

The development and testing of a communication skills training intervention for healthcare professionals caring for people with dementia in acute hospitals

Protocol V1.0

Sponsor: Nottinghamshire Healthcare NHS Trust

Chief Investigator: Professor Rowan Harwood

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1. SUMMARY OF RESEARCH

Background:

This proposal aims to develop and then test a communication skills training intervention for health care practitioners (HCPs) caring for people with dementia (PWD) in acute hospitals. There are increasing numbers of PWD in acute hospital beds, and improving the quality of care they receive is a priority for the NHS following the Francis Report. Communication problems between staff and people with dementia are likely to be a key barrier to effective healthcare. The challenges of communicating with PWD in acute settings have not been fully explored so there is a need for some exploratory research on the linguistics, context, and facilitators that overcome some of the communication challenges commonly experienced between HCPs and PWD. This can then form the basis for the development of a communication skills training intervention specifically for HCPs working in acute hospitals caring for PWD.

Aims:

This research aims to develop and test a communication training intervention for healthcare professionals (HCPs) caring for people with dementia (PWD) in acute hospitals. Improved HCPs communication skills will reduce distress and challenging behaviour, improve dignity and patient experience and their inclusion in decision making.

The specific objectives are to:

1. Analyse the structure of communication patterns used by HCPs communicating with PWD in the acute hospital environment
2. Identify the communication skills that overcome the challenges of interacting with people with dementia in this setting
3. Train actors to simulate the communication of a person with dementia in this setting, in order to support the training and assessment of HCPs
4. Develop a new intervention to effectively teach these communication skills to HCPs
5. Pilot the intervention to establish effectiveness on intermediate outcomes measures (self-rated competence and confidence) and objective blindly-assessed skills using videoed simulated communication encounters and the usability and acceptability of the training intervention.

Setting:

The research will take place in two hospitals. The initial data collection and analysis of communication between HCPs and PWD will take place on Health Care of Older People (HCOP) wards of a large teaching hospital. The evaluation of the communication skills training intervention will take place in two large acute hospitals.

Design:

Work Package 1. Identification of Good Communication Skills (12 months): We will use Conversation Analysis (CA), supplemented by observations, to analyse the structure of communication patterns used by HCPs to communicate with PWD in the acute hospital environment. The aim will be to identify the communication skills that overcome some of the challenges of communicating with PWD in this setting. Interactions between HCPs and PWD will be video-recorded and transcribing to give up to 400 minutes of data. Applied CA will be used to reveal systematic patterns in the interactions between HCPs and PWD, and identify the practices that HCPs use in effectively addressing some of the challenges of interacting, for example, improving understanding, reducing resistance to care, easing distress.

Work Package 2. Intervention Development (6 months): From the results of Work Package 1 we will develop a communication skills training intervention which can be realistically implemented across acute trusts. Members of the research team have experience of developing similar interventions for communication training in other areas of healthcare. We will draw on this expertise, as well as the expertise of carers of PWD and established knowledge about good practice in communication training. The intervention will include the use of simulated interaction and online e-learning resources (Reusable Learning Object, RLO) with commentaries from patients and carers and real life excerpts of successful communications.

Work Package 3. Intervention Testing (9 months): The intervention will be tested on 40 HCPs in two acute hospitals using a before and after design. HCPs self-assessed competence and confidence in communicating with PWD will be measured using a purpose-built scale prior to training, immediately after training and at 4-

week follow-up. The communication behaviours of HCPs will be videoed before the training and at follow-up, and will be objectively assessed using blind-rating by two independent raters (including researchers and carers).

The flowchart in Appendix 1 shows the overall design of the study, and how these Work Packages relate to one another.

Potential Outputs and Impacts:

The main output from this research is a standardised training intervention and associated training manual and RLO. In addition, we will produce briefing material and resources for actors to support their simulation of dementia patients. Finally, knowledge about effective HCP communication behaviours when caring for PWD will also be generated, which could be used to help develop further interventions to support quality care for PWD.

2. BACKGROUND AND RATIONALE

A quarter of people in acute hospital beds have dementia [1]. A key barrier to effective healthcare in acute hospitals is the problem of communication between staff and people with dementia (PWD). Communication impairments associated with dementia include difficulties with word finding, repetition of thoughts and lack of coherence in their own speech, and difficulty understanding the language of others, with potential progression to a state where no intelligible speech is used [2]. These communication and cognitive disabilities are likely to be aggravated by admission to hospital for acute care because of the unfamiliar environment which is noisy, busy, with lots of new faces, and a communication model based on intensive and repeated questioning. Whilst there is a national drive to ensure older people are treated closer to home wherever possible, there will remain a need for acute hospital admission for the acute ailments that commonly affect older people.

Improving the quality of hospital care for this growing population is a national priority [3]. PWD have poorer outcomes in hospital compared to those without dementia [4], which evidence from elsewhere suggests may be partly due to communication difficulties; for example, communication impairments increase the probability of preventable adverse events [5], increases length of stay, results in poorer functional outcome and institutionalisation in stroke patients [6,7,8].

Relatives report that ineffective communication in hospitals is associated with a lack of inclusion of patients, and a lack of dignity and respect shown to them [9]. Poor communication by staff despite their best intentions can be perceived as intimidation, imposition, ignoring, accusation and disparagement [10]. Staff also experience the stress and reduced job satisfaction that comes from difficulty in communicating with their patients with dementia [11,12,13].

The importance of communication between hospital staff and patients has been highlighted in policy and practice guidelines in recent years. The role of improved communication in reducing errors and improving patient care has been underlined by the Bristol Royal Infirmary Inquiry [14] and the report 'Building a Safer NHS for Patients' [15], both of which recommended communication skills training for HCPs. The importance of nursing staff regularly engaging with their patients in 'constructive and friendly interactions' was emphasized in the Francis Inquiry [16]. The government's initial response to Francis, "Patients First and Foremost", includes a commitment to "listen most carefully to those whose voices are weakest and find it hardest to speak for themselves", and commits to improving education and training on dementia, and ensuring that all healthcare provider training includes a strong emphasis on 'frail older people' [17].

