SDO Protocol - project ref: 10/1007/22
Version: 1
Date: 23/09/11

Project title
"Identifying the factors that affect the implementation of strategies to promote a safer environment for patients who have learning disabilities (LD) in NHS hospitals"

Chief investigator	Dr Irene Tuffrey-Wijne
Sponsor	St George's University of London
Funder	NIHR SDO
NIHR Portfolio number	74907
ISRCTN registration (if applicable)	n/a

PROJECT PLAN

Title of project

"Identifying the factors that affect the implementation of strategies to promote a safer environment for patients who have learning disabilities (LD) in NHS hospitals"

Aims and Objectives

Primary aim: To describe the cross-organisational, organisational and individual factors in NHS hospitals that promote or compromise a safe environment for patients who have learning disabilities;

Secondary aim: To develop guidance for NHS Acute Trusts about the implementation for successful and effective measures to promote such safe environment.

Research questions:

1. What systems and structural changes have been put in place in NHS hospitals to prevent adverse outcomes for patients with LD, in particular with regard to specific safeguarding and safety issues, and to recommendations 2, 3, 9 and 10 of "Healthcare for All"?
2. How successful have these measures been in promoting safe practice? In particular:
    a. What cross-organisational, organisational and individual factors have been barriers and enablers in implementing the "Healthcare for All" recommendations for patients with LD in a sample of six NHS hospitals?
    b. What are the examples of effective, replicable good practice at these six sites?
3. To what extent can the findings and learning from question 2 be generalised to other vulnerable patient groups?

Background

Definition and prevalence of learning disability

The term "learning disability" (LD) covers a wide spectrum of impairments. The presence of a low Intelligence Quotient (IQ) is important; the definition does not cover people who have learning difficulties that may impede educational attainment but who are within the average range of intelligence. A low IQ alone is not sufficient however, in defining people with LD. In the White Paper "Valuing People", the Department of Health (2001) states LD means the presence of:

- A significantly reduced ability to understand new or complex information, to learn new skills (impaired intelligence), with
- A reduced ability to cope independently (impaired social functioning)
- Which started before adulthood, with a lasting effect on development.

There are no definitive figures of the prevalence of LD. The Department of Health (2001) estimated that around 2.5% of the population in England have LD. Emerson and Hatton (2008) suggest that 3% of children and 2% of adults have LD. Of these, 1.2 million people have mild to moderate LD (adults in these categories will need varying degrees of support to live and work in the community, but most can learn to develop some degree of independence, self care and adequate communication skills). Around 210,000 people have severe and profound LD with significant limitations and continuous need for support. The number of people with LD is set to rise by 1% per year (Department of Health 2001). It is estimated that the number of people with LD aged 50 or over will increase by 53% between 2001 and 2021 (Emerson & Hatton 2008).

Health inequalities

People with LD experience more admissions to hospital compared to the general population (MENCAP 2004). They are more likely to use health services as they get older. The health inequalities for people with LD are well documented. Since the 1990s, there have been reports in the literature that people with LD are more likely to die young than the general population. The Department of Health (2009a) quotes figures drawn from Hollins et al (1998), estimating that people with learning disabilities are 55 times more likely to die prematurely than the population as a whole if they are under the age of 50; for those over the age of 50, the figure is 58 times more likely. Over the past decade, there have been a range of reports that have highlighted consistently the poor quality of care for people with LD in both primary and acute secondary healthcare, often adversely affecting patient safety (Disability Rights Commission 2006). This was highlighted most poignantly in MENCAP's "Death by Indifference" report (MENCAP 2007), detailing the case histories of six people with LD who died in hospitals from avoidable conditions. In the report investigating these deaths, the Health Service Ombudsman for England (Parliamentary and Health Service Ombudsman 2009) highlighted distressing failures in the quality of health and social care, and found patients with LD were treated less favourably than others, resulting in prolonged suffering and inappropriate care. When relatives complained, they were left drained and demoralised and with a feeling of hopelessness. One of the cases investigated was that of Martin Ryan, age 43, who went without food for 26 days whilst he was in Kingston NHS Hospital following a stroke. By the time staff realised what was happening, he was too weak to be helped. Martin died. He had severe learning disabilities and no speech. The Ombudsman concluded that "had service failure not occurred it is likely the patient's death could have been avoided" (p,14). The Ombudsman recommended that all NHS care organisations in England should "review urgently the effectiveness of the systems they have in place to enable them to understand and plan to meet the full range of needs of people with learning disabilities in their areas" (p.12).

"Healthcare for All": Recommendations from the Independent Inquiry

An Independent Inquiry into access to healthcare for people with LD, completed in 2008, found "appalling examples of discrimination, abuse and neglect across the range of health services". In "Healthcare for All" (Michael 2008), the report of this Inquiry, several reasons for such clear evidence of unsafe and unlawful treatment are highlighted, including cross-organisational, organisational and individual influences. The report concludes that "the evidence... suggests very clearly that high levels of health care need are not currently being met and that there are risks inherent in the care system. People with learning disabilities appear to receive less effective care than they are entitled to receive. There is evidence of a significant level of avoidable suffering and a high likelihood that there are deaths occurring which could be avoided" (p. 53). The report sets out ten clear recommendations for service planners, providers and practitioners to improve this unacceptable situation.
Four out of the ten recommendations fall within the responsibility of Acute Care service providers:

- All hospitals should ensure that they collect data and information necessary to allow people with LD to be identified and their care pathways tracked (Recommendation 2)
- Family and other carers should be involved as a matter of course as partners in the provision and treatment of care (Recommendation 3)
- All Trust Boards should ensure that the views and interests of patients with LD and their carers are included, in line with the requirement of the National Health Service Act 2006 (Recommendation 9)
- All Trust Boards should demonstrate that they have effective systems in place to deliver effective, "reasonably adjusted" health services (Recommendation 10

Patient safeguarding and safety

A patient safety incident (or "adverse event") has been described as "any unintended or unexpected incident that could have or did lead to harm for one or more patients receiving NHS-funded healthcare" (National Patient Safety Agency 2004). It is estimated that 4-16% of patients admitted to hospital experience an adverse event (Raleigh et al. 2008). Many of these incidents go unreported (Baba-Akbari Sari et al. 2006).
The Care Quality Commission (CQC) has identified a range of Trust outcomes for safeguarding and safety issues (Care Quality Commission 2010). Whilst some of these are likely to affect all patients equally, regardless of disability and vulnerability (eg ward cleanliness and security), others can be expected to be more challenging for patients with learning disabilities. This is particularly so for safety measures related to medication. For

example, measures around patients being given medication to take home include patients "being told what side effects to watch out for; being told how to take medication and having the purpose of their medicines explained to them in a way they could understand; being given clear written or printed information about their medicines". The recent consultation document on proposals for an NHS Outcomes Framework (Department of Health 2010), which is to be fed into NICE guidelines, highlights the following patient safety issues for people with learning disabilities:

- medication errors (communication and comprehension)
- preventable deterioration
- misdiagnosis (communication and comprehension)

These issues are a particularly relevant part of the recommendation to have "reasonable adjusted" health services. Our study will focus on those safety issues as a specific aspect of the recommendations of "Healthcare for All".

What this study will add

There are examples of good practice, but these are patchy. One positive example is the appointment of a consultant nurse in LD at St George's Hospital, which appears to have had a positive impact on patient safety. Referrals of patients with LD from across this NHS site have risen steadily; adverse incidents are more clearly tracked; complaints involving patients with LD have risen in number but reduced in seriousness; and user forums of people with LD and family carers have been established. Other positive examples highlighted in the literature include a good liaison structure between acute general and specialised services.

However, the extent to which these initiatives are effective in promoting safer care, and the factors that promote effective long-term change, are poorly understood. In particular, it is not clear:

- what particular organisational and management structures contribute to the safer care of patients with LD;
- how effective "change agents" (such as the LD nurse consultant or liaison nurses) are in promoting safer practice for people with LD in NHS hospitals;
- how patients with LD and their relatives can be effectively engaged in improving safety in hospitals;
- what contribution to patient safety can be effected within the NHS hospitals, and what needs a wider approach (for example through regulatory bodies).

