 1 in 6 people aged over 80 years[1].

The Alzheimer's Research Trust[4] estimate the cost of health care for people with dementia to be £1.2 billion of which hospital inpatient stays account for 44%. Dementia increases the length of hospital admission by an average of four days to more than 23 days[5 6], resulting in an increase in complications[7] and the risk of iatrogenic harm through polypharmacy[8]. A recent study found that 42% of acute hospital inpatients had a diagnosis of dementia[9]. Furthermore, nurses and nurse managers reported that 97% of responders had either sometimes or always cared for someone with dementia on a hospital ward, although healthcare professionals and clinicians do not always have skills, confidence and training to address the needs of people with dementia[10]. In England the National Dementia Strategy has prioritised the need to improve the quality of care for people with dementia in general hospitals

(objective 8)[11].

Detecting and managing pain in people with dementia is of significant concern, especially in those who may be unable to self report (88-95% of people with dementia have difficulties with verbal communication)[12,13]. There is a wealth of evidence to suggest that pain is commonly under-detected and poorly managed in people with dementia, particularly within acute care[14,15], leading to an increase in functional decline, slow rehabilitation, disturbances in sleep routine, poor appetite, impaired movement and an increased risk of falling[16-18].

There are considerable challenges related to the evaluation of pain experiences in patients with dementia; they may fail to recollect, interpret and respond to recent pain and report only the 'here and now' experiences[19]. People with dementia are susceptible to the same potentially painful conditions as those who are cognitively intact, and there is no evidence to suggest that people with dementia experience any less pain as a consequence of their cognitive impairment[20]. Recognising pain in people with dementia has often been described as a "guessing game" by some healthcare professionals[21] and the Counting the Cost report[10] identified that 51% of carers and nurses were dissatisfied with their ability to detect pain, and 71% of hospital staff wanted more training in recognising pain.

A study undertaken in one UK hospital showed that 95% of patients with advanced dementia were in pain[22] and research suggests that patients with dementia are less likely to receive pain control in acute hospital care settings[23]. The experience of pain may lead to protective responses such as aggression, agitation, vocalisations, depression and withdrawal[24]; however, there are no behaviours which are exclusively associated with pain. In people with dementia such behaviours may also indicate boredom, hunger, depression or disorientation[25]. Therefore, pain behaviours lack specificity and some pain scales may actually be detecting distress rather than pain. This is particularly relevant in the acute hospital where the person with dementia is in an unfamiliar, fast moving and confusing environment. Most pain tools for use with people with dementia have been developed within long-term care and more work is required to establish whether the use of pain tools is feasible in the acute hospital and whether these tools are reliable in detecting pain. To date, there have been no studies in the United Kingdom exploring how pain is detected and managed in people with dementia on acute hospital wards.

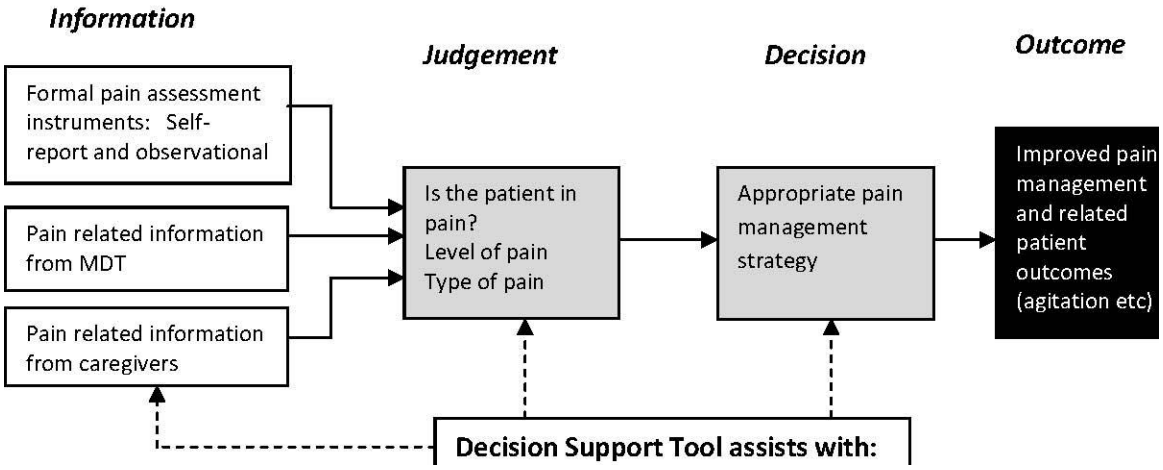
Detecting and managing pain are cognitive activities associated with decision making. Pain detection involves identifying information cues (e.g. from a formal assessment tool, patient self report, observation of behaviour) that would indicate a patient is experiencing pain. Clinicians then evaluate those cues to reach a judgement regarding the nature of a patient's pain, before making a decision regarding what to do to manage that pain (the decision process). If individuals fail to assess a patient's pain effectively or detect they have pain but then decide not to do anything regarding managing it, pain can be poorly controlled. The use of decision support tools can aid clinicians in the decision making process, improve both the processes and outcomes of care[26] and subsequently lead to an improvement in the quality of care for patients. In this study we intend to develop decision support tools that assist clinicians with both the process of judgement (detection of pain) and decision making (what actions to take on the basis of the judgement made). Figure 1 provides an overview of the theoretical framework that is guiding this study.