To date there has been no research to look at the impact of communication skills training for staff in acute hospital settings working with PWD [18]. There is a body of practical expertise amongst mental health professionals but little systematic study of the linguistics, context, and facilitators or otherwise of successful communication with people with dementia. Some of these can be predicted – like ensuring adequate hearing, and reducing distraction or ambient noise, but these may not be within the control of the HCP and elements such as successful use of body language or turn-taking can be difficult to describe. Therefore there is a need for some fundamental research on how to overcome some of the communication challenges that are commonly experienced when HCPs interact with PWD in a hospital setting.

The proposed research aims to fill this gap by developing and then testing a communication skills training intervention for health care practitioners (HCPs) caring for people with dementia (PWD) in acute hospitals. It will describe and analyse the range of current communication practice in one setting, and develop and test the

proof of concept for a training package for HCPs in communication using simulation and online resources to achieve effective and efficient knowledge transfer for NHS staff.

Improving the communication skills of the healthcare professional through an evidence-based intervention is expected to improve the interaction between staff and patient, thus enabling the person with dementia to:

- participate more fully in their care, including engaging in decision making;
- have less distress and fear during their stay, including reduced resistance to care;
- and enabling the healthcare professional to feel better equipped to deal with the challenges of communicating with people with dementia during everyday healthcare tasks.

3. EVIDENCE EXPLAINING WHY THIS RESEARCH IS NEEDED NOW

The ability to communicate sensitively and to achieve meaningful interaction is one of the core principles for supporting people with dementia [19]. The National Minimum Standards for healthcare support workers and adult social care workers in England also include “effective communication” [20]. Therefore, by developing and testing the concept of a communication skills training intervention for HCPs working with people with dementia in an acute hospital setting, this research contributes to an explicit, current need by the NHS and one which will be a sustained area of interest in the longer-term.

There is evidence from reviews of communication skills training interventions for healthcare workers that skills can be improved [21,22,23], but the evidence for their impact on patient health outcomes is currently equivocal [24]. A systematic review of communication skills training in dementia care identified twelve studies but none was based in acute hospital settings or involved the training of doctors [18]. Six of the interventions were delivered in the patient’s own home, with a tendency to be delivered one to one, with a focus on individualised training of the carer, and therefore not generalisable to the hospital staff setting. The other six interventions were delivered in care home settings, with extremely variable duration, from a total of three hours training [25] up to 15 hours training plus two weeks supervised working [26]. Those care home studies which used questionnaire and observational measures showed positive effects on knowledge, skills and attitudes of trained staff, but outcome measures used were inconsistent and interventions and recommended communication techniques were not always clearly defined.

The literature gives some guidance on what the content of communication skills training in dementia care might include e.g. eliminating distractions, simple sentences [27,28,29], though the communication strategies recommended to caregivers for use with PWD may not always be based on empirical research. Small et al (2003) [27] reviewed this literature and identified 10 recurring strategies, of which they found only three strategies impacted positively on observed communication breakdowns between family caregivers and PWD, (eliminating distractions, simple sentences, yes/no questions). One strategy (slowed speaking rate) resulted in more breakdowns. Despite slowed speech being found to be unhelpful in a number of other studies [29, 30] and to be disliked by older people [31] a slow speaking rate is still recommended in a number of current guidelines [32, 33]. The usefulness of ‘yes/no’ (closed) questions for communication success is consistent with other findings [2], but open questions have also been found to be useful for facilitating personal conversations about feelings and concerns in PWD [34]. Sentence comprehension in the PWD has been found to be assisted by limiting utterances to one proposition [35], paraphrasing and verbatim repetitions [29]. When presented with vignettes, nurses perceive carers who use simplified language as less patronising and perceive the PWD as more competent [36]. Critical communications from caregivers has been found to predict negative behaviours in PWD over time [37], and so positive and affirming communications may be recommended [38].

Whilst this literature gives some guidance on what the content of communication skills training for communication partners of PWD might include, none of the evidence comes directly from the general hospital context, nor from communication partners other than family and nurses or carers. However, these strategies remain untested in acute hospitals, and no single training intervention can be identified which could be trialled directly with a mixed group of HCPs in this context. The acute hospital is very different from a care home setting as a communication context because:

- greater variety of staff groups interact regularly with patients
- the PWD is often acutely ill, with increased risk of added delirium and pain
- information related to the acute illness needs to be elicited from the PWD to inform the management plan.
- the PWD is experiencing an unfamiliar place, people and situation, increasing their disorientation
- the environment is noisy, busy and more difficult to control than other settings

To develop an effective communication skills training intervention for interacting with PWD in acute hospitals, we now need a better understanding of what works in this setting through basic research to explore the communication challenges and how they can be overcome [39]. There is evidence that the communication strategies that communication partners thought were effective, when examined in more detailed analysis, have been shown to lead to no improvement in communication breakdowns (eg. paraphrasing, asking only one question, approaching slowly) or even to make things worse (eg. slowed speech) [27], suggesting that even seeking expert [carer/ patient / professional] opinion may not be adequate for the planning of the most effective training. Therefore, recommended attitudes, techniques and approaches should not simply be based on what is assumed to be best practice, but on what has as far as possible been demonstrated through analysis of interactions.