Implementing the recommendations requires changes in both the organisation of systems and services, and staff practice. As Iles and Sutherlands (Iles & Sutherland 2001) review of the organisational change literature on the NHS reveals, managing change is a complex process. Theoretical models used in the analysis of organisational change generally focus on strategy, structure, culture and action, and the relationship between them (Mintzberg, Quinn, & Ghoshal 1998) (Paton & McCalman 2008). These draw attention to the imperative to explore both organisational context and wider environment in which change programmes operate as well as the response of the actors who implement them (Iles & Sutherland 2001;Newton et al. 2003;Pettigrew, Ferlie, & McKee 1992). With regard to the organisational context, a number of barriers to change have been identified in the NHS that explain a gap between senior manager's strategic objectives, policies and guidelines and actual practice .The administrative rather than strategic approach typically found in the NHS may impede change especially at lower organisational levels (Bach & Della Rocha 2000;Iles & Sutherland 2001). Rigid bureaucratic structures and cultures of the NHS are designed to manage risk and ensure standardisation and may not be sufficiently flexible to accommodate the different needs of patients. They also inhibit the cross sector and departmental working necessary to provide the integrated care required by vulnerable patients (Nembhard et al. 2009). Professionals may resist change which threatens their status or resources and, middle manager's failure to implement change because of overwork or lack of priority has been noted in a number of studies (Currie, Finn, & Martin 2009;Dawson 2003;Edwards & Robertson 2004;Edwards & Robinson 2001;Ferlie.E. et al. 2005;Frost & Egri 1991;McGovern et al. 1997;Truss 2003). There is also the question of leaders as change agents. Several studies suggest that the charismatic and transformational leadership necessary to lead change is not often found in healthcare settings (Bolden & Gosling 2006;Gilmartin & D'Aunno 2007). More fundamentally, others have noted that whereas charismatic leaders can be effective change agents in the initial change process, they also raise problems of sustainability. Long term embedding of change may require a different, more dispersed leadership form. Finally, the capacity for organisational and individual learning in the NHS has been questioned (Currie, Finn, & Martin 2007;Davies & Nutley 2000).

Thus we would argue examination of these issues at organisational, group and individual level is essential to understand how change may be facilitated with regard to LD practice. Without a clear understanding of these issues, improved safety for patients with LD in hospitals is likely to remain haphazard. So far, most insights and understanding of what works well has been gathered through case reports and reports of service initiatives. There is a distinct lack of empirical evidence in this area.
This proposed research will provide a baseline study of the effectiveness of the implementations of the four "Healthcare for All" recommendations in six NHS hospitals. It will give detailed insight into the structures and cultures of these hospitals. By carrying out both audit trails and organisational ethnographies of these six hospitals, with a focus on the impact of changes implemented in the light of "Healthcare for All" recommendations, we will be able to extrapolate both the enablers and the barriers to improving patient safety. The generalisability of findings to other vulnerable patient groups will be assessed through (a) presentation of our findings to a panel of clinical and patient safety leads for other vulnerable patient groups at the participating hospitals, and (b) comparison of our findings with the literature on the provision of healthcare to the following vulnerable groups: older people; people with dementia; people with mental health problems; people with communication problems.. We will translate this into recommendations for senior managers across the NHS in England.

Need

Health need
There are extensive reports of what is not working well for people with LD in health care settings; recommendations for improvement; and embedding of such recommendations in government policy as described above. All NHS hospitals are now required to consider how they provide treatment and care for people with LD, and how they can improve safety for this group. However, MENCAP still receives regular reports from relatives who believe that the person with LD was treated unfavourably, and their health and safety (or even their life) was compromised as a result.
This study will identify effective, replicable examples of good practice that enhance safety of patients with LD in hospitals. There will be clear benefits to the cost effectiveness of the NHS in improving healthcare for patients with LD, for example, in preventing the avoidable mortality and morbidity that has been highlighted in the reports described above. One example of cost-effective ways of improving healthcare for people with LD is the reduction in the rate of re-admission to hospital following the interventions of a newly appointed consultant nurse in LD at St George's Hospital. This study will investigate and highlight a range of such measures.
The study will also identify which factors affecting patient safety are likely to be inherent to the presence of learning disability, and which are due to general vulnerability and communication problems. This will enable the identification of findings that are transferrable to other vulnerable patient groups.

Expressed need
A number of reports have expressed the need for monitoring the health inequalities and safety of patients with LD in hospitals. In "Health Inequalities: progress and next steps" (Department of Health 2008b) it is noted that "the Government will use progress in relation to this particularly vulnerable group [LD] as a way of testing whether its approach to tackling health inequalities is working" in the NHS (p. 38). "Valuing People Now" (Department of Health 2009b), a follow-up from the Government White Paper on LD (Department of Health 2001), notes that access to the NHS is often poor and characterised by problems that undermine dignity and safety. It states that the Government is determined that lessons are learnt and that action is taken to improve this. The successful implementation of the recommendations of "Healthcare for All" has been recognised as a priority within the NHS management community. On 29 June 2008, the then NHS Chief Executive, David Nicholson, wrote to all chief executives of SHAs, PCTs and provider NHS trusts to ask them to "immediately consider whether there are questions to ask about your own service that follow from the findings and recommendations *[of the Independent Inquiry Report]*, and to satisfy yourself that reasonable adjustments are being made". The Department of Health, in their proposed Outcome Framework for the NHS, has highlighted

the particular risks for patients with learning disabilities with regards to patient safety issues (Department of Health 2010).

Sustained interest and intent

The growing numbers of people with LD, in particular older people with LD who are more likely to need hospital services, means that their equitable access and safety in hospitals will be an issue of ongoing concern. The way in which NHS hospitals implement the recommendations of the reports described above is of long-term interest and cannot be a matter of complacency. The fact that this issue has been endorsed by the most senior managers (including the NHS Chief Executive) and at government level, indicates the high relevance to the NHS both now and in the future. It is likely that NHS Boards will consider the findings of this research when auditing and improving their own track record on ensuring reasonable adjustments are made for patients with LD.

Capacity to generate new knowledge

"Healthcare for All" concludes: "The evidence shows a significant gap between policy, the law and the delivery of effective health services for people with learning disabilities" (p.53). There is a lack of knowledge about how to translate hospital policy and guidelines into effective practice and improved services. This research is needed in order to identify the factors that affect the implementation of such strategies, which is currently poorly understood. We will translate this into clear recommendations for managers across the NHS, and disseminate these widely through conferences and publications.

Organisational focus consistent with SDO mission

The aim of this study is to develop guidelines for NHS trusts to improve safety for patients with LD. By getting it right for this vulnerable group of patients, care of all patients will benefit. This study has strong input from users. Two co-researchers who have LD will be employed on the research team, to support all aspects of the research (development, data collection, analysis and dissemination). An Advisory Group will include two further members with LD, as well as two family carers; this group will guide the research throughout. Our research team has long-standing expertise in user involvement. This study will strengthen the SDO mission of inclusive research, and bridging the gap between theory and practice.

Generalisable findings and prospects for change

This study consists of detailed local case studies followed by a stage of data synthesis and generalisation. A comparative case study approach will enable the identification of generic features of change as they are indicated across contrasting areas. Comparison between our six sites, in particular when taking differences between samples into consideration, will provide insight into where the barriers and facilitators of the safety of patients with LD will have generic importance. It will also distinguish changes in practice and culture that are generic from those that are condition specific. We will aim to understand the extent to which evidence of good practice in promoting safety for patients with LD is driven by (a) policy and its communication downwards through the health service organisation, and/or (b) bottom up initiatives originating from new patient/practitioner partnerships, innovative teams and charismatic leaders.

The final stage will establish to what extent the study findings at the six study sites can be generalised to other patient groups with similar vulnerabilities and risks, and therefore the extent to which the examples of effective good practice emerging from the six sites might reasonably be expected to be replicable for other conditions, such as dementia or other patients with communication problems. One example of tools and practices shown to be effective for patients with learning disabilities, and currently being planned for rolling out to other vulnerable patients, is the "One Hospital Passport" to help with the communication of essential patient information (Mencap, personal communication). Whilst it is beyond the scope of this study to evaluate the possible transferability of good practice measures in other conditions, it will suggest ways in which this might be the case.The empirical framework of factors that affect safety of patients with LD in hospital, emerging from this study, will be presented to panels of leads and experts in other vulnerable patient groups at the 6 hospitals in order to assess applicability to their area.

The research will of necessity study the effectiveness of systems, process and procedures set up to ensure quality and patient safety in general, as well as the provisions within them for dealing with specific vulnerable groups. Owing to the integrated nature of these systems, it could be concluded that the factors associated with success and failures in dealing with patients with LD are likely to be similar for any vulnerable group with "non standard needs". We will examine policies and guidelines for other vulnerable groups, and a small number of questions on the difference and similarities in dealing with them will be added to the interview schedule. The assumption that there are similarities between the groups will be tested by comparing our findings with that of empirical research on other vulnerable groups (and on the quality and patient safety in general.