There is a paucity of research in this area, with one ongoing study evaluating the link between pain and behaviours in patients with dementia in acute hospital settings. This ongoing study has highlighted that pain assessment and management is a problem in acute settings; however it has not explored how to best improve care. Building on these findings our proposed study will address this gap by producing interventions that can be used as the basis for providing better quality care in the management of pain in people with dementia, through supporting the decision processes of clinicians, and providing insights into how carers' expertise can be incorporated into the decision process.

Need

People with dementia are at risk of their pain being unidentified and poorly managed whilst being cared for in acute settings, and staff often find it challenging to manage this group of patients. This study builds on the research currently being conducted by one of the co-applicants (ES) that has identified pain as a key issue for patients

Figure 1: Theoretical Framework



with dementia in acute hospital settings, and the current problems with assessment and management. Our multi-site study will provide valuable insights into the challenges faced by clinical staff when assessing and managing pain in patients with dementia. It will produce decision support tools that have been initially tested for acceptability and feasibility in acute care settings, which can then be fully evaluated in a randomised controlled trial. This study will benefit patients and the NHS by providing guidance and support to clinicians and carers in the management of pain in a vulnerable (and currently overlooked and under researched) patient population.

Methods

The MRC framework for the development and evaluation of complex interventions has been used to guide the study design[27]. In this study we are following a technology development process where we are focusing on developing the intervention (bench testing) before field testing it through the development of associated implementation strategies and assessing its feasibility for use in clinical practice. Clinicians and carers will be involved in all stages of the study as co-designers of the intervention. The study has three components:

1. Two linked systematic reviews of existing evidence. The first review is designed to provide an overview of existing tools for use with individuals who have