Conversation Analysis (CA) is a well-established qualitative method for the analysis of social interaction and communication [40,41,42] which has been used to develop successful communication skills training interventions in fields such as stroke [43], psychosis [44,45], and primary care [46]. For example, in the stroke field, the recommended 'Supported Conversation' approach to training healthcare staff and volunteers to communicate better with people with aphasia [47] was based on a piece of fundamental empirical work which used Conversation Analysis to compare the communication of videoed volunteers, rated as better or worse than others [48]. From this work they were able to characterise the skills needed for communicating with people with aphasia around the concepts of 'revealing competence' and 'acknowledging competence', and the training emerging from this has been found to be effective in several small trials [49,50]. Conversation analysis of outpatient consultations between psychiatrists and clients expressing delusional views has demonstrated how the alternative approaches taken by the psychiatrists can lead to a change in client responses and thus to more or less constructive consultations [44,45]. The investigator has then used this knowledge to develop a training intervention that is being tested in an NIHR funded pilot study (RfPB). CA has also shown that different communication approaches might be more effective at different times. For example, in conversations about advanced decisions and end of life CA has shown that a direct approach from HCPs is harder for the client to deflect and is required when an immediate decision is needed, whereas more easily deflected indirect approaches are more appropriate when end of life decisions can be raised with more patient-led timing [51]. The existing literature therefore supports the use of fundamental research using CA to collect data about communication between HCPs and PWD in the hospital setting, and to use this data to develop a training intervention for HCPs interacting with PWD.

Research suggests that communication skills are not something that improve through experience alone [52]. Consultation and communication skills can be acquired and retained with appropriate teaching, and leads participants to report greater confidence in their communication with patients following training [53,54,55]. For training to be effective it needs to be practical, with opportunities to practice and receive feedback [24,39,56]. Transferring learned communication skills to clinical practice happens best when courses contain role-play with simulated patients, structured constructive feedback and discussion led by a trained facilitator [53,54,55]. The main output of this research will be a training intervention incorporating these features and including a reusable learning object (RLO) to maximise the transfer of skills into practice.

4. AIMS AND OBJECTIVES

This research aims to develop and test a communication skills training intervention for healthcare professionals (HCPs) caring for people with dementia (PWD) in acute hospitals. Improved HCPs communication skills will reduce distress and challenging behaviour, improve dignity and patient experience and their inclusion in decision making. The objectives are to:

1. Analyse the structure of communication patterns used by HCPs communicating with PWD in the acute hospital environment
2. Identify the communication skills that overcome the challenges of interacting with people with dementia in this setting
3. Train actors to simulate the communication of a person with dementia in this setting, in order to support the training and assessment of HCPs
4. Develop a new intervention to effectively teach these communication skills to HCPs
5. Pilot the intervention to establish effectiveness on intermediate outcomes measures (self-rated competence and confidence), and objective blindly-assessed skills (by researchers and carers) using videoed simulated communication encounters and the usability and acceptability of the training intervention.

Work Package 1 of the research is descriptive and will address the first two objectives. It will use Conversation Analysis (CA) to explore the communication and interactions between HCPs and PWD. The aim is to analyse how recommendations for good practice are implemented and operationalised; and analyse episodes where there are challenges to their operationalisation (agitation or distress, off-topic contributions from patient, resistance to care) and the ways these challenges are effectively managed.

Work Package 2 of the research is developmental and will address the third and fourth objectives. Working with carers we will use the evidence from Phase 1 to develop an intervention in communication skills for HCPs which will use simulation with trained actors and include an online training element. We are aiming to develop an intervention that can be realistically implemented across the NHS modelled on communication skills training used in palliative care, and with both didactic and practical elements.

Work Package 3 will address the fifth objective, and evaluate the communication skills training package through a before and after study. This design has been chosen as an efficient research design for detecting changes in competence and confidence in communication in HCPs at this stage of the development of this complex intervention, i.e. theory building and proof of concept testing. Before and after design will allow a lot of between-individual variation (prior experience, personality, accent, knowledge, native interpersonal skills, etc) to be controlled for. The usability and acceptability of the intervention will also be assessed through qualitative interviews with HCPs and ward managers. This work will be a platform for further development and setting of appropriate research questions.

Given the high prior probability that communication training will be beneficial to healthcare interactions, if our programme is successful in improving intermediate outcomes we may not necessarily need further evaluation to recommend implementation. A future research agenda might however include a ward-level cluster RCT looking at patient-level outcomes, such as distress and resistance to care, using a direct observational method such as dementia care mapping. Such a trial would be large and expensive, and we would need to determine the value of this further information.

5. RESEARCH METHODS

Work Package 1: Identification of Good Communication Skills

Update to Systematic Review

As a first step, we will update the existing systematic review on communication skills training in dementia care [18]. This review, published in 2013, examined studies that were published up to January 2010. We will use the same search strategy to identify studies published since January 2010, review their methods and findings, and describe any changes to the results and conclusions of the original review in light of this.

Design and Theoretical/conceptual framework

Work Package 1 will use Conversation Analysis (CA), supplemented by observations, to analyse the structure of communication patterns used by HCPs to communicate with PWD in the acute hospital environment, and identify the communication skills that overcome some of the challenges of communicating with PWD in this setting.

Whilst recognising the difficulty of defining 'good communication' prior to conducting detailed analysis of actual communication episodes, we propose to use as a starting point the available professional guidance and recommendations. These general recommendations include:

- 1) Treating patients as if they are competent to participate in conversations about their care and treating their contributions as meaningful even where this meaning is obscure
- 2) Avoiding focusing on patient's limitations of competence where this is not necessary for the task in hand [57].
- 3) Eliciting patients' views and preferences using practices already known to maximally encourage patients' contributions and engagement [58,59,60]
- 4) Scaffolding patients' contributions, providing assistance to them to complete the communication task [61,62].
- 5) Using Dementia Care Mapping categories of good communication and interaction behaviours: warmth, holding, relaxed pace, respect, acceptance, celebration, acknowledgement, genuineness, validation, empowerment, facilitation, enabling, collaboration, recognition, including, belonging, fun [63]

Having synthesised the core of good communication from current guidelines and literature we will then use the data to elucidate this and to allow for expansion/amendment.

The use of video recordings of the communication between HCPs and PWD, rather than interviews, is required to help identify these 'good' communication practices. No matter how expert, neither patients/family members nor HCPs find it easy to articulate the tacit knowledge they use when communicating, but video-based research can specify such knowledge and skills. Conversation Analysis (CA) is a well-established qualitative method for the analysis of social interaction and communication [40,41,42] in order to identify the features of effective communication practices in specific healthcare scenarios. It has been used to develop successful communication skills training interventions in fields such as stroke [43,49], psychosis [44,45], and primary care [46]. Observation methods have been used alongside CA to elucidate the context in which talk takes place [64].