The final report will provide a set of recommended implementation measures for improving safety for patients with LD that have been shown to be successful in the study. It will clearly set out the factors that can affect innovation and good practice, other than the enthusiasm of energetic individual practitioners (which has been noted in "Healthcare for All" as the current most prevalent factor), but rather at the level of structured engagement by NHS services.

Methods

Theoretical/conceptual framework

This study takes a systematic approach to an empirical identification of the factors that affect the implementation of strategies to promote a safer environment for patients with LD in hospitals, and in particular the implementation of recommendations 2, 3, 9 and 10 of "Healthcare for All", as well as patient safeguarding and safety issues identified by the Care Quality Commission and the Department of Health. We have developed a theoretical framework for understanding the range of factors that might impact on such implementation in NHS hospitals. This framework is based on the literature mentioned above (see "Background" and "Need"), as well as the wide-ranging insights and experience of the multi-disciplinary research team.

The theoretical framework identifies potential barriers and facilitators to improving safety for patients with LD in NHS hospitals, in a number of domains: organisational context; frontline staff – managers, individuals and teams; patients with LD and carers – profile, expectations and experiences. These domains are indicated in boxes A, B and C of the Theoretical Framework (Figure 1). Each box contains a number of factors within each domain that might be expected to function as barrier or facilitator to promoting a safe environment for people with LD in hospitals.

In addition, the framework identifies a number of outcomes that might be associated with effective patient safety measures for patients with LD in NHS hospitals. These outcomes are largely derived from the team's interpretation of the Inquiry, reports and other literature described above.

The figure is derived from the literature combined with the team's expertise in LD in acute care in hospital settings informed by their own relevant research, practice and personal experience. It is the team's intention to re-present this framework at the end of the study, populating the domains with barriers and facilitators to promoting safety of patients with LD that we have identified by systematically testing the theoretical and empirical framework over the course of the study.

From this Theoretical Framework flows our Research Framework (Figure 2), where specific research questions are asked within each domain (A, B and C). The research methods are derived from this Research Framework.

Design

The theoretical and research frameworks pose a number of different research questions best addressed using a range of methods and at a number of levels of enquiry. This is a complex study which integrates qualitative and quantitative methods. An initial stage consists of mapping the systems and structural changes within each hospital site (related to research question 1). The main stage is related to research question 2, and comprises a range of methods, including interviews, questionnaires and case studies. The final stage involves synthesis of the data, including synthesis with the literature on other vulnerable patient groups. We will also gather structured feedback from clinical and patient safety leads in other vulnerable patient groups, to assess generalisability (research question 3).

Figure 1. THEORETICAL FRAMEWORK: "The factors that affect the promoting of a safer environment for patients with LD"

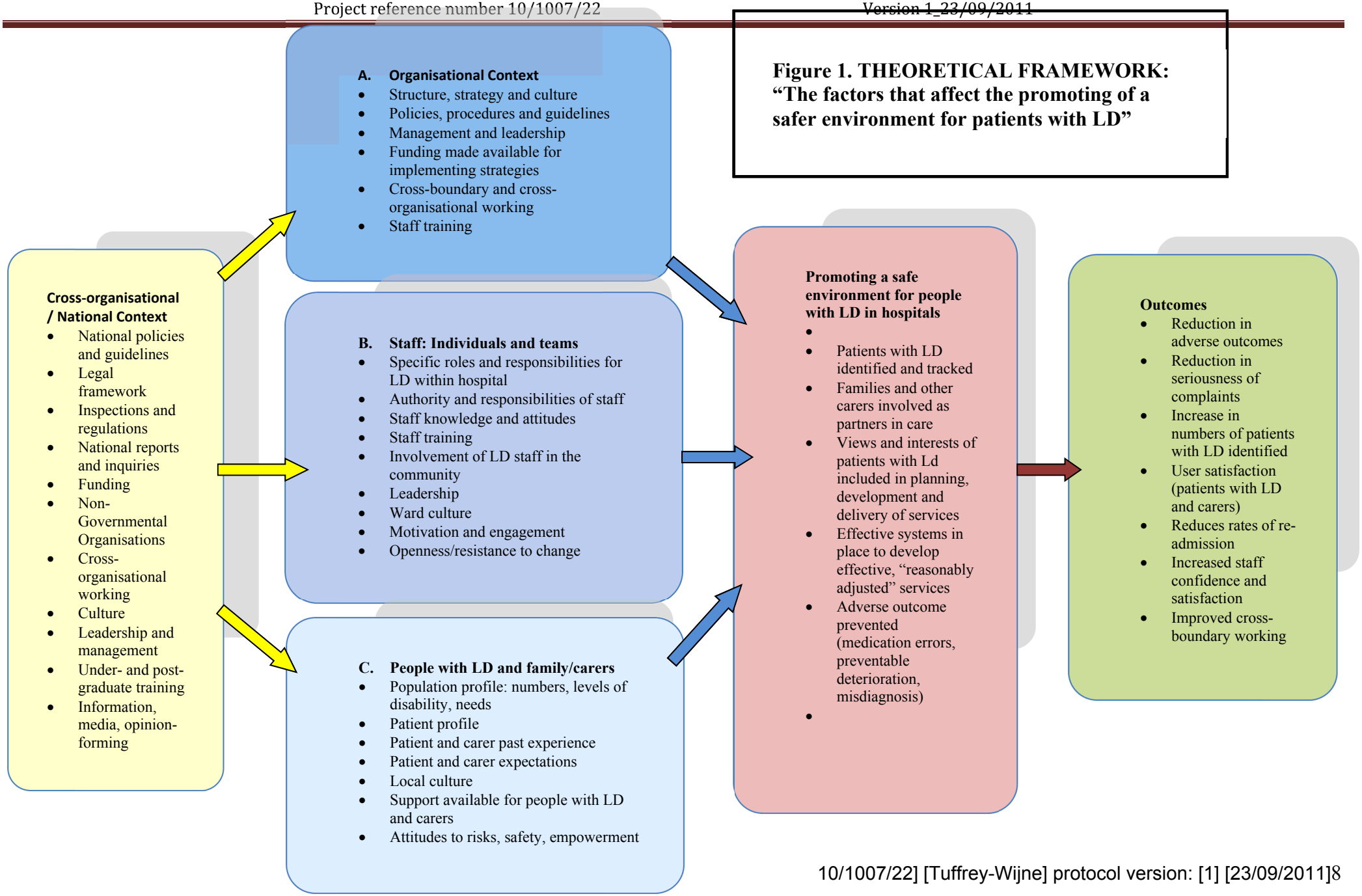


Figure 2. RESEARCH FRAMEWORK – Three levels of inquiry

	A. ORGANIZATIONAL CONTEXT	B. STAFF: INDIVIDUALS and TEAMS	C. PEOPLE WITH LD and CARERS
Recommendation 2 All healthcare organizations, including the Department of Health, should ensure that they collect the data and information necessary to allow people with LD to be identified by the health service and their pathways of care tracked.	**A1.** What are the policies, procedures and systems for identifying patients with LD? **A2.** On admission, what data and information is collected from patients with LD? **A3.** What are the policies, procedures and systems for tracking their pathways of care? **A4.** What do senior managers see as the barriers and facilitators to collecting the necessary information?	**B1.** Are staff on hospital wards aware of the need to identify and track patients with LD? **B2.** Do staff on hospital wards know the policies, procedures and systems for tracking patients with LD? **B3.** Do staff on hospital wards identify and track patients with LD? **B4.** How are staff on hospital wards alerted to the fact that a patient has LD? **B5.** Have LD staff (both within and outside the hospital) been asked to assist with providing the necessary information to enable people with LD to be identified and their pathways tracked?	**C1.** Are patients with LD and their family/carers aware of the requirement that the hospitals identifies their needs and tracks their care pathways? **C2.** Have patients with LD and their family/carers been asked to provide the necessary information? **C3.** Are patients with LD and their family/carers able and happy to provide the necessary information?
Recommendation 3 Family and other carers should be involved as a matter of course as partners in the provision and treatment of care, unless good reason is given, and Trust Boards should ensure that reasonable adjustments are made to enable and support carers to do this effectively. This will include the provision of information, but may also involve practical support and service co-ordination.*(see note 1)*	**A5.** What policies and reasonable adjustments are in place to enable and support family/carers to be involved as effective partners in care provision? **A6.** Does the hospital have guidelines on the provision of information for carers, practical support and service co-ordination? **A7.** Is there a culture among senior managers that encourages partnerships with family/carers?	**B6.** Are staff on hospital wards aware of any policies or the need to make reasonable adjustments to enable and support family/carers to be involved as effective partners in care provision, including care and discharge planning? **B7.** In what ways are family/carers involved as partners in care provision by staff on hospital wards? (is there: provision of information, practical support and service co-ordination?) **B8.** Is there a culture among staff on hospital wards that encourages partnerships with family/carers?	**C4.** Do family/carers feel that they have been supported and included as partners in care provision, including care and discharge planning? **C5.** Have family/carers been provided with information and practical support? **C6.** Are family/carers satisfied with the care provided by the hospital?
Recommendation 9 Section 242 of the National Health Service Act 2006 requires NHS bodies to involve and consult patients and the public in the planning and development of services, and in decisions affecting the operation of services. All trust Boards should ensure that views and interests of people with LD and their carers are included.	**A8.** What policies and systems have been put in place by the hospital to ensure that the views and interests of patients with LD and their family/carers are included in the planning, development and delivery of services? **A9.** Are people with LD and family/carers represented on advisory and decision making bodies within the hospital? **A10.** Is there a culture among Trust Board members and other senior managers that encourages inclusion of the views and interests of people with LD and their family/carers in the planning, development and delivery	**B9.** How are staff on hospital wards made aware of the views and interests of patients with LD and their carers? **B10.** Have LD staff (both within and outside the hospital) been invited to offer the necessary support to ensure that the views and interests of patients with LD and their carers are included?	**C7.** How have the views and interests of people with LD and their carers been included? **C8.** Do people with LD and their family/carers believe that their views and interests are taken into account by the hospital? **C9.** If people with LD and their family/carers are represented on advisory/decision making bodies, what has

