How can frontline expertise and new models of care best contribute to safely reducing avoidable acute admissions?

1. Aims and objectives:

1.1 Aim:

The study aims to investigate how clinician expertise and decision-making pathways in four contrasting hospitals contribute to admission avoidance in acute care, and to make recommendations about Admission Avoidance models and their impact on workload management at the hospital front end.

1.2 Project Summary:

The design comprises a case-study design of four acute admission sites, using primarily qualitative and additional quantitative methods, in two periods of data collection, with a mid-project stakeholders conference and learning sets between these phases. The study incorporates:

- Ethnographic qualitative methods (observation, interview and documentation analysis)
- Up to 6 mini case studies of patient journeys in each of the four case sites
- Quantitative analysis of key processes of care.
- An embedded study of cost.
- A parallel learning set to encourage exchange of ideas and learning across sites

1.3 Study objectives:

1. To investigate the influences that operate on decision making about admissions in acute medical care.
2. To investigate how frontline experience and new models of care contribute to reducing avoidable acute admissions.

1.4 Research Questions:

1. What influences operate on the acute admissions decision process?
    - 1a. How do patients' and families' ideas, concerns and expectations affect decisions? How are they involved in decisions?
    - 1b. How do medical staff and other practitioners contribute to decision making? How do their skills and experience affect decision making? How does early 'experienced' input affect decisions?
    - 1c. How do organisational factors affect decision making?
2. How is the admissions process experienced by patients and practitioners?
3. How are the four models of care similar and different?
    - 3a. How does patient experience vary in each setting?
    - 3b. How are different ideas and policies and incentives taken up in each setting?

3c. How often do the potentially critical components of care (e.g. early senior input) occur for potentially avoidable admissions? And how does this vary by diagnostic group?

3d. How is each model of care are associated with demographically adjusted admission rates?

3e. How is the cost of providing care during the unplanned admission process related to different organisational models and do they have different impacts on workload management?

4. How can front line expertise and new models safely reduce admission?

1.5 Production of new knowledge and expected actionable findings for the NHS

This project will produce new knowledge in five areas that will be of direct relevance to the redesign of acute care at the front-end of NHS hospitals:

1. The project will identify best practice models in organizing acute medical care at the hospital front-end in terms of safe admission avoidance, efficiency and patient experience
2. Within these models, critical process steps in the admission decision process will be identified
3. The utility of early senior doctor input in the admission decision process will be investigated
4. We will estimate the workforce implications of adopting the identified best practice model
5. Based on our data, we will produce an operational research model that could be used throughout the NHS in order to inform local redesign of acute medical admission care pathways

2. Background

Unnecessary admissions are expensive in terms of iatrogenic harm to patients, inconvenience, and wasted resources. One systematic review found that 6-20% of emergency medical admissions in the UK were avoidable (McDonagh, Smith, & Goddard, 2000). Recent increases in unplanned admissions across the UK have been emphasised by the Nuffield Trust (Blunt, Barsley & Dixon, 2010) and acute care providers now have clear instructions to reduce hospital admissions.

New models

Decisions about admission are the focus of a collision between policies generated by financial and safety concerns. Although considerable research effort has been invested in exploring admission prevention and avoidance through the development of community based chronic disease models (Kane et al. 2003), there is limited research to support the variety of interventions currently being developed at the 'front door' of NHS hospitals. Services have been developed ensuring experienced practitioners make decisions about admission, including 'acute GP services' and direct consultant input at the hospital 'front door'. The cost effectiveness of these models is unknown, although there is some evidence that bringing senior experience to early decisions is effective. For example, a recent review found that inpatient admissions were reduced by 12% and admissions to the acute medical assessment unit were reduced by 21%, following early review by a senior clinician (White, Armstrong, & Thakore, 2010). A review conducted by Carson et al. (2010) found fewer referrals for admissions when GPs worked in emergency departments compared with standard care. In December 2010 the College of Emergency Medicine introduced a clinical standard relating to consultant review of high risk patients, and this concept has been adopted by the UK Department of Health as a key quality indicator for emergency care, along with a recognition of increasing ED consultant numbers within the Operating Framework for the NHS in England 2011/12. Another quality indicator relates to "ambulatory emergency care". This is analogous to day case surgery, in seeking to provide an alternative to conventional hospital admission for selected urgent care conditions (e.g. deep venous thrombosis and cellulitis). There is much interest in the potential for ambulatory emergency care, which has been defined by the Royal College of Physicians as "clinical care which may include diagnosis, observation, treatment and rehabilitation, not provided within the traditional hospital bed base or within the traditional outpatient services

that can be provided across the primary/secondary care interface". Detailed guidance was published by the NHS Institute for Innovation and Improvement in March 2010, and is currently being implemented across the NHS. This is separate to the concept that improved community care may prevent patients with chronic conditions from requiring hospital admission, and seeks to deal differently with those patients who have presented to acute care services.

This debate is part of a wider dilemma of "senior first vs. stepped care" being enacted in other parts of the NHS (GP or nurse triage in access to primary care for same day appointments; stepped care vs. experienced practitioner initial assessment in the new Improving Access to Psychological Therapy services). There are potential disadvantages in terms of deployment costs and loss of learning opportunities associated with having experienced practitioners at the front line which might outweigh financial, safety and quality of life benefits. Given the lack of evidence in this area there is a need to understand this.

Influences on the admission decision

The patient journey starts with help-seeking in the community and initial contact with a professional either in the community or at the hospital front door. Although a handful of observational studies have been conducted in emergency settings investigating the role of nurses in the initial assessment of patients presenting to A&E, and there is recent work on shared decision making in emergency situations (Müller-Engelmann et al 2010). Remarkably little is known about the care doctors provide, with no observational studies focusing on the admission decisions of doctors in acute settings.

Decision making may be influenced by patient, practitioner and organisational factors (See Fig 2), individual beliefs, attitudes and expectations (Adams, Smith, & Ruffin, 2001), personal resources and functioning, and specific illnesses and co-morbidity. Domestic resources and family members' and carers' attitudes are also of relevance. Research examining patients' views of hospital admissions found that 70% of patients specified possible alternatives (Campbell, 2001). Professional factors include the experience, attitudes and beliefs of doctors (Pearson et al 1995). Hensher et al (1999) examined decisions made about alternatives to care in hospital, finding that consultants often chose hospital admission and were more likely than GPs to state that there was no alternative to hospital care. Finally, organisational factors including commissioning and monitoring arrangements, the model for the admissions pathways and the governance and culture of the organisations, as well as, the wider health and social care system, including the availability of community based care, might all contribute to the likelihood of hospital admission. These factors may also contribute to ensuring that service users and potential service users are given timely, appropriate and good quality services. Greater clarity is therefore needed to understand variation and influences on decision-making in acute admission settings.