any form of cognitive impairment. It will provide an overview of existing tools to map out potential available assessment tools and the settings where they have been evaluated. The findings of this overview will then be used as a focus for the second review. This review will explore the psychometric properties and clinical utility of tools to assess pain in older people with any degree of cognitive impairment in acute settings. We are carrying out the two reviews, as we may identify tools in the first review that have been developed for use in the acute setting, but have never been tested, that would be missed if we only carried out the second review. We will synthesise the findings of the two reviews to provide an overview of the evidence for existing tools that could be used in the decision support intervention designed in stage three of the study. Both reviews will be conducted in collaboration with the Nottingham Centre for Evidence Based Nursing and Midwifery, a collaborating centre of the Joanna Briggs Institute (JBI). *Search Strategies:* Search strategies for both reviews will be based on the approach adopted by the JBI. An initial search using key words derived from Zwakhalen[28] including (Pain) AND (Scale OR assessment OR measure) AND (Elderly OR geriatric OR cognitive impairment OR dementia OR Alzheimer) for review 1 and including (Pain) AND (Scale OR assessment OR measure) AND (Elderly OR residents OR geriatric) AND (cognitive impairment OR dementia OR Alzheimer) AND (hospital OR Acute Care OR inpatient OR secondary care) for review 2 will be entered into a number of databases. These will include (but not be limited to) MEDLINE, CINAHL EMBASE and PSYCHINFO using both MeSH headings and keywords. Retrieved papers will be analysed for key terms and a full search strategy developed in consultation with information specialists. The Cochrane collaboration and JBI libraries of systematic reviews and the Centre for reviews database will also be searched. Following a full search, the references of the retrieved papers will be reviewed for any papers not already identified. A hand search will be conducted of key journals and conference abstracts and thesis. Thesis will be searched using resources including Index to thesis (http://www.theses.com/) and the British Libraries EThOS service (http://ethos.bl.uk/Home.do). Key experts in the area will be consulted including contacting members of the International Association for the Study of Pain's Pain in Older Persons special interest group and the British Geriatrics Society Pain Group. *Study Inclusion:* For review 1 papers will be included if they are reviews carried out systematically and address the use of pain assessment tools in older adults with any degree of cognitive impairment. Reviews addressing studies of clinical utility and psychometric properties of any tool using any measures will be included. While verbal report is acknowledged as the gold standard for pain assessment and some studies have compared verbal report with behavioural assessment in those with mild impairment, comparisons with staff assessment have also been reported. There is no clear agreement on the best approach to the assessment of accuracy in pain assessment tools for older adults with cognitive impairment so reviews addressing all approaches will be included. For review 2 papers will be included if they address the clinical utility and psychometric properties or measures of diagnostic accuracy including sensitivity, specificity, positive and negative predictive value, overall classification rate, and likelihood ratio (LR). The review will include all comparators including but not limited to patient verbal report, staff or relative assessment or any other tool. To be included the assessment scale should be used to measure pain by means of self-reports by patients or behavioural or physical measures. For both reviews case reports or secondary sources/reviews and papers not available in English will be excluded. Whilst we recognise that best practice to review world wide literature, given our understanding of the strength of pain research in the English language journals we have decided it would not be a fatal flaw of the study to restrict to studies published in English.

Reviews will be reviewed for the inclusion criteria by two reviewers initially on the basis of titles and abstracts. Included papers will be retrieved and read by two

reviewers to confirm their inclusion in the review. Any disagreements will be referred to a third reviewer. Critical appraisal will be will be carried out by two independent reviewers, using a tool based on the AMSTAR[29] systematic review critical appraisal tool and the PRISMA (http://www.prisma-statement.org/) statements for review 1 and the Quality Assessment Tool for Diagnostic Accuracy Studies (QUADAS) and tools developed by JBI for review 2. *Data extraction:* Data extraction will be conducted by two reviewers using a data extraction form developed for the study based on the standardised tools developed by JBI. For review 1 this will include inclusion/exclusion criteria, total sample size, assessment of methodological quality, results of meta-analyses or narrative summary, measures of sensitivity, specificity and accuracy, measures of clinical utility and overall conclusion of the authors. For review 2 this will include inclusion/exclusion criteria, total sample size, assessment of methodological quality, results of metaanalyses or narrative summary, measures of sensitivity, specificity and accuracy, measures of clinical utility and overall conclusion of the authors.

Data Analysis: For review 1 the papers will be synthesised using a narrative synthesis. For review 2 we will consult a statistician in relation to the appropriateness of a meta analysis should there be sufficient homogeneity in the studies obtained. Meta analysis methods of diagnostic accuracy papers are being developed but are complex and of questionable use in clinical judgements. If there is not sufficient homogeneity in the studies a narrative synthesis will be conducted.

2. A multiple case site study with embedded units of analysis (individual, ward, organisation). Case studies are an empirical design which focuses on describing phenomena within their real life context[30]. In this study we will be using the case studies to identify:

- Information currently used by clinicians when detecting and managing pain in patients with dementia,
- The existing process of decision making for detecting and managing pain in patients with dementia,
- The role (actual and potential) of carers in detecting and managing pain in patients with dementia,
- The organisational context in which clinicians operate, with regard to the detection and management of pain in
- patients with dementia,
- How decision tools could be introduced into acute care settings to assist with the detection and management of pain in patients with dementia.