We will harness the potential of video-based research by using CA to classify verbal and non-verbal practices and patterns within healthcare interactions involving experienced clinical communicators; analyse how the broad recommendations for good practice actually get implemented and operationalised; and analyse episodes where there are challenges to their operationalization (aggression, lack of any topically meaningful contribution from patient) and the ways these challenges are managed.

The research team has experience of using video recordings with PWD and is familiar with the ethical requirements and considerations for both patients, carers and HCPs [65].

Setting/context

This Work Package will take place in eight Health Care of Older People (HCOP) wards in a large acute hospital. Communication events between HCPs and PWD are prevalent on these Wards. We will use CA to identify the structure of communication practices between HCPs (doctors, nurses and Allied Health Professionals (AHPs)) and people with dementia (PWD) in the context of a wide range of interactions in the hospital setting.

Sampling

We will oversample interactions between HCPs and PWD to generate a large collection of conversation data and then sample within this for the actual analysis. To achieve this, we will recruit up to 40 patients with dementia and up to 20 HCPs on the HCOP wards. We estimate that this will allow us to collect up to 40 conversations, between 200 and 400 minutes of data which will include thousands of conversational turns or communication behaviours. Conversation analysts will search through these rapidly to retrieve particular episodes that cover the variety of challenges that arise during interactions with PWD including problems of understanding, responses to off topic talk, agitated responses from patients, resistance to treatment or healthcare activities etc.

To obtain data from patients with a range of abilities, we will ask nurses working on the wards to assess patients' levels of cognitive impairment as either mild, moderate or severe, and sample across all three levels. Inclusion criteria will be: a diagnosis of dementia in their past medical history on admission; some difficulties communicating with staff experienced; patients are known to be a fluent English speaker. Patients will be excluded if they have Parkinson's disease, and are not a fluent English speaker.

Recruitment and Data Collection

We will adapt protocols for recruitment, consent and data collection that we have used in our previous studies in dementia settings [66] and in our previous video-research studies [24,39,43] – these are protocols that have been developed with user input, which have been found appropriate by NHS research ethics committees, and which have resulted in data collection for studies that have been successfully completed [67].

Many patients will not have capacity to give informed consent. The researcher will assess whether the patient participant has capacity to consent to take part (following the requirements of the Mental Capacity Act 2005). Where possible, a family member or informal carer will be sought and contacted in person or by telephone to explain the study and arrange a meeting. If the patient participant has capacity to consent, permission will be sought to contact the carer first.

Information sheets will be given. For patient participants who have capacity, informed consent will be taken. If the patient does not have capacity, 'consultee agreement' will be sought from an informal carer.

We will recruit any HCPs (doctors, nurses, allied health professionals) working in the HCOP wards who communicate with PWD as part of their work on the wards. We will aim to achieve an equal spread across these categories of HCPs. Recruitment of HCPs will be done in advance of PWD recruitment. HCPs on each ward will be informed of the study and asked to consider if they would be willing to participate in the study and have future encounters with PWD video-recorded. If they consent in advance, they will be reminded of their right to withdraw consent immediately prior to an interaction with a consenting PWD being video-recorded.

Ward staff will be asked which PWDs are appropriate to approach to recruit to the study and will make the initial approach. Researchers will use communication aids and supports to explain what we want to do in the study i.e. show the PWD the camera and clipboard and where the researcher might sit. A baseline communication screening tool (language items from the Addenbrookes Cognitive Examination (ACE-iii) [68]) will be completed for each participating PWD to assess and describe their language ability.

Interactions between HCPs and PWDs will be video recorded. To identify possible interactions for recording, we will talk to ward staff at the beginning of each day to see what interactions are expected to occur during the day e.g. an OT is due to visit patient X about coping at home, the consultant will be talking to patient Y). We will record a wide-range of interactions which can be classified according to either the clinical tasks or the social actions being performed. For example, for social actions, we would classify an interaction as greetings, seeking and providing information, troubles telling and reception, making requests/invitations/proposals, making and responding to announcements and reports, giving/receiving/rejecting advice, disagreements/arguments, topic changing, closing conversations, and dealing with troubles of hearing/speaking/understanding. This is in preference to focusing on one type of interaction (e.g. discharge discussions) which may limit the range of patients and staff who could be included in the sample, as well as the scenarios encountered in this setting. We will video record up to 40 patient-HCP encounters, each approximately 5-10 minutes in length, yielding up to 400 minutes of data.

A researcher will set up the equipment to video record the discussion or conversation. A camera with a wide angle lens will maximise capture, and will be pre-positioned using a pole and clamp and remotely connected to a microphone worn by the HCP. To maintain anonymity, any patient names visible to the camera will be covered up in advance of the recording. A remote stop/start control will be provided to participating HCPs. To minimise intrusiveness, the researcher will avoid looking through the camera. Recordings will be digitised and stored according to University data protection policy and as required by ethics/R&D. Each encounter will be allocated a code to indicate the patient and HCP whilst maintaining anonymity.

Observational field notes on each interaction, and before and after each interaction, will also be recorded by the researcher to identify any contextual events that may have influenced the interaction. The observations will also be used to clarify practical procedures for audio and video data collection, to acclimatise participants to presence of researchers in a less threatening mode than cameras. This data will also provide some insights into the effects of recording on behaviours in this particular environment. This would add to bodies of knowledge already available in this matter, and again will feed into design of data collection so as to maximise validity of data we collect.

Data Analysis

Applied CA will be used to reveal recurrent and systematic patterns in the interactions between HCPs and PWD, considering both linguistic and interactional features. We will focus on the range of practices that HCPs use in addressing some of the challenges of interacting with PWD and identify those that are effective in, for example, improving understanding, reducing resistance to care, easing distress. The method is not traditional CA, but is best referred to as 'applied' CA, since it is motivated by a clinical problem - the identification and need to train good staff communication skills when interacting with PWD.