This study will add to the evidence, by being the first study to examine the patient journey from initial help seeking through to the consequences of the admission decision, in four hospital settings spanning novel and traditional approaches. It seeks to describe and analyse 1) the contribution of patients, family members, and 2) health care professionals at all levels, including senior clinicians to the key admissions decision, and 3) the system characteristics and the organisational factors that influence patients' and health professionals' decisions. It aims to investigate the key factors involved in the decision making process and to identify successful approaches to decision making and admission process productivity focusing on patient flow, and resource use. It does not aim to test one approach against another but rather to develop models of best practice from the lessons learnt across the sites.

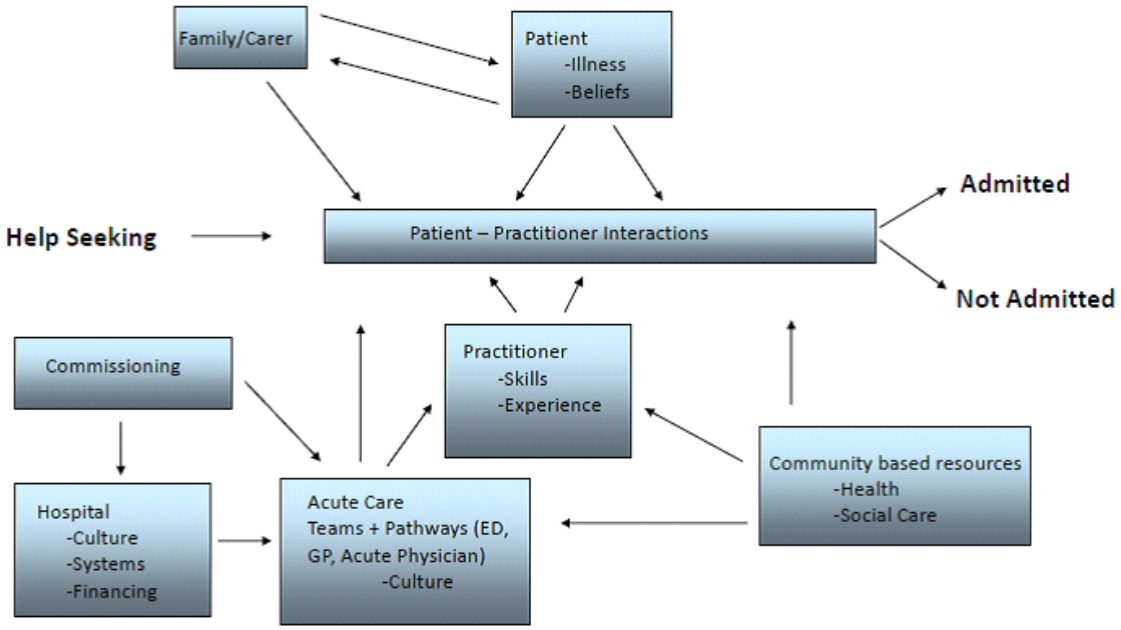


Figure 1: A Conceptual map of the influences on acute admission decisions

3. Need

3.1 As outlined above, our review of the relevant literature has identified a remarkable paucity of evidence about the patient journey through the acute admission process or the organisational and professional factors which contribute to the decision about whether a patient should be admitted to hospital or not. To address this gap the following objectives have been developed:

1. To investigate the influences which operate on decision making about admissions in acute medical care.
2. To investigate how frontline experience and new models of care contribute to reducing avoidable acute admissions.
3. To identify the contexts in which specific components of care are likely to reduce unnecessary admissions.

3.2 The proposed research will contribute to all four topic areas identified in the call, but primarily to the acute care workload management area. This is possibly the most important arena in the NHS where two of the most powerful policy drivers – safety and cost containment – come into conflict. We have chosen to focus on patients with 'medical' rather than 'surgical' conditions, as these make up the great majority of 'bed-days' following unscheduled admissions.

3.3 Case studies will include a systematic examination of commissioning arrangements including the regulation and control exerted by commissioners and health authorities and an assessment of the impact of different processes of monitoring. The research will contribute to the area of demand management by generating, via observation and interviews (patients and practitioners), data both about the patient journey (both the physical and temporal journey, and the patient's experience of this), as well as practitioner decision-making during acute admission pathways.. The study will also provide an investigation of the process and impact of placing a more experienced clinician at the hospital "front door" – a potential solution that has been discussed and utilised in a variety of health care settings in

the UK and abroad. Primarily, the research will contribute to the examination of 'acute care workload management' by providing a whole systems study of current practice and early senior input, and then developing flexible models for best practice (also incorporating a business model). It will also involve stakeholder assessments of these new models of care.

3.4 This research will contribute to understanding the needs of patients and the NHS, by providing a systematic, comparative investigation of three innovative and one traditional settings and a detailed assessment of the ways in which they contribute to improved outcomes, defined in terms of both reduction in avoidable admissions, and in a qualitative analysis of patient experience. Study findings will contribute to our understanding of which components of care are likely to lead to the improved organisation and delivery of unscheduled care.

3.5 This research focuses on addressing health care need and improving quality by facilitating change in the organisation and delivery of care at practitioner and team levels. By illuminating how decisions are made in acute settings, and the influences on these decisions, this study has the potential to inform optimal decision making regarding admissions, with potential to lead to an improvement in the quality of care: both to increase quality of life by ensuring the most appropriate care location and treatments are achieved; and also to address potential adverse effects involved in hospitalising patients with avoidable admissions. The study will also address issues of acceptability and satisfaction by considering evidence to support, or not, patient-centred service redesign. While patient involvement in decision making is accepted as good practice in primary care and in care for long term conditions, it is less clear as to how patients' and families' beliefs, concerns and expectations affect decision making and how they should be taken into account in the acute care setting.