	of services?		been their experience?
Recommendation 10 All trust boards should demonstrate that they have effective systems in place to deliver effective, "reasonably adjusted" health services. This should include arrangements to provide advocacy for all those how need it, and arrangement to secure effective representation on PALS from all client groups including people with LD *NB "Reasonable adjustments" in this context are described in the literature and include:* • *Providing accessible information* • *Meeting individual needs, including communication needs* • *Allowing enough time*	**A11.** What systems have been put in place by the hospital to ensure reasonable adjustments are made? **A12.** What do senior managers understand by "reasonably adjusted services"? **A13.** What funding has been made available to ensure that reasonable adjustments are made? **A14.** What are the arrangements for provision of advocacy to all those who need it? **A15.** What partnerships are in place with other agencies who have a remit to support patients with LD? **A16.** Are there professionals within the hospital with a specific remit to promote the delivery of effective, reasonably adjusted health services? **A17.** Are the views and interests of people with LD represented on PALS?	**B11.** What do individual staff members and teams understand by "reasonable adjusted services"? **B12.** How do individual staff members and teams ensure that they deliver effective, reasonably adjusted services? **B13.** Are individual staff members aware of the specific needs of patients with LD, and do they know how to ensure those needs are met? **B14.** Do individual staff members know how to arrange advocacy for patients who need it? **B15.** Have LD staff (both within and outside the hospital) been asked to assist with ensuring that hospital services are reasonably adjusted? **B16.** Are PALS staff aware of the needs of patients with LD?	**C10.** Do patients with LD, and their family/carers, feel that the patient's individual needs have been met? **C11.** Was the patient given information in a way he/she could understand? **C12.** Did staff allow enough time in their care of the patient? **C13.** Were patients provided with advocacy when they needed it? **C14.** If people with LD are represented on PALs, what is their experience?
Safeguarding and safety: **Prevention of adverse outcomes** *(see note 2)* With specific focus on: • Medication errors • Preventable deterioration • Misdiagnosis	**A18.** What measures are in place to ensure the safe administration of medication to patients with LD, including giving clear information about medicines to the patient? **A19.** What measures are in place to avoid preventable deterioration and misdiagnosis for patients with LD? **A20.** What systems are in place for monitoring adverse outcomes and complaints involving patients with LD?	**B17.** Are individual staff and staff teams aware of the measures to ensure safe administration of medication to patients with LD? **B18.** Are individual staff and teams aware of the measures in place to avoid preventable deterioration and misdiagnosis for patients with LD? **B19.** Are individual staff and teams aware of the systems in place for reporting adverse outcomes? **B20.** Are adverse outcomes involving patient with LD reported by staff?	**C15.** Do patients with LD and their family/carers think they have been given understandable information about medicines, including medicines to take home? **C16.** Do patients with LD and their family/carers think that preventable deterioration was avoided? **C17,** Do patients with LD and their family/carers feel they received an accurate and timely diagnosis? **C18.** Do patients with LD and their family/carers know how to make a complaint? **C19.** What adverse outcomes and complaints involving patients with LD or their family/carers have been recorded within the hospital during the data collection period?

Generalability to other vulnerable patient groups	**A21.** What policies, guidelines and measures have been put in place by the hospital, similar to those for patients with LD, to ensure the safety of other vulnerable patient groups? **A22.** What do senior managers see as the differences and/or similarities between the implementation of these safety measures, and the implementation of safety measures for patients with LD?	**B22.** Are individual staff and teams aware of any hospital policies, guidelines and measures for other vulnerable patient groups? **B23.** What do individual staff and teams see as the differences and/or similarities between the safety issues and implementation of safety measures for patients with LD, and those for other vulnerable patient groups?	

Note 1: The Government's National Carers Strategy (Department of Health 2008a) sets out how carers should be included as partners in care; this will be used to guide more detailed questions on all levels
Note 2: The "adverse outcomes" with regards to safety and safeguarding issues have been taken from "Quality and Risk Profiles of NHS Trusts in early 2010" (Care Quality Commission 2010) and the proposed Transparency in Outcomes Framework for the NHS (Department of Health 2010)

Sampling

Operational definition of LD

The theoretical definition of LD (see "Background") is not always easily operationalised in practice, as many people with LD (particularly those with mild or moderate LD) may not previously have been labelled as such on admission to hospital, or may not be known by hospital staff as having LD. For the purpose of this study, we will include any patient who has been identified by the referrer as having LD. For those patients who have not been thus identified, we use the operational definitions of LD as they are used by each individual hospital site. For example, at St George's Hospital, staff are given a checklist of indicators that suggest the person may have LD; if they suspect LD, the LD nurse consultant is called to confirm presence of LD. This checklist includes that the patient: did not go to a mainstream school; finds it hard to answer questions; is unable to read, write, interpret and process new information; finds recalling information difficult; finds it hard to maintain their own self care; needs significant assistance to carry out their daily lives.

The research team acknowledges that some patients with LD will not be included in the study because we have not been able to identify them as such; this is particularly likely for those who are not known to LD services. Our efforts to identify this patient population, and the lessons learnt, will form part of our findings.

Selection of hospital sites

A purposive sample of six hospital sites has been selected for the study. Selection was made according to the following 3 criteria, which are likely to impact on the implementation of the strategies under investigation:

1. The sites represent a range of urban/rural and socio-demographic environments, and a range of sizes. They include a large university teaching hospital in London, two smaller hospitals in Greater London, two hospitals in towns within 60 miles of London, and one rural hospital in South West England.
2. Active engagement with issues around safety for patients with LD. Reasonably expected performance and/or improvement in promoting a safe environment for patients with LD (leading to an expectation that good practice will be identified at these sites), based on the hospital's record since 2008 in prioritising the safety of patients with LD*:
    - A range of recent or more long-standing implementation plans for the recommendations in the Michael Report. Some hospitals are just beginning to introduced certain strategies, whereas one hospital has started implementing strategies to improve care for people with LD before the Michael Report was published.
    - Three hospitals had recent a situation involving avoidable death of a patient with LD, or were accused of such a situation. These hospitals can be expected to have learnt lessons as a result
    - Two of these three hospitals were among the first to sign up to Mencap's "Getting it Right" campaign.
3. Six contrasting examples of initiatives/appointments of an LD professional with a remit to improve care for patients with LD at the hospital
    - Three hospitals employ a nurse for LD with a remit to improve services for patients with LD; these roles (and the profile of the nurse) vary between the hospitals
    - Three hospitals have no dedicated LD professional in employment but works closely with community LD teams. Two hospitals have introduced, or are introducing, a system of 'link nurses for LD' on each ward. One hospital has formal links with an LD liaison nurse from the community LD team.

*As the study will look for examples of replicable good practice in promoting a safe environment for patients with LD, sites were selected on the basis of their interest and willingness to engage in research around this topic, and in actively promoting good practice. We purposively included several hospitals with previously poor records on safety for patients with LD.