The aim is to distil and generalise a profile of 'good' communication behaviour, from an initial analysis of individual staff and patient interactions, using as a starting point the available professional guidance and recommendations, thus reflecting generic good practice not just individual style. Furthermore, we will analyse episodes where there are challenges to the operationalization of good communication (agitation or distress,

off-topic contributions from patient, resistance to care) and the ways these challenges are effectively managed. This method is well established and has proved influential in the field of doctor-patient interaction [69,70].

Observations of the same interactions will be used to collect secondary data that is not able to be captured in the video recording. Field notes will be analysed to identify, for example, the behaviours of the HCPs and PWD, the context within which the interaction occurred, any interruptions to the encounter or distractions, any events on the Ward that may have a bearing on the interaction such as recent staff rotations, increased levels of noise etc.

Recordings will be digitised using Adobe Premiere, transcribed verbatim, anonymised, and analysed using CA. The approach, used successfully in our previous studies [39,43,57], follows three stages:

1. All recordings will be viewed/listened to rapidly in conjunction with their verbatim transcripts, produced by a professional transcriber. The goal is to identify all occasions where particular episodes that cover the variety of challenges that arise during interactions with PWD including problems of understanding, responses to off topic talk, agitated patients, resistance to treatment or healthcare activities etc. The researchers will then produce detailed transcripts of these sections, using a notation system for recording features of speech (e.g. emphasis, pauses, overlapping talk, laughter). We will also transcribe aspects of body movement. ELAN software will facilitate data management.
2. This full collection of cases will be examined to identify different strategies used by the clinicians to overcome challenges in communicating with PWD (e.g. agitation, misunderstanding, resistance to care, off-topic contributions). Close attention will be paid to patterns of similarity and difference (e.g. in words or phrases used).
3. Patients' responses to the strategies will be compared to identify any patterns (e.g. some strategies may typically be met with minimal responses, others might typically result in extensive engagement in discussions by patients). Focusing on details of talk and body movement (including pauses, markers of agreement/disagreement, touch and gaze), then - at a late stage - counting frequencies of different patterns and responses, our aim will be to see whether some strategies are more effective at engaging patients in healthcare tasks.

Analysis will draw on relevant evidence generated by other observational studies [42,47,57,70], as a means of increasing validity and generalisability of findings. We will use the findings to generate recommendations for practice, for example, if one form of clinician talk systematically meets with minimal responses by patients/family members, while another meets with engagement, this provides evidence to support the implementation of the latter. Procedures to verify and augment findings will include analysis sessions with experienced researchers, dementia clinicians and user representatives, using raw or disguised data according to consents [71].

Work Package 2: Intervention Development

Design and Theoretical/conceptual framework

From the results of Work Package 1 we will develop a communication skills training intervention which can be realistically implemented across acute trusts. An initial framework is provided by similar interventions for staff working with patients with other communication impairments [49,50,72] and relevant reviews [24,39].

The techniques of role modelling, skill practice and feedback are all supported by social learning theory as leading to better learning of communication skills [73]. The use of 'simulated' or 'standardized' patients (SPs) allows these techniques to be used in the communication training of HCPs, with training provided to the actors to enable an illness or scenario to be presented in a relatively standardized manner [74]. Whilst there is a cost incurred in the use of professional actors, they allow for more realistic, experiential and controlled learning than would be possible with volunteers or trainee peers [75]. Comparison studies have found SPs to have high authenticity, good accuracy and consistency over time [76] and trainee preference with similar outcomes [74].

In the proposed study, it is anticipated that professional actors will be required because of the level of skill and consistency required for both the interactive practical training sessions and the pre and post training outcome assessments. The actors will require specific training in the communication behaviours of people with dementia, including their likely responses to a given range of communication behaviours from HCPs, based on the Phase 1 empirical findings. The coaching of SPs is a well-developed field, particularly in medical

training. Guidelines suggest that good training of actors requires key communication behaviours to be first identified, key elements of cases decided and then scripts developed and piloted. Training manuals for actors then need to be prepared and actors trained and assessed carefully, prior to implementation in the 'field' [77]. Therefore, as part of Work Package 2, we will develop guidance, alongside actors, on understanding the cognitive and communication impairments, how they impact on interactions, and behavioural responses (including being overwhelmed or misunderstanding). This training of the professional actors is an integral part of this proposed programme of research. The actors in this project will be involved in the planning of training materials to be used for future actors, so that the training can be disseminated following completion of the programme. It is envisaged that the actors in this project may benefit from access to the full transcripts, the results of the analysis and possibly to the original video footage, if ethical approval was obtained for this. Access for the research actor to the ward environment for observation will also assist with the development of the actor training package.

The design of the intervention and accompanying materials will be based on the findings of Work Package 1 and draw on our team's expertise and established knowledge about good practice in communication training, including the use of simulated interaction [78] and the expertise of carers. The resources will incorporate video clips of actor simulations, alongside detailed transcripts and written text briefly summarising the communication strategies, making teaching suggestions, and summarising learning points. They will be designed for use by communication trainers during their face-to-face staff training events, but we will also develop an online training resource or a Reusable Learning Object (RLO) including patient and carer video recorded commentaries to support and reinforce the training. Members of the team have experience of developing such materials for communication training in other areas of healthcare [67].

The outcome measures to assess communication behaviour change in HCPs in Work Package 3 will be developed during Work Package 2. These will take the form of frequency counts of a small number of specific communication behaviours which were identified in Work Package 1 as effective in interacting with PWD.

Work Package 3: Intervention Testing

Design and Theoretical/conceptual framework

The intervention will be tested through a proof of concept study to establish effectiveness on intermediate outcomes using a before and after design [79,80] to assess changes in self-assessed competence and confidence, and communication behaviours, in HCPs who have completed the training intervention. Outcomes will be objectively-assessed competence (assessed by researchers and carers) using blind-ratings of videoed simulated communication encounters and self-assessed confidence and competence. This design has been successfully used to evaluate Supported Conversation Training for adults with aphasia [49], and dementia communication skills training in nursing homes [25,81,82].