Furthermore the research will go beyond the issue of "choice", which is sometimes at odds with promoting equity, by contributing to knowledge that will help to ensure that vulnerable populations are neither admitted unnecessarily nor discharged from the hospital front door settings to less safe or unsuitable community provision. By taking account of wider, community provision, the research will also contribute to knowledge about appropriate admissions and discharge for vulnerable populations. Potential secondary cost benefits to the NHS may arise if the models proposed result in a reduction in unnecessary admissions.

3.6 The existing strong collaborative relationships between academics and the NHS within PenCLAHRC represent a strength of the research team. PenCLAHRC has a current portfolio of collaborative projects, with topics generated by NHS clinicians and patients. While the project will be set up to enhance immediate decisions by the healthcare community involved and to offer a range of solutions to the NHS beyond the South West, it will also provide the first in depth study of this patient journey, which will have enduring value.

The project will be a true collaboration between the NHS and research community, including managers, patients and clinicians, not just as stakeholders but as part of the research team. Mid-point feedback of results and a learning set for clinicians and managers from each site will facilitate stakeholder input to the research process, cross site learning and more rapid evidence informed redesign.

3.7 The focus of this research, different models of early senior clinician input, is influenced by a three way push – policy drivers; grass roots led service redesign; and the literature. Professionals and managers have also identified this as a knowledge gap, and as a result this area has been prioritised by the PenCLAHRC. Each of the four hospitals approached has welcomed the opportunity to be involved in the project. The hospitals include a wide range of people involved in the decision making process - three different senior clinicians, emergency department consultants at the front door, acute physicians within the triage unit, acute GPs within the triage unit, and within one centre all three.

4. Methods

4.1 Overall Design

The study uses a case-study design of four acute admission sites, using primarily qualitative, with additional quantitative data collection (Teddlie & Tashakkori, 2003):

- Ethnographic qualitative methods (observation, interview and documentation analysis).
- 6-10 mini case studies of patient journeys in each of the four case sites.
- Quantitative analysis of key processes of care.
- A linked study of the cost of the different models of care.
- A parallel learning set to encourage ideas exchange and learning from clinicians and managers across sites.

The design comprises two periods of data collection (See Fig 2). *Phase 1* (months 6-12) will examine pathways, roles and influences on decision making. Tentative hypotheses as to key clinical mechanisms for improved care will be developed. A mid project stakeholders' conference will bring together learning sets and researchers to jointly interpret results from phase one. *Phase 2* (months 14-19) will focus on quantifying the pathways observed in Phase 1 using a Value Stream Mapping methodology. The mixed methods design incorporates a sequential process. Qualitative research in Phase 1 will describe decision making and influences, and map these within and across sites. In Phase 2, quantitative methods will be used to assess the extent to which key processes occur and how costs compare. As a part of to this 'qual-quant' sequence, the data from each source will be summarised into predictor outcome matrices, within and between cases, during integrated analysis phases, to identify likely key mechanisms for safely reducing avoidable admissions. Table 1 shows how each type of data will contribute to each research question.

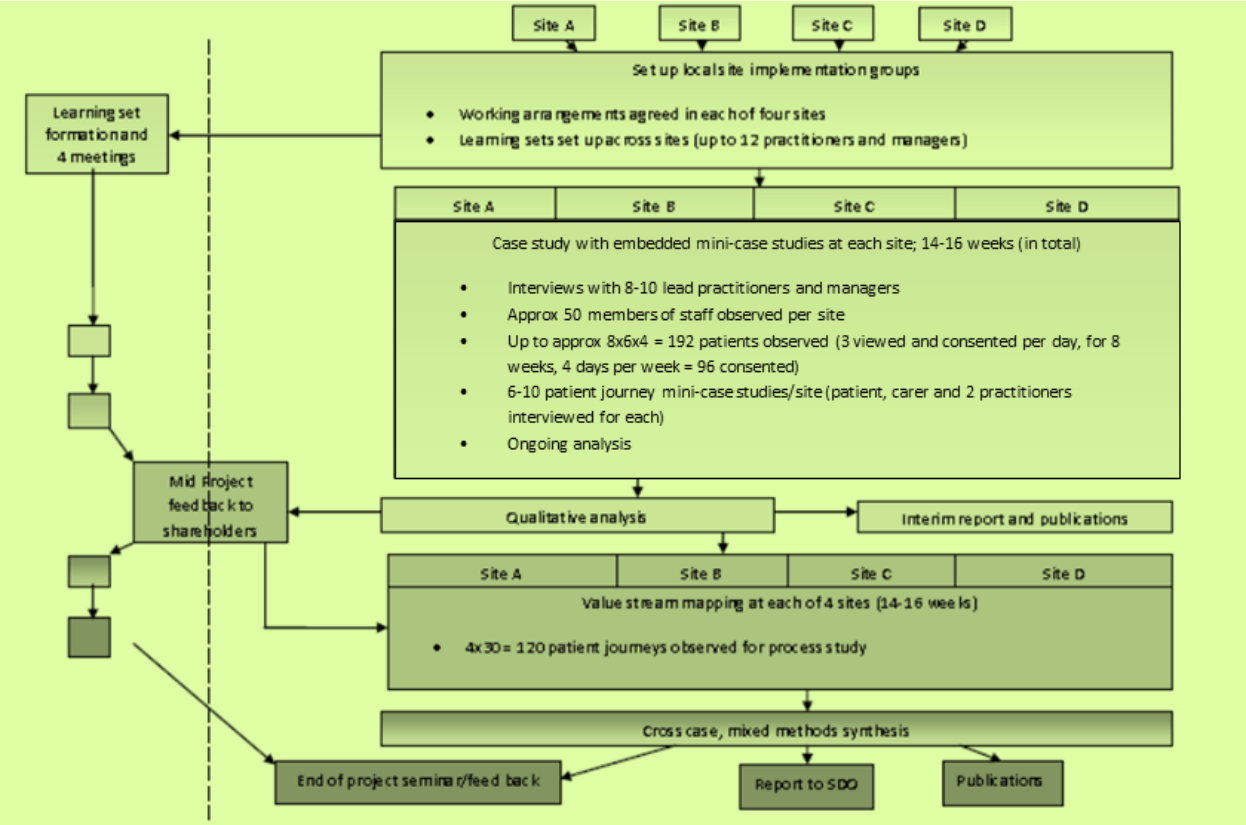


FIGURE 2: Project Research, Learning Set Activities and the recruitment of participants through the study