Case site selection

Four case sites (hospitals) will be theoretically sampled to provide varying settings of acute care. Criteria for sampling will include type of hospital (tertiary referral centre/secondary care) and type of service provision available to health care professionals (HCP) in the hospital (e.g. a specialist pain management team, dementia outreach team). In each site two wards will be selected for data collection. Selection of wards will also be theoretically driven to ensure that across the sample we have representation from a variety of clinical settings in acute care where patients with dementia may be cared for (e.g. orthopaedic, acute medicine, care of the elderly). This is to ensure that we derive a detailed comparative overview of how pain is currently detected and managed in patients with dementia in acute care settings.

Data collection: In each case site a variety of data collection methods will be used to provide multiple sources of evidence for addressing the research questions. Non-participant observation of HCPs interacting with patients who have dementia will be used to identify how information appears to be used to detect and manage pain and the care processes that are currently used (e.g. how and where pain is documented, interactions between HCPs, patients and carers, interactions between members of

the multi-disciplinary team (MDT) and availability of resources). An observation protocol derived from the theoretical framework will be used to guide data collection.

Semi-structured interviews will be carried out with clinical staff (nurses, doctors, other members of the MDT) and carers to explore their perceptions of how pain is currently detected and managed, how carers are currently involved in the process, how the process may be improved and what an effective tool would look like (e.g. format, content, resources). In addition, we will interview managers (at unit and organisational level) to gain a wider organisational perspective on the importance attached to the detection and management of pain in patients with dementia, and organisational policies/procedures in place or currently being planned to deal with the issue. Where possible we will also obtain copies of existing policies and procedures in place in the unit and/or organisation that are specifically focused on the detection and management of pain in patients with dementia. *Sample:* There is no consensus regarding how many periods of observation or interviews are necessary to provide an adequate overview. Based on our previous case site work[31], a sample of 40 periods of observation per case site provided a detailed insight into relevant decision processes. We therefore intend to carry out non-participant observation of 40 shifts per case site where HCPs interact with patients who have dementia (total n=160). We anticipate carrying out approximately 15 interviews with clinical staff per site, although the number may vary depending on whether interviews are revealing new data (total n = 60). Similarly we anticipate interviewing 10 carers (total n = 40) and 5 managers per case site (total n = 20). Again this number may vary depending on the type of data being obtained. *Data Analysis:* Data for analysis will consist of verbatim transcripts of observation sessions, field notes and interviews, together with copies of existing policies and procedures. Data will be analysed with the assistance of the specialised software NVivo using thematic analysis. Themes for the analysis will be derived both from the theoretical framework (e.g. information used to inform pain management decisions, sources of information, types of judgements, types of pain management decisions) and inductively from the data. Transcripts will be read and re-read to identify themes or categories, which will be used to code the data[32]. Data in each theme will then be examined to ensure that all manifestations of each theme have been identified, before interconnections between themes are explored[32]. To increase transparency in the analytic process, two researchers will be asked to verify the identification of themes and assignment of text to analytic codes.

3. Development of decision tools and feasibility testing.

Decision Tool development: Following stages 1 and 2 we will have identified existing evidence based tools that are currently in use for the detection and management of pain in patients with dementia, together with a detailed picture of how pain is currently managed, the role of carers in the process and insights into how care processes could be improved in acute hospital settings. Using the theoretical framework as a guide, we will produce a synthesis of the findings to provide a structure for decision tool design. The exact nature of the format of the tool(s) will be decided upon, on the basis of the findings from stages 1 and 2; however, it is likely that it will include the following elements:

- A framework for identifying relevant information to be used to assist with detecting whether or not a patient is in pain. This will include identification of appropriate pain assessment tools, observational cues, information derived from carers and from the MDT.
- Guidance on pain management strategies once the presence of pain has been detected based on established pain management protocols.
- Mechanisms for evaluation and feedback to ensure that if strategies are ineffective, pain is reassessed and different pain management approaches are put into place.

When designing the tool we will draw on evidence into the effectiveness of decision support interventions which suggest that tools should be integrated into a clinician's practice, provide guidance at the point of decision making and provide care recommendations[33]. We are anticipating that the tool will be paper based; this can then be adapted for a computerised format at a later stage if the tool is shown to be acceptable in practice.