Sampling

We have not calculated a sample size to detect a particular effect as the purpose of the study is to establish proof of concept rather than testing effectiveness [83]. However, we estimate that it will be feasible to train 40 HCPs over a 9-month period taking into account staff rotas and release from the wards. Other studies using a before and after design [33] have had similar sample sizes ranging from 15 to 38 [25,81,82].

Setting/context

The intervention will be carried out in two acute hospitals.

Data Collection

The main outcome measures will be self-assessed competence and confidence, which will be assessed at baseline (prior to training), immediately post-training (at the end of the training course) and at follow-up (4 weeks post-training). Self-assessed competence and confidence in communicating with PWD will be measured using a purpose-built scale. This approach has been used by similar studies as skills taught will be very specific to communication and not able to be assessed using standardised tools [84,85].

In addition, we will pilot a count measure approach to two or three specific communication behaviours to assess change in these. We will assess both the presence of positive behaviours that we have identified as facilitators, and the absence of negative behaviours that act as barriers to communicating with PWD. Video data from each HCP completing the training will be collected both pre-training and at follow-up (4 weeks post-

intervention) during interactions with actors simulating PWD. Instances of the communication behaviours in these video data will be coded by two independent raters (who will be researchers and carers and who are blind to the pre- or post-intervention status of the data). The behaviours will be selected on the basis of their identification as important communication behaviours (both positive and negative) in Work Package 1, their place in the training intervention, and their salience to independent raters observing them. Coding guidelines will be developed to allow behaviours to be coded, and two independent raters trained to carry out the coding [86]. Inter-rater reliability will be assessed using 20% of the video data. Following any additional training requirements that are identified, the raters will assess the remaining video data. A coding and counting process based on behaviours previously identified using CA has been used successfully as a measure of conversation partner training in post-stroke aphasia [87,88], and in doctor-patient interaction [70].

Interviews with ward managers and HCPs (n=16) will examine the acceptability and experience of the training, their perceptions of its effectiveness, barriers or facilitators in transferring skills into practice, and their willingness to participate. These will be carried out by a member of the team who was not involved in delivery of the training.

Data Analysis

Quantitative analysis will be conducted using paired t-tests of trainees' before and after scores. We will also analyse the data to address feasibility issues such as levels of non-response, completion rates, discrimination of and within/between variation in outcomes measures. Qualitative data will be analysed using a framework method [89] drawing out themes concerning the usability and acceptability of the training intervention and the facilitators and barriers to transfer of the learning into clinical practice. Framework analysis allows for unexpected themes to emerge from the data whilst also allowing the research team to ask questions of the data which it is felt will best help us generate guidelines relevant to future practice and dissemination [90].

6. DISSEMINATION AND PROJECTED OUTPUTS

The focus of this research is on the effective delivery of healthcare for people with dementia through improving the communication skills of the health care professionals working with such patients, thus directly addressing the remit of HS&DR. The research aims to develop and test a standardised training intervention for healthcare professionals using simulation training with actors experienced in delivering communication training in other settings. It is expected that the change produced through the intervention would be generalisable elsewhere, with the prospects of positive change across all acute settings in the NHS. To support this, we will design training resources for online use, as well as face-to-face delivery.

The results from the research will be disseminated through the following methods:

- Interim and final reports
- Best practice guides for HCPs and Speech and Language Therapists (SLTs)
- Conference presentations at HS&DR, British Geriatric Society, Conversation Analysis and Clinical Encounters (CACE) conference
- Peer reviewed journals and healthcare publications

Members of the team have experience of developing reusable learning objects (RLOs) that can be disseminated online. Such resources are suitable for a range of educational uses, including self-directed and blended learning. We will work with our very experienced colleagues in HELM (Health E_Learning and Media Team) who have produced scores of RLOs to devise an online version of the communication skills training package. This can be disseminated for free via the HELM platform (<http://www.nottingham.ac.uk/helm/resources/learning-objects/rlo-school.aspx>) and the University of Nottingham Improving Dementia Education and Awareness (IDEA) web portal.

Members of the team are actively involved in educating HCPs to work in acute settings and will use the communication skills training package in their routine teaching. In addition, once its effectiveness has been demonstrated, we will work with Health Education England, the Strategic Clinical Network for dementia and the East Midlands Academic Health Sciences Network to ensure that the communication skills training package is promoted through their networks and made available through their websites.

We will exploit un-anticipated opportunities to maximise dissemination (such as broadcast and newspapers) and will use social media (blogs and twitter), linking with the communications departments of the University

and NHS trust, the Alzheimer's Society and the BGS. Dissemination of our previous NIHR-funded work has been innovative and successful. We commissioned an award winning documentary on ward-based person centred dementia care, which has been seen by over 1000 HCPs. The same work has been cited in Parliament, subject to 3 appearances on national TV, an article in a national newspaper, and a BMJ video abstract. JS commissioned a play about the experience of dementia (Inside out of Mind, which is about to start a national tour), which is used to support frontline staff training.

The expected knowledge products and outputs from the research will include:

- A profile of effective staff communication behaviour with PWD
- Briefing material and resources for actors who specialise in communication training to enable them to simulate PWD effectively and convincingly in acute healthcare interactions with HCPs
- A training intervention for healthcare staff working with PWD in an acute setting, with accompanying training manual and RLO
- An understanding of whether a ward-level cluster RCT looking at patient-level outcomes is feasible or required

As a proof of concept study, the main output of this research will be knowledge about whether the communication skills training intervention can have an impact on the competencies and confidence of the HCPs who attend the training. It will also show the acceptability and transferability of the training, and whether the research can evolve to further stages of evaluation, such as a ward-level RCT. HCPs in acute settings who care for PWD will be the immediate beneficiaries of the research. Our study has the potential to provide a testable form of training which should demonstrate improvements in communication skills and competencies and confidence in communication with PWD. This should in turn reduce some of the feelings of stress and frustration that are commonly reported by staff working with PWD [11].