4.2 Theoretical framework

The research approach used in this project is underpinned by two complementary theory driven frameworks. Realistic Evaluation (Pawson and Tilley, 1997) will be used to determine key processes of change within acute care system, how these relate to outcomes, and when they are context dependent. 'Theories of Change' (Weiss et al, 1996) will be used in the learning set discussions to elaborate how practitioners perceive different elements of care and contextual factors as contributing to (the acute admissions pathways) achieve their aims. A 'Theories of Change' approach will be useful in uncovering 'taken for granted assumptions' about practice, in this case, relating to how and why acute admission decisions are taken in different circumstances. Discussions within the learning set will aim to examine the extent to which theories hold and to demonstrate which assumptions underlying models of practice break down, which are best supported and to further refine the theories (Weiss, 1995). Our approach also includes the use of ethnographic methods within a subtle realist framework (Hammersley, 2002), in which real events and beliefs are studied, accepting that accounts of these are provided from clinicians' researchers' and participants' perspectives and assumptions. The Realistic Evaluation framework provides a way to help explain why programs or models of care vary (Clark et al. 2007) and is also an effective way of looking at resource use and cost (Anderson, 2008). The approach aims: (1) to understand the mechanisms through which interventions produces change; (2) to understand the contextual conditions necessary to trigger these mechanisms; and (3) to develop outcome pattern predictions according to the context and mechanisms triggered. A key objective of this approach is to understand what, within a programme (model of care), influences outcomes. Positive outcomes in this project relate to appropriately avoided admissions and appropriate admissions. Negative outcomes are those admissions which could have been avoided, and those not admitted who should have been admitted. Four of the applicants have experience of using realistic evaluation methodology (RB, SS, RA, RE).

Table 1. Research questions and data map

	Organisational Data					Patient Data		
Research Questions	Documents	Routine Hospital Data	Manager Interviews	Observation	Practitioner Interviews	Patient /Carer interviews	Process of Care audit	Learning set discussions
1. What influences operate on the acute admissions decision process?	X	X	X	X	X	X	X	X
1a. How do patients' and families' ideas, concerns and expectations affect decisions? How are they involved in decisions?				X	X	X		X
1b. How do medical staff and other practitioners contribute to decision making? How do their skills and experience affect decision making? How does early 'experienced' input affect decisions?				X	X	X	X	X
1c. How do organisational factors affect decision making?	X	X	X	X	X			X
2. How is the admissions process experienced by patients and practitioners?				X	X	X		X
3. How are the four models of care similar and different?	X	X	X	X	X	X	X	X
3a. How does patient experience vary in each setting?	X	X		X	X	X	X	X
3b. How are different ideas and policies and incentives taken up in each setting?	X		X		X			X
3c. How often do the potentially critical components of care (eg early senior input) occur for potentially avoidable admissions? And how does this vary by diagnostic group?				X			X	
3d. How is each model of care are associated with demographically adjusted admission rates?		X						
3e. How is the cost of providing care during the unplanned admission process related to different organisational models?	X	X					X	
4. How can front line expertise and new models safely reduce admission?	X	X	X	X	X	X	X	X

A framework approach to qualitative data management and analysis prioritises the research questions and objectives, rather than starting from the themes emerging in the data, and as such fits well with the proposed research model (Richie & Lewis, 2003). Research objectives form the starting point of the analysis (Pope et al, 2000), and emerging themes are incorporated within this framework. The Realistic Evaluation framework facilitates methodological pluralism, and consequently fits well with our depth and participant focused ethnographic approach, in which we propose to use qualitative methods, followed by quantification.

4.3 Data collection

Following an initial period of methods training and piloting, accessing and familiarisation with sites, shadowing gatekeepers and identifying key informants, data collection will take place as follows:

4.3.1 System-level data

Setting and sample:

The organisational case study design will comprise a comparative analysis of four acute admission sites in the South West. Three sites (Plymouth, Exeter and Gloucester), each with innovative ways of providing experienced clinician input (including general practitioner, emergency medicine and acute physician) early in the pathway. One further site, Bath, with a traditional model, has been selected to ensure variation in models of care. Each participating NHS trust has agreed to participate (letters of permission available in uploaded documents). Sites have been compared against a range of criteria to demonstrate that they are both different and are comparable with a range of hospitals nationally (see Table 2).

Table 2. 2009-2010 data showing new emergency department attendances, total admissions via the emergency department and hospital acute beds and occupancy percentage for Gloucestershire, Plymouth, Exeter RD&E and Bath RUH Trusts.

	Gloucester	**Plymouth**	**RDE (Exeter)**	**RUH (Bath)**
New ED attendances	102,243	94,657	88,346	65,738
Admissions via ED	32,484	23,069	22,726	25,396
Hosp acute beds & occupancy [%]	914 [89.5]	735 [87.2]	601 [84.8]	547 [92.8]

Data sets:

In order to describe decision making roles and input of senior/expert clinicians, practitioners and managers and to identify the organisational pathways, spaces and resources affect decision making, data will be collected as follows:

- ***Formal Interviews*** *(*8-10 per organisation) with key informants will be carried out (expert/front line clinicians : acute care consultants, acute GPs, lead nurses, Emergency Department consultants and Senior managers and commissioners (RQ 1,3 & 4); During the set up period key informants will be identified and topic guides for interviews will be developed and piloted. Interviews with clinicians will combine semi-structured questions about qualifications, experience of acute care settings, and open ended questions to explore clinician perceptions about decision making processes and key factors in admission avoidance. Where feasible, practitioner decision diaries will be used as a focus for the interviews – structured diaries facilitating record of what decisions made and how practitioners felt about the outcomes.
- ***Participant observation*** of organisational processes; team make up and function (RQ1,3,4). During initial set up, acceptable and data rich spaces and times within the four case sites will be identified. Figure 3 depicts a simplified version of the four different systems (detailed diagrams have been uploaded and are available on request). Observation along with interviews will be used to map out these four systems from an ethnographic perspective. Sampling will be purposive and pragmatic, taking account of treatment needs and practitioner/patient preferences. Observation of organisational processes will be made in relation to patients identified as having potentially avoidable admissions who will be identified as detailed in 4.3.2 below. There are no targets for 'recruiting' patients to this part of the study but it is estimated that about 192 will be observed per site per phase. Researchers will record field notes as close to observations as possible. Field notes will be recorded using the Smartpen process which enables researchers to take handwritten notes which can subsequently be uploaded and transcribed using handwriting recognition software.
- ***Documentary analysis*** including financial and business planning, governance, and implementation of process change (RQ1,3,4).
- ***Data on costs and admissions***; staffing costs including typical staff mix, grades and sessions/hours worked at different times in each hospital (RQ3,4).