The tool will be iteratively evaluated and refined using focus groups with HCPs working in acute care environments and carers of individuals with dementia. Findings from one focus group interview will be used to refine the format and content of the decision tool(s), which will then be used as the focus for the next interview. Focus groups are a form of group interview that specifically use the interaction between group members to generate data[34]. In this part of the study we are interested in exploring health care professionals and carers evaluation of the decision tool(s) and their attitudes towards their use in practice. Focus groups are ideal in this situation, as they facilitate expression of criticism and enable the examination of participants' different perspectives[34 35].

Sample: we will use a purposive sample of participants drawn from the clinical areas where the decision tools are planned to be implemented, and carers of patients with dementia. Each focus group will consist of 6-8 participants and will either consist of HCPs or carers. There is no consensus on how many focus groups are necessary for an individual study[35]. Based on the experience of our previous studies[36] we anticipate running a total of 8 focus groups with clinical staff (2 in each clinical site implementing the tool) and 4 focus groups with carers (1 in each clinical site). The focus groups will be held on hospital premises for staff, and in a convenient location in the community (if appropriate) for carers. We will try to maximise attendance at the groups by providing refreshments, paying the travel expenses of attendees (where appropriate) and giving a £20 gift voucher to all participants as a thank you gesture for their time.

Analysis: Each focus group will be audio-recorded digitally and transcribed verbatim as soon as possible after the interview. The process of analysis will be similar to that for the qualitative data analysed in stage 2; using thematic analysis and assisted with a software program such as NVIVO. At the end of the focus group study we will have refined the decision tool(s), and ensured they have acceptability for health care professionals and carers of individuals with dementia. *Assessment of acceptability and feasibility of decision tool(s) in clinical practice:* Final versions of the decision tool(s) will then be assessed for feasibility and acceptability in acute hospitals. We will also collect data on potential outcome measures and conduct an economic sub-study to inform a full RCT of the decision support tools, providing they are evaluated as feasible and acceptable. Concurrently, we will test methods for identifying individuals with previously undiagnosed dementia (estimated to be approximately 50% of people with dementia in general hospitals).These are likely to be simple screening tools that are used in clinical practice, such as the Abbreviated Mental Test Score (AMTS). We will define inclusion/exclusion criteria in relation to individuals with delirium superimposed on dementia. Data from Stage 2 of the study will be used to inform an implementation strategy for each care setting, to ensure that the decision tools can be integrated into clinical practice, be used at the point of decision making, and are adapted to the organisational and care processes of each clinical ward. The exact process of implementation will need to be developed in liaison with the clinical areas, but is likely to include:

- Education and training of clinicians.
- Identification of 'champions' that can help with the implementation process.
- Provision of information and support to patients and carers in the clinical units.

- Negotiation with unit managers regarding how to integrate the decision tools into normal working processes (including documentation processes).

The decision support tool(s) will be introduced into 4 acute hospital wards, sampled from the units participating in stage 2 of the study. Evaluation of the acceptability of the tool(s) in practice will include use extent of tool use (through analysis of completed documentation), non-participant observation of the practice settings to identify when and how the tool is used by clinicians to detect and manage patient pain, semi-structured interviews with clinicians and patients/carers.

Sample: As highlighted in the discussion of sample size in section 2, there is no consensus regarding the 'optimum' number of observations or interviews that can provide data on decision tool use. We therefore propose to collect a similar number of observation sessions and interviews in each ward to compare to the data collected pre-decision tool implementation in each case site. This will provide a data set of 20 observations per ward (total n=80), 8 interviews with clinical staff per ward (n=32), 5 interviews with patients/carers (n=20) and interviews with 3 managers (n=12). As before, the exact number of interviews may vary, depending on the depth of information being collected. *Outcome measures:* We will collect data on pain and distress levels using validated tools. Validated tools will be identified via the systematic reviews, but are likely to be similar to the Abbey pain scale and the PAINAD[37 38]. Distress will be measured using the DisDAT[39], which has been used for patients with cognitive impairment, but not in acute care settings. We will also audit the medical and nursing notes for documentation of pain assessment, action taken, pain reassessment and medication administration.