The partnership between St George's University of London, Kingston Business School at Kingston University, and the six Acute Trusts provide a strong basis for the study.

STAGE I *(Research question 1)* Month 2-3

The aim of this stage is to provide a baseline of the systems and structural changes that have been put into place at the six hospital sites, with regards to research question 1. It will answer most questions under "Organisational Context" (figure 2), as follows: A1-3, A5-6, A8-9, A11, A13-20. This stage forms the basis for the data collection in Stage II, where questions will be asked around the implementation of existing policies and procedures.

Methods: Structured face to face or telephone interviews with strategic managers at each site, using a questionnaire specifically developed for this purpose in order to answer the above questions.
The questionnaire may be filled in by email if it is not possible to arrange time for an interview. There will be initial telephone enquiries with at least one board level Director within each Trust. They can either answer the questions themselves, or nominate someone else in strategic management in the Trust who is well placed to answer the questions. Sampling will continue in this way until all questions have been answered.
Documents relating to all relevant policies, procedures and systems will be examined.

STAGE II *(Research question 2)* Month 4-15

This stage forms the main part of the study, and is concerned with examining the effectiveness of the measures identified in Stage I. A range of mostly qualitative methods will be used to address a range of specific research questions, mostly related to "Staff: individuals and teams" and "People with LD and carers" (see figure 2). The methods and sampling strategies related to specific groups of participants is set out below.

SENIOR MANAGERS
At each site, interviews will be held with one executive board member and two other senior managers with hospital-wide responsibilities (to be indentified during Stage I as key figures in the implementation of the relevant strategies) *(n=15).*
Interviews will be semi-structured, and cover the following questions: A4, A7, A10, A12, A18-22; as well as the interviewees' views on barriers and facilitators in improving safety of patients with LD.

STAFF: INDIVIDUALS AND TEAMS
Selection of data collection sites within the hospital: In order to keep the study within manageable proportions, and to focus data collection where it is likely to yield the most insightful findings, we will purposively select three wards/units as follows: one Accident & Emergency Unit or Medical Assessment Unit; one Older People; and one of the following types of wards: Orthopaedics; Neurology; Surgical. These ward/units are expected to have a relatively large proportion of patients with LD. The selection of these wards/units is based on an analysis of referrals of patients with LD at St George's Hospital in 2009.

Interviews: Interviews will be held with (i) the most senior ward manager/sister on each selected ward/unit, and (ii) two ward nurses that are available for interview. Sampling of these two nurses will be purposive to ensure that it includes as wide a range as possible of staff responsibilities and experience. If there are staff with specific responsibilities for implementing the LD policies, they will be selected (eg staff responsible for triage in A&E). Interviews will be semi-structured, covering the following question: B1-2, B4, B6-9, B11-14, B17-22. Part of the interview will consist of a Tracer Scenario (Hornby & Symon 1994), designed to assess staff knowledge on policies, procedures,

structures and issues related to LD. *(n=45)* The sampling strategy recognises the important place of the senior manager with regards to ward culture. Interview guides will be developed during Stage I.
Questionnaires: All clinical staff across the hospital (including doctors, nurses and Allied Health Professionals) will be sent an electronic semi-structured questionnaire, covering the same issues as the above interviews *(n=750)*. The questionnaire will be based on the same questions as the staff interviews, and will be further developed and piloted during the beginning of Stage II.

PEOPLE WITH LD AND CARERS
Tracer patients: Tracing individual patients can show how things are and what happens, rather than what should happen. It can also help to diagnose problems and identify areas for improvement (NHS Institute for Innovation and Improvement 2008). The aim of tracing patients with LD in this study is to establish how policies and procedures work in practice, how the patients' specific needs are met, and how their safety is ensured. This will give in-depth insight into the factors that promote or compromise their safe environment, on both organisational and individual levels, that cannot be obtained from interviews and questionnaires alone. It answers the following questions: B3, B5, B7-10, B12-13, B15, C1-8, C10-13, C14-17. Interview guides, observational guides and record analysis checklists will be based on these questions.
Two patients will be selected on each participating ward (a total of six patients per hospital: one every 2 months). Within each ward, the first patient with LD admitted following a specified date will be invited to take part; if he/she declines, the next patient will be invited, until a participant is found. If the patient lacks the capacity to give informed consent, the research team will identify and consult someone who is not the patient's professional care worker, to establish whether the patient should take part; this is in line with current legislation in England under the Mental Capacity Act 2005 (Department for Constitutional Affairs 2007). For each participating patient, the following data will be collected: participant observational data (two episodes of 2 hours, preferably once as close as possible to admission and once near discharge); interview(s) with the patient if he/she has verbal understanding and ability; interview with 1 or 2 carers (family carers and/or paid carers); interviews with up to 5 relevant, purposively selected hospital staff; (telephone) interview with relevant LD professional in the community, if appropriate. The patient's hospital records and notes will be studied. *(tracer patients: n=30; up to 10 interviews and 4 hours participant observation per tracer patient)*
Data collected from Tracer Patients (including interview data) which will be recorded ethnographically, as follows: Observational data will be written by the researcher, using a process of pre- and initial writing (mental notes/jotted notes), writing field notes (representing action and dialogue) and researcher reflection (Emerson, Fretz, & Shaw 2001). This way of recording interviews allows for greater flexibility and freedom, and can yield meaningful insights as respondents may be less inhibited than during more formal tape recorded interviews. Descriptions of interviews will be sent to the interviewees for verification/comment/further additions.

Interviews with people with LD: The following people with LD will be invited for face-to-face interview: All those who are members of advisory/decision making bodies or patient representation groups (such as PALS) within the hospital; all those who have made a formal complaint themselves. Interviews with people with LD will be conducted by a researcher with LD, plus a research assistant. Interview guides will reflect the following questions: A9-10, A17, B16, C9, C14-18. It must be noted that flexibility will be used to allow for individual communication needs and comprehension. Whether or not to use tape recording will be agreed with each interviewee *(n=15)*.
All patients with LD identified within the six hospitals during Stage II will be given information about the study in accessible format, and invited to contact the research team if they wish to contribute. Patients with LD will be selected purposively (to ensure a range of abilities and hospital experiences) for face to face interview by a researcher with LD plus research assistant. Sampling will continue until saturation of data has been reached (i.e. no new themes, issues or topics arise from the interviews); it is anticipated that this will be approximately 60 patients (10 per hospital). Interviews will have a

structured component, using a pictorial questionnaire (to answer the questions in figure 2) and an open component, in order to allow the patient to raise any other issues he/she deems relevant.

Questionnaires to families/carers: For each patient with LD identified at the hospital sites between study months 4 and 12, one main carer will be identified and sent a semi-structured questionnaire, to be developed to answer the following question: B5, C1-8, B7-10, B12-13, B15, C10-13, C15. *(n=600).* On the questionnaire, respondents will be asked whether they are willing to be interviewed by telephone. Carers will be selected purposively for telephone interview, in order to clarify issues raised in the questionnaire; sampling will continue until data saturation has been reached. It is anticipated that this will be approximately 60 interviews (10 per hospital site). All family/carers who are members advisory/decision making bodies or patient representation groups will be invited to participate in face-to-face, group or telephone interview, depending on interviewee preference and convenience *(n=15).* All face to face interviews will be tape recorded and transcribed, with the exception of interviews conducted as part of the "Tracer Patients". Telephone interviews will be described by the researcher immediately following the interview; this transcript will be sent to the interviewee for verification/comment/further additions.

MONITORING OF RECORDS
The following data will be monitored throughout Stage II, related to the policies/procedures/systems identified in Stage I:

- Keep a log of patients with LD identified, with relevant details if they can be monitored at each particular site, as follows: where in hospital was the patient admitted; length of stay; re-admissions to hospital within 7 days of discharge.
- All adverse incidents and complaints that involve patients with LD and/or their family/carers. Incidents will be classified using the 10 categories of the International Classification for Patient Safety (ICPS)(Sherman, Castro, & Fletcher 2009). *We note that higher incident reporting rates may be associated with a more positive safety culture (Hutchinson et al. 2009).*

STAGE III *(Research question 3)* Month 15-16

This stage consists of synthesis of our findings with existing literature, guidelines, policies and measures related to other vulnerable patient groups, as follows: patients with dementia; patients with communication problems due to other causes (including brain injuries and dysphasia); patients with mental health problems. The exact nature of Stage III is dependent on the findings from Stage II. We will (a) search the literature for congruence with our final analytical framework of factors that affect the promoting of a safer environment for patients with LD (see "Qualitative analysis" below); and (b) present our emerging Empirical Framework of factors that affect the promoting of a safer environment for patients with LD (see below) to one panel at each hospital, consisting of clinical and patient safety leads of other vulnerable patient group, and inviting feedback on the relevance of our Framework to these other groups, We will then make projections of the likelihood that effective measures for promoting safety of patients with LD are effective for promoting safety of other vulnerable groups. This is based on the question whether measures have been effective because of the nature of LD itself and the particular issues affecting this group (highlighted in section C or our Theoretical Framework), or because of certain problems arising from the presence of LD (which may be present in other vulnerable groups, e.g. communication problems). The findings from this stage will indicate the generalisability of our findings to other patient groups.