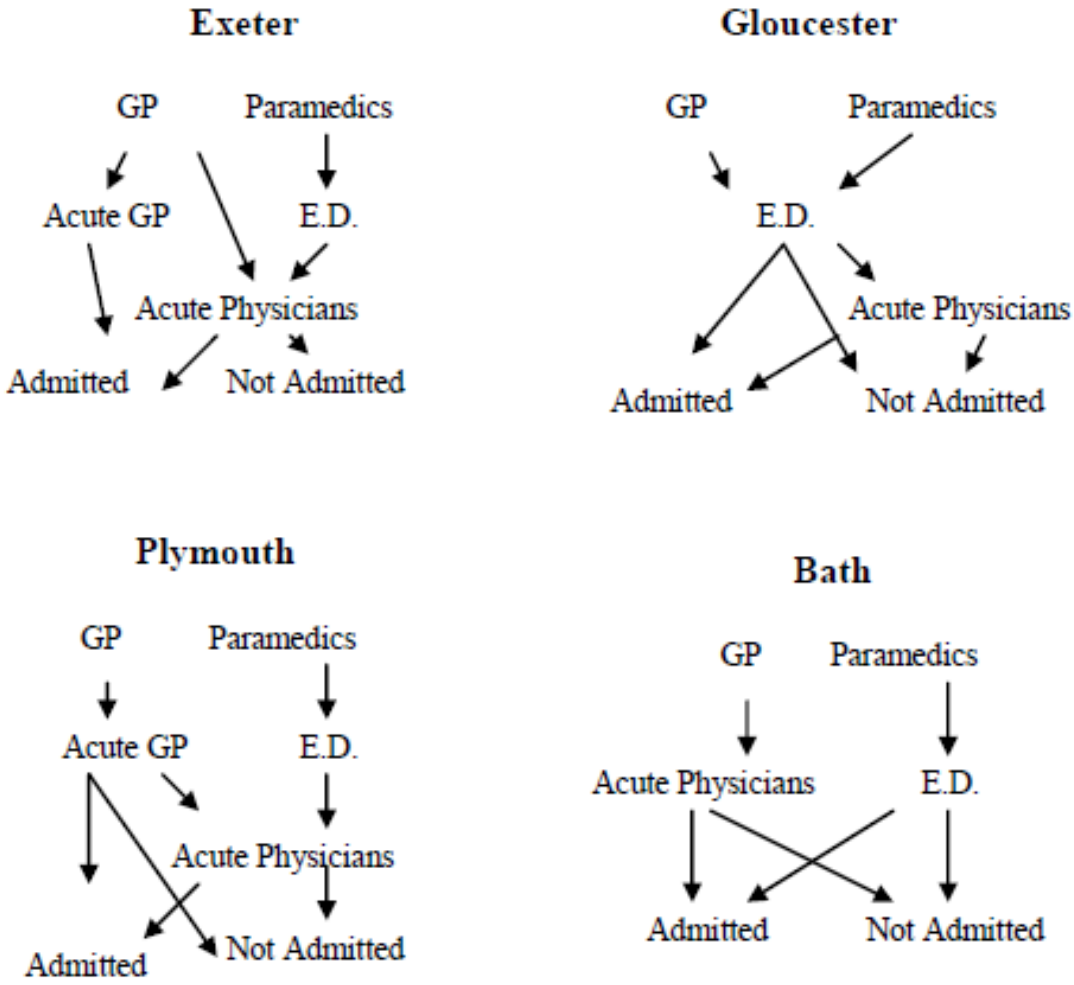


Figure 4. Diagrammatic representation of the four systems of care.

4.3.2 Mini case studies – the patient journey

Sample and setting:

Within each organisational case study, the in-depth study of 6-10 patient journeys per site will allow a detailed comparison of patient level clinical and patient pathway variation across the sites, as well as how admissions decisions are made in general. Individual patient cases will be selected on the basis of being 'potentially avoidable' according to presentation– those for whom an initial triage would not be definite admissions nor definitely able to go home. The researchers will work closely with Research Network nurses and hospital staff to recruit these patients in ED and acute admission ward settings. Based on the experience of redesigning medical admission pathways at the RDE Hospital is estimated that very early in the pathway, 20-40% of those on the medical admission pathway can be identified as 'potentially avoidable'. Protocols for identifying these 'potentially avoidable' admissions will be developed based on the following factors: a) presentation and clinical state (e.g. short of breath but with relatively normal oxygen saturation; b) Social and personal resources (e.g. ability to self care or presence of family/social support); c) diagnosis (e.g. pyelonephritis, cellulitis, for which pathways may exist); d) those for whom acute hospital admission is inappropriate (e.g. requiring end of life palliative care). This

method of identification will be refined and protocolised during the initial phase, and used by the researchers both to identify the detailed mini case studies and for following patients to observe the whole system as above. A sampling framework for the mini case studies (and those studied in the Process study 4.3.3) will be created and maintained on site to ensure individuals observed systematically represent key demographic and system features (age, gender, types of illness, time of day admitted, team involved) as well as diagnosis/presentation types (50% of mini case studies will have chest pain and/ or shortness of breath). Ongoing monitoring of this sampling framework for the detailed mini-case studies will allow researchers to purposively select to ensure a range of patients is represented within and across sites. Consent will be obtained (see Ethics section).