The economic sub study will identify resource use associated with the interventions, develop health economic data collection forms and explore use of the outcome measures to assess proxy issues and generate hypotheses about the domain of impact. Initial data collection forms will be developed drawing on existing literature in the field. These data collection forms will be designed to capture health and social care resource use associated with the intervention and its implementation and will be designed to allow tick box completion where ever possible. Feeding into the semi-structured interviews with clinical staff, patients and carers, opinion will be sought in respect of:

- Identification of resource use associated with the intervention,
- Acceptability/feasibility of draft questionnaires and their content,
- The optimal method and timing of data collection.

The data collections forms will be adapted in line with the results from the interviews. The semi-structured interviews will also provide a forum in which to assess the feasibility of patient self-completion of outcome measures suitable for use in an economic evaluation. This will include the EQ-5D, the EQ-5D proxy version (http://www.euroqol.org/home.html), DEMQOL and the DEMQOL-Proxy (developed for completion by carers of people with dementia)[40].

Contribution to collective effort and research utilisation

The outcomes of this programme of research will initially be disseminated through academic channels including publication in a peer reviewed journal and presentation of findings at national and international conferences. This will particularly focus on events targeted to clinical and nursing professionals.

The primary deliverable of this research will be a new decision support tool for professionals in acute care settings based on robust evidence and stakeholder consultation. The tool will be developed with a view to further evaluation in a randomised controlled trial. In addition to the tool, a further output will be the publication of evidence-based guidance for professionals on the assessment and treatment of pain in people with dementia. The guidance will be developed in hard copy and online format through Alzheimer's Society. The Society recently produced a

best practice guide for clinicians (www.alzheimers.org.uk/bpsdguide) and has expertise in producing and disseminating high quality publications and resources for professional audiences. Further guidance will also be developed in hard copy and online formats to support people with dementia and carers and encourage them to be actively involved in their treatment and care.

A dedicated dissemination plan will be created to promote these resources through Alzheimer's Society's extensive communications channels. This will include targeted publicity for professionals through trade journals and professional channels, as well as general publicity through print, broadcast and new media. The Society will provide further support to work closely with policy makers, commissioners and governing organisations such as the Royal College of Nursing to promote the guidance and to raise awareness of the importance of good assessment and treatment of pain in people with dementia. This work will ensure that the findings of the research are translated into tangible outputs that will help to change clinical practice and behaviour according to the best evidence, thus improving the treatment and care people with dementia receive in acute care settings.

Plan of investigation and timetable

The project will be for 36 months with the following milestones:

Pre-study: Application for ethical and governance approval for case sites
Months 1-10: Systematic review 1 and 2.
Months 1-3: Organisation of case site data collection.
Months 4-8: Data collection at case sites: Interviews with clinical staff, carers and managers. Observation of practices.
Months 7-12: Analysis of case site data
Months10-12: Dissemination of systematic review: production of paper for publication.
Months 12-13: Year 1 progress report
Months 13-19: Dissemination of case site study, development of preliminary decision tools, application for ethical and governance approval for focus groups and feasibility study
Months 19-21: Focus group data collection
Months 20-24: Focus group data analysis
Months 24-25: Year 2 progress report
Months 25-30: Feasibility study. Implementation of tool in clinical areas, observation of tool use, interviews with clinical staff, carers and managers.
Months 28-33: Data analysis feasibility study
Months 33-36: Final report, dissemination from feasibility study. Production of materials for professionals and carers. Production of papers for publication.

Approval by Ethics Committees

The project is in three stages. Stage 1, a systematic review of reviews does not require ethical approval and can commence immediately the project commences. Stage 2, the case site study and stage 3, the development of the decision tool and feasibility study will require NHS ethical and research governance approval. We propose to carry out data collection across 4 NHS acute hospital settings, involving NHS staff, patients who have dementia and their carers in the study. The research team has considerable experience carrying out research with these patient groups and obtaining the requisite approvals to do so. We will apply for ethical approval for stage 2 of the study pre-project. We will need additional approval for stage 3 of the study; this will be applied for during year 2.