We expect our study to also benefit PWD's who require healthcare in an acute setting and their carers. Although the study will not quantitatively assess the impact of the intervention on patient outcomes at this stage of the intervention development, we will explore this in qualitative interviews with trainees and their managers. Further beneficiaries are the NHS employers. This research aims to develop and test a patient focused intervention which is likely to improve patient and carer experience, as well as the ability of NHS staff ability to deliver high quality care.

7. PLAN OF INVESTIGATION AND TIMETABLE

The timetable for the project is presented in Appendix 2. The milestones within this timetable are as follows:

Workpackage 1 (months 0-12)

- M1 Ensure all ethical and local governance approvals in place (month 2).
- M2 Systematic review of communication and dementia updated (month 3).
- M3 Site set up, equipment purchased and researcher familiarised with equipment, ward staff briefed, study documentation in place. HCPs recruited to study. Ready to start recruiting patients (month 3).
- M4 First patient recruited to observational study (month 4).
- M5 All patients recruited and observations completed (month 6).
- M6 Observations completed, transcribed and analysed using CA (month 12).
- M7 Papers on CA submitted for publication (month 15).

Workpackage 2 (months 13-18)

- M8 Training intervention completed, including writing of actors manual and training intervention manual and production of RLO (month 18).

Workpackage 3 (months 19-27)

- M9 Local governance approvals in place at both sites (month 18).

- M10 First cohort of HCPs recruited and trained on communication skills (month 19).
- M11 All HCPs trained and followed up (month 24).
- M12 Interviews with HCPs completed (month 27).

HS&DR Reporting (28-30)

- M13 Best Practice guides published and paper on proof of concept study submitted for publication (month 30).
- M14 Interim report submitted to HS&DR (month 12)
- M15 Final report submitted to HS&DR (month 30).

8. PROJECT MANAGEMENT

The chief investigator will assume overall responsibility for day to day management of the project including ethical considerations, scientific rigour of the research and financial control. The project manager will report directly to the chief investigator and will meet on a weekly basis with the clinical researchers to ensure satisfactory progress of the study. During the study there will be 15 project management group meetings and 4 study steering committee meetings.

A project management group (PMG) will be set up and attended by all members of the research team and three PPI representatives (including the PPI co-applicant). Meetings will be held at two monthly intervals throughout the study with informal contact and consultation being maintained between meetings.

Overall supervision for the study on behalf the study sponsor and funder will be provided by a Study Steering Committee (SSC). This will have an independent chair who will have a primary reporting line to the NIHR HS&DR Programme Director. The SSC will include independent clinicians, patient and public representation and appropriate qualitative expertise. The SSC will meet four times over the duration of the study. Quoracy to conduct business will be 67% of appointed members and the SSC will have a minimum of 75% majority of independent members. Observers including representatives of the sponsor and the clinical research network will be invited to attend. Minutes from the meetings will be sent to all members, the sponsor, the funder and the study master file.

Financial management will be overseen by the Institute of Mental Health's Finance Manager. Study conduct will be subject to the systems of audit and controls required by the University of Nottingham's research governance arrangements.

Regular reports will be submitted to the HS&DR as required.

9. APPROVAL BY ETHICS COMMITTEE

As this study involves patients, we will need to apply to a Research Ethics Committee (REC) for ethical approval. The REC will judge whether the risks and benefits of participating are acceptable. We envisage no problems with being granted ethical approval because what we are developing is a training intervention to improve how staff communicate with PWD rather than a new drug or procedure. REC will also wish to know that participation is not unduly burdensome, and our design requires very little burden upon the participants or informants. REC also has to decide whether the study is too intrusive, but it has previously permitted similar studies without concern.

Many of the patients recruited to this study will lack capacity to give informed consent. As a team we have extensive experience in training researchers to recruit such patients and the requirements of the Mental Capacity Act 2005 and have successfully recruited and collected data from PWD and the HCPs working with them [66,91,92]. Agreement to participate in research is an on-going process and it is important to confirm that the person with dementia agrees to continue with research irrespective of consent in place [93]. We will use a form of 'process consent' [94] and, irrespective of patients' mental capacity at the time of recruitment, verbal agreement to undertake the observations will be sought from the patient prior to the period of observation.

Patients may be under strain when we recruit them to this study, being approached for research may be considered a burden. Again, we have extensive experience of recruiting patients from hospital wards and have found that the vast majority of patients and their carers are keen to help with this type of research. We have kept data collection to a minimum to reduce the burden and our researchers will be SLT clinicians with experience of working with this patient group.

Researchers themselves may become distressed by events they witness on the wards. However, the clinical researchers working on this study are both experienced SLTs and used to working with patients in distress. Supervision and support will be provided by the clinicians within the research team.

The REC may be concerned about the ethics of videoing patients during the study. Video recording of the interaction between HCPs and PWD is vital for this project in order that both nonverbal and verbal communication can be collected and analysed. Our PPI group have been consulted as part of the preparation of this bid and they agreed that videoing was vital and justified, provided privacy and dignity, consent etc were maintained. We have successfully collected video data in sensitive environments in previous studies [57,87,88].

10. PATIENT AND PUBLIC INVOLVEMENT

During the research study, we aim to ensure that meaningful and active patient and public involvement (PPI) is embedded in relevant research activities to add value and impact to benefit patients and carers. Our approach is based on the principle that PPI is a continuous process throughout the research cycle.

To make PPI effective necessitates a whole organisation perspective and supportive infrastructure, with serious commitment from the research team. To achieve the benefits associated with meaningful and comprehensive PPI, the project manager will be appointed as PPI Co-ordinator to achieve this approach across the project. An existing PPI group member is a co-applicant and will be the first point of contact for all other PPI members. The PPI co-applicant has experience of working with members of the research team on previous studies and in the preparation of this bid, and will work closely with the project manager to ensure that carers' and patients' voices are heard throughout the research project.