Data sets:

Data collection for the individual (patient journey) level will comprise the following:

- ***Participant observation*** of the acute admissions location including field notes and conversations with participants and staff before, during and after the admissions process, reflections by the researcher (and by patients and family members). Written field notes will be made by the researchers during the participant observation. These will be recorded in as close proximity to the key events as possible, and will include descriptions of people, scenes, dialogue, and decision making processes, as well as personal experiences and reactions. (RQ1, RQ2).
- ***Individual interviews*** with up to 10 patients per site, two of each patient's practitioners, and family members at key points on the journey, particularly at point of admission, and follow up interviews (in hospital, or at home) (RQ1, RQ3). These interviews will both assess the patients journey in time, space and key decisions, but also enquire as patients and practitioners emotional and reflective experience of this care and how that impacted on decision.
- ***Analysis of medical and nursing records*** to identify the range of input to the acute admission process.(RQ3)
- ***Analysis of quality of admissions decisions*** by a clinician led panel and will focus on the quality of the decisions made based on the collated mini case data: both to ensure the people followed up from the start of their hospital journey really were 'potentially avoidable' (i.e. should have been in sample), and then to form a judgement as to whether the decision to admit or send home appeared correct,(i.e. whether the outcome was positive or negative) and to make comments on how care might have been improved. (RQ4)

Since it would not be possible to precisely classify admissions decisions as correct or incorrect based on morbidity or mortality outcomes and existing tools such as the Appropriateness Evaluation Protocol (Lang et al. 1999) have been shown to have low validity (Kalant et al. 2000), we will use an adaptation of the confidential enquiry methodology developed by the National Confidential Enquiry into Patient Outcome and Death (NCEPOD) in which all NHS hospitals in England and Wales participate. This approach to confidential enquiry uses practising clinicians to identify deficiencies in care. Each set of case notes will be reviewed independently by two clinicians and graded for quality of admission decision using NCEPOD definitions of: 'good practice', 'room for improvement (organisational care)', 'room for improvement (clinical care)' and 'less than satisfactory'. Any of the last three would mean would classify them as an inappropriate admission or non-admission. Cross-site reliability of categorisation will be established by having one internal and one external clinician review each case. A third external senior clinician will be involved in cases of disagreement to attempt to gain consensus and if required, make a final decision.

4.3.3 Measuring key processes of care: Value Stream Mapping

In order to quantify the differences in the acute admissions processes between the four participating NHS trusts, and estimate the extent these occur across the NHS, we will map patient pathways for core common presentations that test different aspects of the assessment process and reflect a quantitatively significant component of avoidable

admissions. To reduce heterogeneity these will focus on the two most frequent cardio-respiratory presentations chest pain and shortness of breath, which are a subset of those studied in 4.3.2 above, using a modified Value Stream Mapping (VSM) approach. VSM is a lean management method derived from the Toyota Production System which is a well validated tool in industrial engineering and organisational redesign (Braglia et al 2006, Serrano et al 2008) that has now been used in a number of research projects in North American and European hospitals for studying improvements in patient flow and pathway efficiency across departmental boundaries (Graban 2009, Ng et al 2009, (Bertholey et al. 2009; Cima et al. 2011; Kim et al. 2007; L'Hommedieu and Kappeler 2010; Teichgraber and de Bucourt 2011)) as well as in UK primary care (Grove et al. 2010). Like other tools used in total quality management, the resulting value stream maps (VSMs) are structured diagrams that document the steps in the care process and the activities that take place.

VSMs quantify the average duration of each process and the waiting time between process steps which is very important for quantifying and improving patient flow and subsequently improving processes. For each site a minimum of 30 patients' movements will be mapped after consent has been given, recording timing, place and type and length of professional contacts (including seniority of clinicians). VSMs are recorded through direct process observation after gaining a detailed understanding of the pathways during the qualitative study (4.3.2 and 4.3.3). Analysis of the mini-case studies will be used to identify potentially important processes before micro-measuring them using VSM. These will be two separate parts of the study. The direct observation of the process involves: 1) observation of what is happening (or not happening) to the patient at every step, and 2) assessment of the process from the nurses' or doctors' perspectives. Timing of the process steps utilises a stopwatch and notepad, facilitated by smartpen technology. The clinician's perspective on the process steps is particularly important as this will allow us to also assess important process steps that have been missed and not only those that were observed and about the correct timing of each step on the pathway. Thus each process step will be assigned a clinical value by the treating clinicians using a 4 point Likert scale: high, medium, low, useless.

Table 3 shows an example of the data collected for the VSM.

The VSM procedure will be adapted for this project to provide additional data for key liaison activities (e.g. nurses discussing patients with doctors or providing treatment, juniors gaining advice from seniors) which may be gained from debriefing with key staff and analysis of records. This activity data will be classified as contextual or as mechanisms, incorporated within a Realistic Evaluation approach. In contrast to traditional VSM our study will not focus on flow improvement but, in addition, on measuring the value of each process step. With regards to admission avoidance, fast through-put might not always be desirable, as observation time in A&E might be valuable to judge a patient's condition and decide not to admit. On the other hand delays in assessment and treatment in a moderately ill patient who was not prioritised could lead to deterioration, staff hand-overs and delays which lead to admission. Both insights are crucial to an understanding of missed opportunities to safely avoid admissions.
This data will then be used to estimate the opportunity cost of the alternative models of care (see below). This will be supplemented by data on other resource-relevant activities (e.g. diagnostic tests, occupancy of critical care beds)
The key outcome measure of admission avoidance will be assessed through a retrospective case record review for each patient observed for VSM. Data extracted (length of admission, treatment, procedures etc) will be judged by the clinician consensus panel (s. above) on whether the admission decision was appropriate.

Table 3. Data collection for Value Stream Mapping (with practical examples)

	Condition	Age	Sex	Process step 1	Timepoint (sequence)	Time (length)	Decision maker	Value	Process step n+1	Timepoint etc.	Diagnosis	Outcome
Patient 1	Chest pain	53	M	Clinical exam	10:41	11 min	SHO	High	ECG	11:05	Acute MI	Appropriate admission
Patient 2	Short of breath	72	F	Triage	21:54	6 min	Triage nurse	Low	History & exam	22:30	Heart failure	Avoidable admission
Patient 3	Short of breath	64	F	History	12:45	8 min	Triage nurse	High	ECG	13:10	Anxiety	Appropriate non-admission
Patient 4	Short of breath	81	M	History & exam	23:20	15 min	SHO	High	Blood tests	00:10	COPD, dementia	Inappropriate non-admission
Patient n+1	Chest pain	46	F	History	7:24	3 min	Triage nurse	High	ECG	7:45	Acute MI	Appropriate admission

This will be complemented through a routine data check for each VSM patient that will allow us to capture other relevant outcomes that are not directly observable most importantly deaths after discharge and re-admissions. This includes both patients who are admitted and those who are not admitted.

Sampling strategy: Similar to Phase 1 an opportunistic sampling frame will be used. Researchers will observe and time the patient journeys for 30 consecutive patients per site (total 120 patients) who fulfil the inclusion criteria (target presentation, consent).

Sample size calculation: Based on our experience in redesigning the acute medical admissions pathway at the RDE Hospital where we were able to reduce the number of medical admissions by 35% in routine NHS care, we need 29 participants per site to detect a statistically significant reduction between sites with 90% power at 5% level of significance.