Initial stakeholder conferences Month 14-15
A conference will be held at each site towards the end of the data collection period, inviting all participants at that site and all local stakeholders. This is an opportunity to present preliminary findings

at a plenary session, and invite feedback in workshops of mixed stakeholder groups. This is an additional way of inviting reflections on facilitators and barriers in promoting a safe environment for patients with LD in hospitals. In order to begin assessing the generalisability of findings, stakeholders will include experts in other vulnerable patient groups, as follows: elderly care; dementia care; neurology/brain damage; mental health. Data from these conferences will be collected by workshop facilitators, and used in the final data analysis and data synthesis.

Data analysis

Qualitative analysis
All qualitative data (including face to face interviews, telephone interviews, ethnographic data from Tracer Patients and data from open-ended questionnaire questions will be collated and analysed together. This will be facilitated by Nvivo, a computer software programme for qualitative analysis. Data analysis will take place throughout the data collection period, and will involve discussions with the entire research team. During the first months of the data collection period, a sub-sample of initial data will be analysed thematically in order to develop an initial analytical framework for organising qualitative data, following Grounded Theory principles (Strauss & Corbin 1998). This common analytical framework will be based initially on our Theoretical Framework, and used across all data sets in order to aid data synthesis. Preliminary data will be presented to the research team; if new data sets do not fit into the framework or are difficult to synthesise, the team will be used to generate new themes. In particular, themes emerging from all three levels of inquiry (organisational, staff, and people with LD/carers) will be compared and accommodated within the framework, ensuring that any commonalities or differences (for example, between different stakeholder groups, wards, or hospital sites) will be highlighted in the analysis. Throughout the data collection period, the analytical framework will be revised and refined to accommodate newly emerging themes. All qualitative data will be coded into the final analytical framework.

Quantitative analysis
There are two sources of quantitative data in this study, semi-structured questionnaires with carers and with ward staff, and the monitoring of records. These quantitative data will be described and summarised as appropriate (using relevant measures of location and spread) in order to both provide a context for and support the qualitative findings

Data synthesis Month 16-18
The amount of qualitative and quantitative data generated by the study will be large. During the stage of data synthesis, the research team will use qualitative data to explain and illustrate qualitative findings, and look for congruence and incongruence between qualitative and quantitative findings. In particular, the team will look for instances where there is incongruence between policy and practice, using specific queries within the Nvivo programme to address these issues and explain any incongruence. It is at the stage of data synthesis that the factors that promote or compromise a safe environment for patients with LD will be highlighted, looking for specific examples of successful and effective measures that promote patient safety. The final analytical framework will be compared with our Theoretical Framework and the initial common analytical framework, in order to generate a final "Empirical Framework of factors that affect the promoting of a safer environment for patients with LD".

Contribution to collective research effort and research utilisation

- *Full report,* including proposed interventions and recommendations for NHS decision makers, will be produced and made freely accessible online

- *Final feedback conference:* A final conference will be held at St George's University of London, inviting all study participants, local and national stakeholders, providing an opportunity to present the findings.
- *Publications* in international peer-reviews journals (aimed at service managers and decision makers) and on www.intellectualdisability.info
- *Presentations* at national and international conferences (aimed at service managers/decision makers)
- *The findings will be disseminated in accessible format* for people with LD, through publication of an accessible paper in the British Journal of Learning Disabilities (peer-reviewed) and through the networks of Mencap. All participants with LD will be sent an accessible version of the study findings.

Plan of investigation and timetable *(see also flow chart on the last page)*

Pre-grant: Jan-Jun 2011 (6 months): Develop data collection tools and participant information materials (2 months); followed by application for ethical approval (6 weeks); followed by application for R&D approvals (6 weeks); update literature review; put together Advisory Group; advertise for research assistant.
Month 1 (July 2011): Finalise the above; Recruit research assistants; set up interviews for Stage I; 1st Advisory Board Meeting; select participating hospital wards
Month 2-3: STAGE I: Interview strategic managers (3 per site); 1 structured questionnaire to be completed at each hospital by relevant manager; examine policies, procedures and systems; researchers undergo training as needed; training of co-researchers with LD; pilot questionnaires for stage II; set up data bases for quantitative data; develop initial coding framework for qualitative data and set up qualitative data bases in Nvivo
Month 4: STAGE II: Set up systems at each hospital for monitoring/tracking records; set up interviews on each participating ward; begin development of staff questionnaires; begin distribution of carer questionnaires to carers of all identified patients with LD at each hospital (n=600) (data collection until month 15); begin distribution of information to all patients with LD (n=600)
Month 5: First tracer patient on ward 1 at each site; set up interviews with people with LD and carers who are on advisory/decision making bodies or patient representative groups (n=15) (until month 7); begin interviews of ward staff (n=45) (until month 14); 2nd Advisory Board Meeting; start preliminary data analysis
Month 6: Begin individual confidential stakeholder interviews: with carers (face to face at the hospital site, or by telephone) (10 per site, n=50); and with patients with LD (face to face at the hospital) (5 per site, n=25)
Month 7: First tracer patient on ward 2 at each site; ongoing data collection as above
Month 8: Distribution of electronic staff questionnaires. Ongoing data collection as described above; adjust coding framework for qualitative data
Month 9: First tracer patient on ward 3 at each site; ongoing data collection; 3rd Advisory Board Meeting
Month 10: Second tracer patient on ward 1 at each site, ongoing data collection
Month 11: Ongoing data collection
Month 12: Second tracer patient on ward 2 at each site; ongoing data collection; adjust coding framework for qualitative data
Month 13: Ongoing data collection; stake holder conferences at 2 hospital sites; develop survey for stage III; 4th Advisory Board Meeting
Month 14: Second tracer patient on ward 3 at each site; stake holder conferences at the other 3 hospital sites; end of all interviews/questionnaires data collection; develop final coding frameworks and start final data analysis
Month 15: Complete tracking of records

Month 16: Search literature for congruence with other vulnerable patient groups; hold panel discussion at each site
Month 17: Complete literature search and integrate with panel discussions
Month 18: Complete final data analysis; start data synthesis;
Month 19: Complete data synthesis; write final report
Month 20: Write academic papers; give presentations; hold feedback conference; publish final report
Month 21: Complete presentations & papers

Ethical issues

Approval by ethics committees
Ethical approval for the study will be obtained via IRAS. All data collection tools and participant information materials need to be submitted at the point of REC application – we have allowed 2 months for the development of these materials. We expect the study to be adopted by the South London Comprehensive Local Research Network, who will be able to assist us in obtaining R&D approvals from the 6 NHS Trusts involved. We have allowed 3 months for obtaining ethics and R&D approvals. We propose to commence the study in April 2011, which will give us 6 months for the preparatory work, giving 2 months flexibility in obtaining relevant approvals before the start of data collection in month 2.

Ethical issues
This study includes data collection involving vulnerable adults. The research team has longstanding expertise in conducting research in sensitive areas involving participants who have LD, including death, dying, bereavement and abuse, and have gained international recognition in this area (Tuffrey-Wijne, Bernal, & Hollins 2008). As well as her post at St George's University of London, Dr Tuffrey-Wijne is Senior Research Fellow at Maastricht University in the Netherlands (at 10%WTE), where she offers advice and supervision on including people with LD in research.
The research team feels strongly that ethical considerations for this study need to be given attention above and beyond any requirements of Research Ethics Committees. Therefore, a range of steps will be taken in order to safe guard all informants from undue harm in accordance with the principal of beneficence. We will pay particular attention to obtaining informed consent from research participants with LD, using a range of accessible study information materials, and ensuring sensitivity to the various ways in which people with LD may express withdrawal of consent.
Further ethical issues arise from the inclusion of researchers with LD on the team; we will ensure that appropriate support and supervision is given to all team members, including team members with LD.