The project manager and PPI co-applicant will work closely with our PPI group which has been developed over the last 18 months to make an informed and effective contribution to our research, and is supported by a facilitator to ensure a properly governed approach. Most of the members of the group are carers of people with dementia, with first-hand experience of communication between staff and patients. We will provide opportunities for our PPI group to actively contribute to aspects of the research including: development of materials for participants (patients and carers); recruitment of participants; design of the communication training intervention; the training of actors; interpretation of research findings; the development of effective communication processes to disseminate the research.

Our carer co-applicant will ensure that these activities are properly managed and implemented. The members of our PPI group regularly receive training. The group supports the individual members and the facilitator is available to provide additional support.

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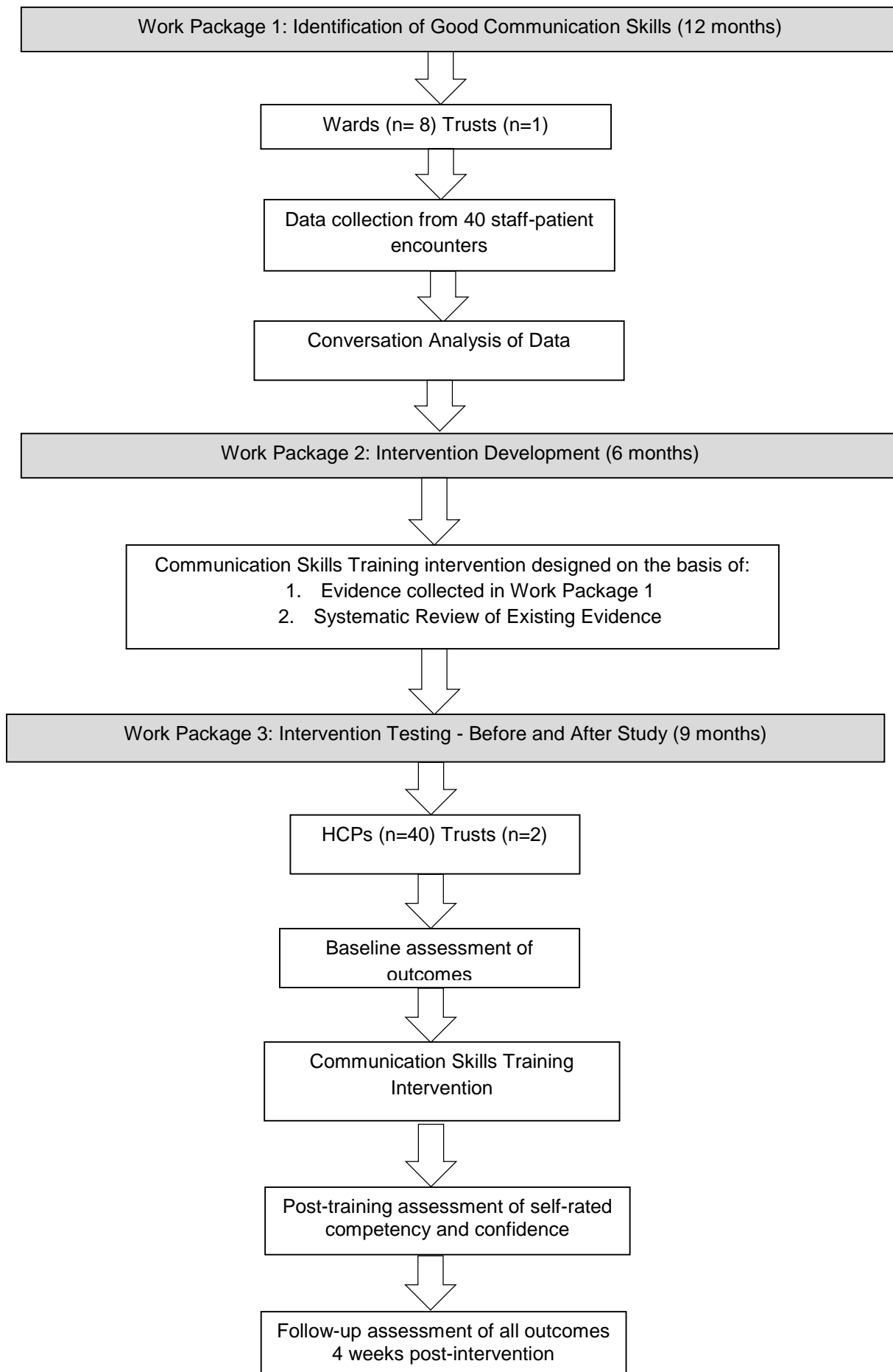
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Appendix .1 Flow chart



Appendix 2. Gantt chart

	Months																													
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
Research Governance																														
Project Management Meetings	X	X		X		X		X		X		X		X		X		X		X		X		X		X		X		X
Study Steering Committee meetings	X								X											X										X
Ethical and local governance approvals	M1																													
Workpackage One																														
Update systematic review	M2																													
Study set up and recruitment of HCPs	M3																													
Recruitment of patients			M4	M5																										
Data collection and transcription																														
CA analysis												M6																		
Writing of paper													M7																	
Workpackage Two																														
Development of training intervention																														
Writing of actors and training manual																														
Production of RLO																														
Workpackage Three																														
Local governance approvals																														
Recruitment and training of HCPs																														
Follow up of HCPs																														
Interviews of HCPs																														
Qualitative analysis of interviews																														
Write up proof of concept study																														M12
Write best practice guides																														M13
HS&DR reporting																														
HS&DR interim report																														M14
HS&DR final report																														M15

M1 ethical and local approvals in place
 M2 systematic review updated
 M3 NUH site set up wards briefed and HCPs recruited.
 M4 first patient recruited to study
 M5 last patient recruited to study

M6 CA analysis completed
 M7 papers from WP1 written and submitted
 M8 training intervention developed including actors and training manual RLO
 M9 local governance approvals in place
 M10 First cohort of HCPs recruited and trained.

M11 All HCPs trained and followed up.
 M12 Proof of concept submitted for publication
 M13 Best practice guide published
 M14 interim report submitted to HS&DR
 M15 Final report submitted to HS&DR