In Figure 3 (appendix) an example of a Value Stream Map is given for a previous study by our team on improving patient flow on a labour ward. For the proposed study, we will add the clinician-assigned value for each step.

4.3.4 A parallel learning set to encourage exchange of ideas across sites and learning from clinicians and managers

The learning sets will be based on action learning methodology to promote self-awareness, critical enquiry, ideas generation, active reflection and solution finding. The underpinning philosophy is that the most effective learning takes place when there is the opportunity to address real issues and to try new ways of actively addressing these through action. The learning set will therefore have a clear purpose by focusing on the aims of the study, and the engagement of the key stakeholders (the learning set members) in the research process will promote shared ownership, an element that will be pivotal to the facilitation of organisational change. The learning set will consist of eight people (allowing for 2 members from each site, see Figure 3) and an expert facilitator, alongside a member of the research team. Establishment of ground rules at the first meeting will clarify the specific roles of the members and the facilitator. The four meetings over the timeframe of the study will enable each member to work on their own project or task while being guided by as well as learning from the other members. They will act as a resource for one another and be both supportive and challenging while pooling their knowledge and expertise to inform the researchers and share ideas and solutions with colleagues in their own sites.
The first meeting will, using methods based on theories of change, identify key processes and inputs that contribute to good decisions. The second meeting will allow participants to reveal reflections in preceding months and to comment on initial findings. Involvement in mid project workshop and third, meeting will allow participants to develop proposals for improving systems. In the final meeting will provide an opportunity to reflect on differences identified across the sites and to appraise and feed into the models being developed by the research team.
The four days will be recorded and will contribute to the research data (analysed within the qualitative data stream) as well as inform data collection and interpretation.

5. Data analysis

5.1 Overall approach to analysis

This mixed methods study has several integrated strands of data collection. Table 1 summarised how these relate to the primary research questions. While each of the first four components of data outlines above will be able to stand alone, the domains of investigation are related to one system as depicted in figure one (conceptual map). Within each component of the study data will be categorised as outcomes (positive and negative admissions decisions)

mechanisms (process of care at individual or organisational level) or contexts (pre-existing patient, professional or organisational factors) according to the Realistic Evaluation Framework. This will not be done slavishly, as categorisation is not always obvious (Byng et al., 2005), but will allow the identification and validation of potential context-mechanism-outcome (CMO) configurations, as a means of developing mid-range theory in this field.
While analysis is carried out in each separate strand as described below, overarching themes and hypotheses will be noted and then explored formally through a system of intra and cross case analysis. Overall, this mixed methods study incorporates a range of strategies recommended for synthesising data:

- "Following a thread"– Ideas and results seen in one data stream will be sought in others during data collection and analysis (O'Cathain, Murphy and Nicholl, 2010).
- A crossover design is imposed on the research through a mid-project feedback of interim analysis encouraging not only translation across cases, but changes to data collection within each strand of the overall methodological design.

Intra-case and cross-case matrices where data is reduced and kept together within a) within cases and b) for different key outcomes of interest.

5.2 Analysis of qualitative data (System level, mini case studies and learning sets)

Data from observations and field notes will be uploaded using Smartpen technology and converted to text. Interviews and learning sets will be audio-recorded and transcribed.

Framework analysis is a data management approach which aids analysis of qualitative data (Richie and Spencer, 1994; Pope et al 2000), comprising five stages: familiarisation, defining a thematic framework, indexing, charting and mapping/interpretation. This approach is particularly useful for applied or policy-related qualitative data (Pope et al 2000). A thematic framework will be derived initially from the project brief and literature review and refined using themes emerging from the data. In this approach data is organised to facilitate interpretation to answer specific, policy and practitioner driven research questions.
Phase one analysis will aim to describe organisational level data and individual patient journeys and subsequently compare cases. Within the realist framework, initial analytical aims will take account of the study focus on the contexts and processes of acute admission decision-making, initially coding data from the diverse sources, relevant to the study questions. In this way, data from the organisational and patient journeys will be read, sifted, charted and sorted according to identified key issues and themes, while ensuring that all data sources, time periods and cases are systematically represented. As analysis proceeds the analytical framework will be revised in line with emerging concepts and themes, again maintaining a focus on key decision-making processes and contexts. Analytical discussions will aide this process. Analytical questions will relate to individual patient, practitioner and family experiences, the cross case comparisons within themes, as well as the meta-themes across the data set. This will facilitate comparison across sites and patient journey mini-cases (see below re synthesis). Each mini case study will be summarised using a consistent framework and discussed with the clinical panel to obtain views on appropriateness of care.

Transcribed textual data will be stored using Nvivo computer software, which permits individual interview data, observational field notes, and documents to be integrated, initially structured within and across the four site sites and patient journeys. Patients and practitioners views and how they construct their experience are considered as potentially important factors for acute admissions decisions and will be analysed alongside more 'objective' pathways of care. Subsequent Analysis matrices will facilitate a structured approach to data analysis both within organisational level data and patient journeys, as well as subsequent cross case/themes.

To ensure rigor and credibility in the qualitative methods, the researchers will meet regularly with either JS and/or SS. Strategies to enhance quality and internal validity (such as member checks with participants, thick descriptions and researcher discussion of analysis and interpretations) will be utilised and recorded. Researchers will record and

discuss analytical memos. There will be opportunities for critical reflection and researchers will keep reflexive journals. To ensure a strong connection between the analysis and clinical perspectives, emerging themes will be discussed with acute care practitioners (clinician panel) during the analysis stage, in the learning sets and mid-point conference.

Predictor outcome matrices will be produced for the mini case studies. These will focus on describing:

i How patients' and families' beliefs, concerns and expectations affect decisions and how they are involved in decisions.

ii Mechanisms for avoiding admission, preventing unsafe discharge and key contexts that hinder or facilitate these.

iii Cross case analysis of mini case studies will take place at the mid-point and end of the study.

iv Appropriateness of admission decision and factors involved in reaching this conclusion.

The appropriateness of the admission decision will be assessed both by the clinician who saw them and the clinical panel (discrepancies will be reported). Our study will identify the factors that support the decision maker in reaching what might be considered safe appropriate decisions.