Project management

This is a complex project that involves a number of active staff members with varying responsibilities. Dr Tuffrey-Wijne is Principal Investigator and will act as project manager at 20%WTE. The data collection will be carried out by Dr Nikoletta Giatras, who is responsible for day to day management and directing the more junior researchers (100%WTE). Two research assistants will be employed during the active data collection months. Two co-researchers with LD are employed at 8%WTE to support all elements of the research, including data collection. The other joint applicants will provide guidance, advice and supervision as needed, according to their specific skills (including methodological and management skills).
Dr Tuffrey-Wijne will provide day to day supervision for the research team and lead regular team meetings, ensure the team receives adequate training (including training for particular aspects of the research through the SGUL research training programme), assist with day to day management of the project as needed, monitor progress, guide data analysis, and communicate with the joint applicants.

All research activities will be based at St George's University; researchers will travel to the various research sites as needed. She herself will receive supervision from Prof Hollins.

- Specifically, the following core team of researchers will hold weekly team meetings to monitor progress, discuss difficulties encountered, plan the day to day workload and discuss (preliminary) data analysis: Dr Tuffrey-Wijne; researcher responsible for day to day management; research assistants when employed; Mr Adeline.
- The following research team members will be called upon by Dr Tuffrey-Wijne to meet with the core team and provide their expertise as needed: Prof Baronness Hollins (overall guidance and LD issues), Prof Edwards (organisational research), Ms Christian (change management), Dr Gillard (qualitative methodologies), Dr White (quantitative methodologies), Ms Gordon (patient safety), Mr Blair (local advice on LD, data collection, access and Trust management issues).
- All joint applicants will be called to meet with the core research team bimonthly
- The Project Advisory Group will meet every 4 months

Project Advisory Group

A Project Advisory Group will be established prior to the start of the project. The group will have an independent Chair, Sir Leonard Fenwick, who is Chief Executive of Newcastle Upon Tyne NHS Foundation Trust and was a panel member of the Independent Inquiry into access to healthcare for people with LD. The Advisory Group will further consist of: all joint applicants who are researchers; Mr Lloyd Page (service user with LD, likely to b recruited as LD researcher); one further people with LD; Ms Monica Stannard (parent carer, "Caring Solutions"); one further family carer; Ms Beverley Dawkins (MENCAP, involved in "Death by Indifference"); Ms Alison Robertson (director of nursing, SGH); Ms Yvonne Connolly, head of patient safety, SGH; Dr Mark Cottee (consultant and senior lecturer in Geriatric Medicine, Head of Academic Geriatric Medicine at SGUL and Chair STC Geriatric Medicine for London).

The Advisory Group is necessarily large, as this project involves a large variety of research settings and strands, requiring wide-ranging expertise and view-points. The Advisory Group will meet five times during the course of the research. Its tasks include guiding the direction of the research, in particular around any unexpected barriers and any emerging ethical issues; monitoring progress; commenting on emerging findings; promoting the research among their own stakeholder groups and supporting dissemination of the findings.

Service users/public involvement

We believe strongly that it is crucial to involve people with LD in all aspects of research affecting the lives of people with LD. The research team has long-standing expertise in involving service users in research, and has gained international recognition in this area. The work of Dr Tuffrey-Wijne was highlighted by INVOLVE as an example of good practice around user involvement in research. For nearly two decades, two people with LD have been employed by St George's University of London to advise on all research projects related to people with LD, and to act as co-researchers involved in all aspects of the research process. In this research project, we will employ two co-researchers with LD at 8%WTE. In addition, one further person with LD and two family carers will be part of the Advisory group.

Co-researchers with LD: The main aim of their research role is to ensure that any data collection involving participants with LD is carried out in an appropriate, accessible, sensitive and ethical manner. In particular, they will: play a crucial role in developing data collection tools that are suitable for use by patients with LD (study information and interview guides and questionnaires); conduct interviews with patients with LD (supported by a researcher without LD); be involved in data analysis (Tuffrey-Wijne & Butler 2009). Dr Tuffrey-Wijne and Dr Giatras will provide research interview training prior to data collection.

Advisory group members: The aim of involving additional advisors with LD, and family carers, is to ensure that the research is carried out in a way that is acceptable and sensitive to the needs of these

crucial groups. They will be asked to advise on the development of data collection tools relevant to their stakeholder group, and to give feedback on the results. Experience has shown the importance of having at least 3 people with LD on a Research Advisory Board.
Dissemination: Although the findings of this research will be primarily aimed at NHS decision makers and will be disseminated in ways that will reach them, we feel it is important to explain the results to all stakeholders, including people with LD. The research team is expert at making complicated research findings accessible to people with LD, for example, through accessible journal articles and through the acclaimed "Books Beyond Words" series of picture books on health topics, as well as meetings and conferences accessible to people with LD and carers. The presence of Mencap on the research team is particularly important in this respect. Four of the team including a co-researcher with LD, are on the editorial board of an e-journal for healthcare students and professionals: www.intellectualdisability.info which is accessed by more than 500 people daily.

References

Baba-Akbari Sari, A., Sheldon, T., Cracknell, A., & Turnbull, A. 2006, "Sensitivity of routine system for repoting patient safety incidents in an NHS hospital: retrospective patient case note review", *British Medical Journal*, vol. 334, pp. 79-81.

Bach, S. & Della Rocha, G. 2000, "The management strategies of public service empolyers in Europe", *Industrial Relations Journal*, vol. 31, no. 2, pp. 82-96.

Bolden, R. & Gosling, J. 2006, “Is the NHS Leadership Qualities Framework missing the wood for the trees?” In Casebeer, A., Harrison, A. & Mark, A. (eds) *Innovations in healthcare: a reality check,* pp. 17-29, Palgrave Macmillan, Basingstoke.

Care Quality Commission 2010, *Quality and risk profiles of NHS trusts in early 2010.*

Currie, G., Finn, R. & Martin, G. 2007, “Spanning boundaries in pursuit of effective knowledge sharing within healthcare networks in the NHS”. *Journal of Health Organization and management* vol. 21, no. 4/5, pp. 406-417.

Currie, G., Finn, R. & Martin, G. 2009, “Professional competition and modernizing the clinical workforce in the NHS”, *Work Employment Society,* vol. 23, no.2, pp. 267-284.

Davies, H. & Nutley, S. 2000, “Developing learning organisations in the new NHS”, *British Medical Journal*, vol. 320, pp. 998-1001.

Dawson, P. 2003, *Reshaping change: a processual approach* Routledge, London.

Department for Constitutional Affairs 2007, *Mental Capacity Act 2005: Code of Practice* The Stationery Office, London.

Department of Health 2001, *Valuing people: A new strategy for learning disability for the 21st century. A White Paper* Department of Health, London.

Department of Health 2008a, *Carers at the heart of 21st-century families and communities*, Department of Health, London.

Department of Health 2008b, *Health inequalities: progress and next steps*, Department of Health, London.

Department of Health 2009a, *Improving the health and well-being of people with learning disabilities* Department of Health, London.

Department of Health 2009b, *Valuing people now: a new three-year strategy for people with learning disabilities* The Stationery Office, London.

Department of Health 2010, *Transparency in outcomes: a framework for the NHS. A consultation of proposals*, Department of Health, London.

Disability Rights Commission 2006, *Equal treatment: closing the gap - a formal investigation into physical health inequalities experienced by people with learning disabilities and/or mental health problems*, Disability Rights Commission, London.

Emerson, E. & Hatton, C. 2008, *People with learning disabilities in England*, Centre for Disability Research, Lancaster.

Edwards, C. & Robinson, O. 2001, "Better quality part-time jobs? A study of part-time working in nursing and the police", *Employee Relations*, vol. 23, no. 5, pp. 438-453.

Edwards, C. & Robinson, O. 2004, "An evaluation of the business case for flexibl working among qualified nurses in the UK National Health Service", *British Journal of Industrial Relations,* vol. 42, no. 1, pp. 167-183.

Emerson, R., Fretz, R., & Shaw, L. 2001, "Participant observation and fieldnotes," in *Handbook of ethnography*, P. Atkinson et al., eds., Sage Publications, London, pp. 352-368.

Ferlie, E., Fitzgerald, L., Wood, M. & Hawkins, C. 2005, "The nonspread of innovations: The mediating roles of professionals", *Academy of Management Journal,* vol. 48, no., 1, pp. 117-134.

Frost, P. & Egri, C. 1991, "The political process of innovation", *Research in Organisational Behavior*, vol. 13, pp. 229-295.

Gilmartin, M. & D'Aunno, T. 2007, "Leadership research in health care: A review and roadmap", *Academy of Management Annuals,* vol. 1, pp. 387-438.