Project Management

All applicants will be part of the project management group (PMG), which will be led by DD who will have overall responsibility for project management and co-ordination of the study. There will also be local management groups (LMG) at each of the study sites (Leeds, Greater Manchester, Nottingham, London) led by DD, JK, NA and ES respectively, who will have responsibility for the day to day management of research fellows, data collection and data analysis connected with the study site. Each LMG will consist of members of the study team, together with clinicians from each study site who will be acting as clinical consultants to the study and carers. They will meet regularly and report issues directly to the PMG which will meet at two monthly intervals (either via teleconference or face to face). Each LMG will also have a local advisory group consisting of clinicians, service users and their carers, representatives of local user organisations (such as the Alzheimer's Society) who will meet every six months and provide input into each stage of the project. We will also convene a larger project advisory group, made up of representatives from the local advisory groups, together with national stakeholders (e.g. representatives from DenDRON, the Alzheimer's Society, Department of Health) to provide guidance to the project from a national and policy level. We plan for this group to meet three times over the duration of the project.

Public Contributor/Patient Involvement

Patient and Public Involvement for this research will be led by Alzheimer's Society through co-applicant AC. The experiences and opinions of people with dementia and their carers will be integral in the information gathering stage and in the development of the decision support tool and guidance which are the key deliverables from the research. It will be particularly important to consider any challenges or opportunities identified by these consultations to ensure the accuracy and success of the research. This work will be done through focus groups and interviews with these important stakeholders. In addition to the case study sites Alzheimer's Society's Research Network, a group of people with dementia, carers and former carers, will be involved in this work. The Network is experienced in reviewing, prioritising and monitoring research. Care will be taken to ensure that participants from the Network have had experience of the issues raised by this research to ensure their involvement is timely and relevant. Transcripts of sessions will be coded and analysed to capture all the views raised, and integrated into the main project management group.

To ensure a stakeholder perspective across the programme of research, lay representatives will be involved on the Project Management Group and Local Management Groups. Two members of the Alzheimer's Society Research Network will provide oversight for the full programme via the advisory group. In addition, people living with dementia will be fully involved in disseminating the outcomes of the research, particularly in ensuring the key messages are delivered as widely as possible to people with dementia and carers.

Expertise and Justification of Support Required

Expertise: The team comprises the listed co-applicants and clinical collaborators from Leeds Teaching Hospitals Trust (Liz McGinnis, Helen Brooks), Greater Manchester West Mental Health NHS Trust (Lesley Jones), Nottingham University Hospital (Sohota Opinder) and the University of Nottingham (Catherine Vass). Carer representatives from the Alzheimer's Society will become consultants for the research team. The team has expertise in the development and evaluation of decision support interventions (DD), pain research (SJC, NA, MB, CS, CH, CV, ES) and dementia (JK, CS, JH, CH, AC, ES), together with providing clinical and carer input into the study. We have methodological expertise in systematic reviewing (MB, NA, JH), multi-site case studies (DD), qualitative research (SJC, MB, DD, JK, CS)

and expertise in recruiting hospital patients with dementia and their carers into research studies (ES, JH, JK, CS). *Contribution of applicants:* DD as PI will have overall responsibility for project management and study co-ordination. She will be responsible for the management and supervision of the researcher based at the Leeds site. JK, ES and NA will have responsibility for management of the local aspects of the study at each of the local study sites (Greater Manchester, London, Nottingham), including the management and supervision of researchers based in these sites. CS will be the researcher employed on the study at the Greater Manchester site, and will have day to day responsibility for project organisation, data collection and analysis in this site. NA will be responsible for review 2, MB will be responsible for review 1. SJC, MB and NA will provide expertise in how to develop and implement tools for the assessment and management of pain in patients with cognitive impairment. JH, JK and ES will provide expertise on the care and management of people with dementia in acute care settings. AC will provide expertise on public/patient involvement and dissemination of study outputs. CH will provide expertise on the economic evaluation elements of the feasibility study. All co-applicants will be part of the PMG and provide input into project management, study design, organisation of data collection, data analysis and dissemination of study outputs. Clinical collaborators (LM, HB, LJ, SO, CV) are nurses and physicians with expertise in caring for patients with dementia. They will assist with facilitating organisation of data collection for the study in each of the local clinical sites, and provide clinical expertise and guidance to the study. Their input is vital to ensure that study interventions have clinical relevance and can be implemented effectively. *Justification of support:* The project will be conducted across 4 sites (Leeds, Greater Manchester, Nottingham, London) requiring researchers to be based in all four sites. The systematic reviews will be conducted in Leeds and Nottingham; all other aspects of data collection and analysis will be spread across all four sites. We have claimed for 4 researchers to support study activity, one for each study site. The Leeds researcher will be responsible for overall organisation of the study, contribute to the development of study materials, assist with the systematic reviews, carry out data collection in the Leeds site and contribute to data analysis. Researchers at the other 3 sites will be responsible for organisation of the study in their site, and contribute to the development of study materials, data collection at their site and data analysis. The researcher based in Nottingham will also contribute to the systematic review element of the study. All researchers will require project management and qualitative research skills. We have claimed for the following research staff costs:

- One whole time researcher for 3 years at framework grade 8 (Leeds).
- Two 0.5 FTE researchers for 3 years at framework grade 7 (Nottingham and London).
- CS (co-applicant) will also be responsible for the study at the Greater Manchester site and has been costed at 0.6 FTE for 3 years to reflect both her participation in the study and the additional responsibilities associated with being a co-applicant.

There are also costs associated with the time each co-applicant and clinical collaborators will spend on the study as follows:

- DD is PI for the study and has been costed at 20% of her time for 3 years.
- JC, MB, NA, JK, JH, CH, AC will all spend 5% of their time on the study over 3 years.
- ES (co-applicant at UCL) will be grant funded with Marie Curie during the lifetime of this project. Costings reflect the indirect and estate costs associated with her participation but not salary costs.
- LJ (Greater Manchester) has been costed as a consultant to the study. Input from the Leeds Teaching Hospitals
- Trust have been costed at the equivalent of a band 8 nurse and a band 7

nurse, each for 2.5% of their time over the 3 years. CV and OS (Nottingham) have been costed on the basis of 1 day a month for 3 years.

We have also requested costs for secretarial support to the study; 10% of a grade 5 for 3 years, 100% of an information specialist for 3 months to support the systematic review element of the study. We have also claimed for the costs associated with the running of the study. This includes the provision of a laptop computer for each research fellow, digital recorders and transcription equipment. Costs associated with the field work include travel to each of the case sites, transcription of 194 interviews across the duration of the study and vouchers for focus group participants. Travel costs include travel for carers and other members of the advisory group to attend project meetings, together with the costs of all project applicants meeting face to face 6 times during the study. We have requested funding for the provision of 300 inter-library loans (associated with the systematic reviews) and general stationery and printing costs for the duration of the study. We will also be providing payment and expenses to carers who are participating in the study as members of the LMG and PMG. Additional associated costs include PPI input (focus groups) and a dedicated budget for effective dissemination through conferences, publications, information resources and targeted publicity.

Planned or active related research grants

DD: This study builds on the evidence and experience gained from previous national and international studies funded by the DoH, NIHR RfPB and the Commonwealth Fund on the development and evaluation of decision support tools. At the present time DD will have no other ongoing grants held concurrently with this one. ES is currently funded as a PI by the Alzheimer's Society and BUPA Foundation for a study of pain and behavioural problems in people with dementia admitted to the acute hospital (BePAID). She has also been funded by CR-UK to run a three year programme grant to develop interventions to improve end of life care for people with dementia. This is due to commence in January 2012. JK currently holds a Manchester Health Innovation and Education Cluster [HIEC] grant funding an on-going study in developing training materials for general nurses working in the acute sector with people with dementia; this project ends in March 2012. He is currently a grantholder on the Alzheimer's Society QRD funded 'sign language and dementia study' (ending September 2012) and has recently worked as part of the SDO funded multi-site Transitions in Dementia study.

History of past or existing NIHR programme research

DD: One NIHR RfPB grant (no: PB-PG-1207-15081) was given a time extension of 3 months due to problems with the local PCRN**.** JK: Local PI one NIHR HTA multi-site reminiscence trial (trail registration: ISRCTN42430123) which was given a 6month extension mainly due to initial problems associated with securing NHS support and treatment costs.

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