Hollins, S., Attard, M. T., von Fraunhofer, N., McGuigan, S., & Sedgwick, P. 1998, "Mortality in people with learning disability: Risks, causes, and death certification findings in London", *Developmental Medicine & Child Neurology*, vol. 40, no. 1, pp. 50-56.

Hornby, P & Symon, G. (1994), "Tracer studies", Chapter 10 in Cassell, C. and Symon, G. (eds) *Qualitative methods in organizational research* , Sage Publications, London

Hutchinson, A., Young, T., Cooper, K., McIntosh, A., Karnon, J., Scobie, S., & Thomson, R. 2009, "Trends in healthcare incident reporting and relationship to safety and quality data in acute hospitals: results from the National Reporting and Learning System", *Quality and Safety in Health Care*, vol. 18, no. 1, pp. 5-10.

Iles, V. & Sutherland, K. 2001, *Managing change in the NHS: Organisational change* NCCSDO, Southampton.

INVOLVE. Good practice in active public involvement in NHS, public health and social care research. 2007. National Institute for Health Research.

McGovern, P., Gratton, L., Stiles, P., Hailey, H. & Truss, C. 1997, "Human resource management on the line?", *Human Resource Management Journal,* vol. 7, no. 4, pp. 12-29.

MENCAP 2004, *Treat me right! Better healthcare for people with a learning disability*, Mencap, London.

MENCAP 2007, *Death by indifference*, Mencap, London.

Michael, J. 2008, *Healthcare for all: Report of the independent inquiry into access to healthcare for people with learning disabilities*, Aldrick Press, London.

Mintzberg, H., Quinn, J., & Ghoshal, S. 1998, *The strategy process* Prentice-Hall, London.

National Patient Safety Agency 2004, *Seven steps to patient safety: the full reference guide* National Patient Safety Agency, London.

Nembhard, I., Alexander, J., Hoff, T., & Ramanujam, R. 2009, "Why does the quality of healthcare continue to lag?", *Insights from Management Research Academy of Management Perspectives*, vol. 23, no. 1, pp. 24-42.

Newton, J., Graham, J., McLoughlin, K., & Moore, A. 2003, "Receptivity to change in a General Medical Practice", *British Journal of Management*, vol. 14, no. 2, pp. 143-153.

NHS Institute for Innovation and Improvement. Quality and Service Improvement Tools: Tracer Study. http://www.institute.nhs.uk/quality_and_service_improvement_tools/quality_and_service_improvement_tools/process_mapping_-_tracer_study.html . 2008. 29-6-2010.

Parliamentary and Health Service Ombudsman 2009, *Six lives: The Provision of Public Services to People with Learning Disabilities. HC 203 I-VIII* The Stationery Office, London.

Paton, R. & McCalman, J. 2008, *Change management: a guide to effective change implementations* Sage, London.

Pettigrew, A., Ferlie, E., & McKee, L. 1992, *Shaping strategic change* Sage, London.

Raleigh, V., Cooper, J., Bremner, S., & Scobie, S. 2008, "Patient safety indicators for England from hospital administrative data: case-control analysis and comparison with US data", *British Medical Journal*, vol. 337:a1702.

Sherman, H., Castro, G., & Fletcher, M. 2009, "Towards an International Classification for Patient Safety: the conceptual framework", *International Journal for Quality in Health Care*, vol. 21, no. 1, pp. 2-8.

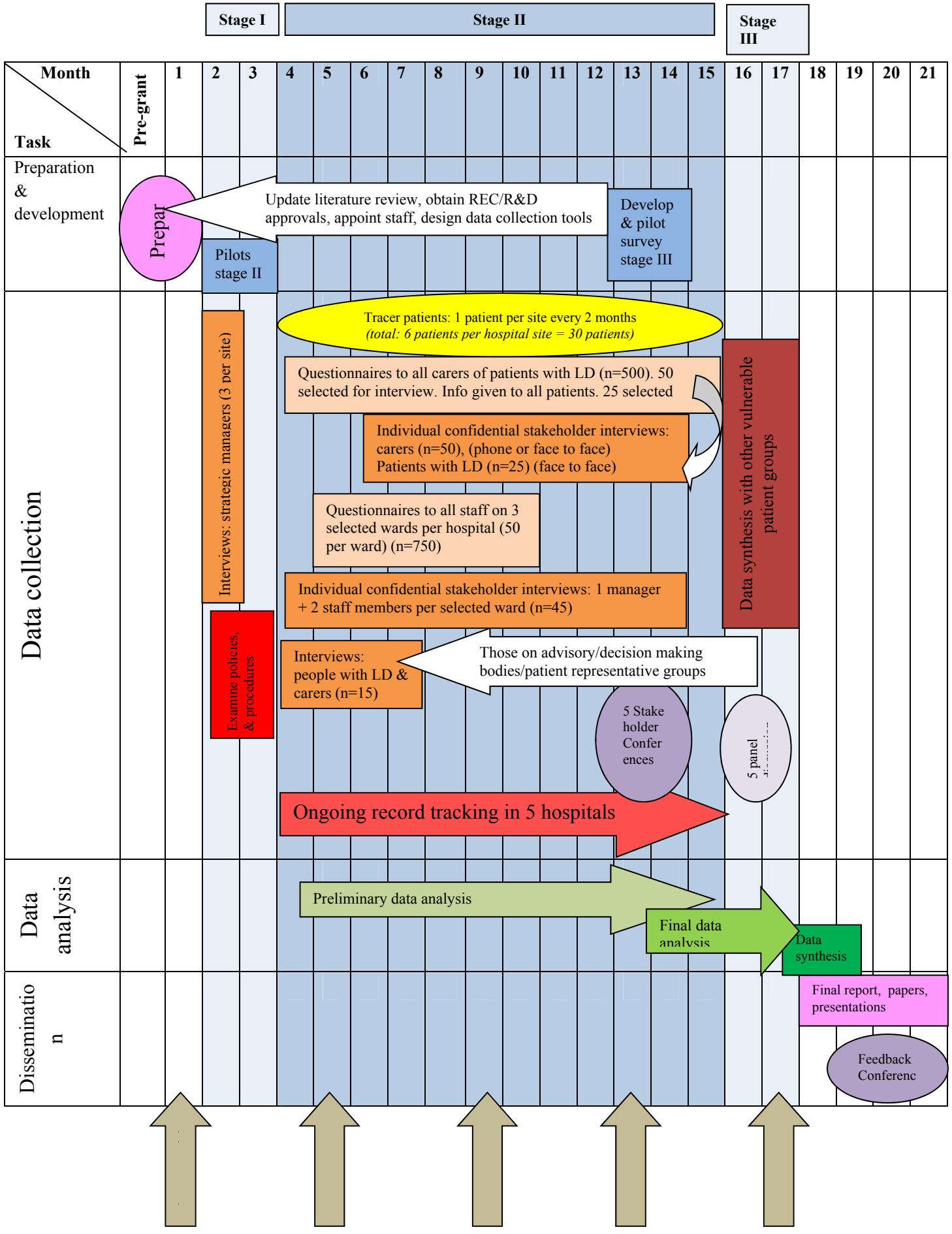
Strauss, A. & Corbin, J. 1998, *Basics of qualitative research: techniques and procedures for developing grounded theory*, 2nd edn, Sage Publications, London.

Truss, C. 2003, “Strategic HRM: Enablers and constraints in the NHS”, *The International Journal of Public Sector Management* vol. 16, no. 1, pp. 43-61.

Tuffrey-Wijne, I., Bernal, J., & Hollins, S. 2008, "Doing research on people with learning disabilities, cancer and dying: ethics, possibilities and pitfalls", *British Journal of Learning Disabilities*, vol. 36, no. 3, pp. 185-190.

Tuffrey-Wijne, I. & Butler, G. 2009, "Co-researching with people with learning disabilities: an experience of involvement in qualitative data analysis", *Health Expectations*, vol. 13, no. 2, pp. 174-184.

Flow chart: Plan of investigation and time table



[**Insert project title**]

1. Aims/Objectives:

2. Background:

3. Need:

4. Methods:

a. Setting

b. Design

c. Data collection

d. Data analysis

5. Contribution of existing research:

6. Plan of Investigation:

7. Project Management:

8. Service users/public involvement:

9. References:

This protocol refers to independent research commissioned by the National Institute for Health Research (NIHR). Any views and opinions expressed therein are those of the authors and do not necessarily reflect those of the NHS, the NIHR, the SDO programme or the Department of Health.