5.3 Quantitative analysis of key processes of care

The data generated using the modified VSM approach will be used to create value stream maps on Microsoft Visio to capture the acute care processes in the four participating NHS trusts graphically. In combination with the data on admission avoidance gathered as part of the VSM this will allow us to identify best practices in terms of process design and to detect statistically significant differences in the proportion of appropriate admissions between the four models.

The VSMs created will thus allow the study team and the participating NHS trusts to:

1. Quantitatively describe and compare the acute care admissions pathways in the four NHS trusts (RQ3)
2. Provide the micro-level data for the cost comparison study of the four pathways which is detailed in the next section
3. Provide a basis for quality improvement in the four NHS trusts in terms of patient flow and process redesign with direct utility to the individual trust management.

Systematic routine data collected across sites on rates of admission, waiting times, case-mix and health outcomes (readmissions, complications, deaths) will explore the different case study organisations' processes of care at a macro level, building on previous work of our team (Morrato, Elias & Gericke, 2007, Purdy et al. 2011a, 2011b). This will provide additional contextual data to interpret the VSM and other data in the mixed methods synthesis.

5.4 Comparative analysis of resource implications and costs

Comparison of resource use and cost implications between the four sites for the core conditions and pathways will be defined mainly through the VSMs of the sampled patient journeys. The economic comparison will firstly use data on staffing costs (grades and sessions/hours worked) from the four sites, to estimate the overall cost of care. Secondly, the data from the VSMs will also be used to estimate how resources from the overall acute care system are re-allocated to patients with potentially avoidable admissions, and the feasibility of estimating the opportunity cost of these resources will be carefully assessed. Finally, the likely resource implications of the hypothesised key mechanisms and contexts which are believed to drive the outcomes of the different models of care (developed in Phase 1) will be explored and documented.

As our study does not have the statistical power to measure health outcome differences between the different sites we are not able to capture differences in effectiveness based on admission avoidance (i.e. a full economic evaluation is not possible). However we will be able to measure productivity differences and thus classify the four admission models broadly according to their productivity profile (RQ3). The results of the three levels of cost analysis (hospital level average costs; per patient journey VSM-based opportunity costs; and by hypothesised mechanisms and contexts) will be presented in the form of a 'cost-consequence analysis' alongside this provisional evidence of potential productivity differences (i.e. simple balance sheet approach). Uncertainty and variability in cost estimates will be expressed, quantitatively wherever possible (although, given the low number of and non-randomly sampled patient journeys for the VSM these results will inevitably be provisional and exploratory).
In addition we will produce an operational research model through PenCHORD (Peninsula Collaboration for Health Operational Research and Development) as part of PenCLAHRC. We will develop a generic modelling framework that can be adapted to model each of the individual participating trusts based on the input of specific average cost data for each trust (RQ4) and that could subsequently be used throughout the NHS for acute admissions care redesign and planning purposes.

5.5 Synthesis and integrated analysis

This section outlines how analysis of qualitative and quantitative data will be brought together to answer the two broader questions (RQ1 and RQ4): The analytical aim here is to focus on 1.influences on decision making within the acute pathway setting and 2. on actions which have the potential to optimise care at an individual and organisational level to ensure admission avoidance is safe and in the best interests of patients. In this sense we will be able to move from our analysis of the settings to making recommendations for practice. Framed within 'Theories of Change' (Weiss et al, 1996) and Realistic Evaluation (Pawson and Tilley 1997), within and cross case analysis will map out pathways, professional involved, skills utilised, and decisions made, with explicit reference to how these made a difference to service, and how they relate to key outcomes of admissions, quality of care, and safety. Outcome predictor matrices (Miles and Huberman, 1994) will be used to identify patterns of mechanisms and contexts at both organisational and individual level, to examine how key processes, particularly practitioner experience and different models of care, relate to admission decision outcomes.

Data will be brought together in a matrix for each site showing the domains of interest e.g. individual practitioner, team, patient against data collection methods. This will involve summarising key qualitative and quantitative findings, and ensures the data from each system can be considered together (O'Cathain et al, 2010). This will provide the opportunity for hypotheses to be developed as context-mechanism-outcome configurations if appropriate.
Cross case analysis will then be performed using further matrices in the predictor-outcome form (Miles & Huberman 1994) to examine patterns of context-mechanism-outcome predictors for a series of key outcomes (admission rates, patient experience, practitioner experience) (Byng, Norman, & Redfern 2005).
This combination will allow us through a process of modified analytic induction (Byng, Norman, & Redfern 2005) to develop hypotheses about both a) the key influences on admissions decisions (RQ1) and b) the best means for developing strategies for safely avoiding admissions (RQ4). This process should also provide some initial findings about the likely cost differences between the different models for managing admissions, including insight into which hypothetical mechanisms of action or conducive contexts have the most significant resource implications (whether implying costs or savings).
At the end of phase one these hypotheses will be tentative and will be tested in phase two by looking across the cases for confirmation, rebuttal and 'silence', and also possibly evidence for successful translation across cases of potentially useful strategies (mechanisms). The results of this further synthesis in phase two will not include definitive causal mechanisms and context dependencies, but will provide weightier evidence as to which

mechanisms are likely to be effective in which contexts. This will allow us to develop guidance for commissioners, as well as develop provisional theories which can be tested further in more quantitative studies.

6. Ethics

The project requires significant ethical consideration. Patients, family members and practitioners will be asked to participate at a critical moment (arrival at a hospital admissions area), requiring sensitive and confident management by researchers, taking account of treatment needs and practitioner sensitivities. Researchers have visited two of the research sites in preparing this full application and this has facilitated an exploration of ethical issues with lead clinicians; these have been incorporated into the application. Patients will be involved throughout, drawing on the PenCLAHRC Patient Involvement Group (PenPIG), who have commented on the ethics section of this proposal. The approach to ethics in this study is one which holds ethics as a common concern for everyone (Parker, 2007). Ethical issues are openly discussed as appropriate and a way forward is negotiated and re-negotiated as the research develops. Key ethical issues of confidentiality, privacy and informed consent will be managed as follows:

- Practitioner confidence in and acceptance of researchers within the research settings is crucial. Clinical Directors, Lead clinicians, Acute GP services and Lead nurses in each of the four sites have given their agreement for the research to take place.
- Processes for asking for consent will be locally determined. An initial period will be spent in each setting to facilitate researcher awareness, build trust, identify local concerns and appropriate strategies for a. identification of patients suitable for participation and b. initial engagement with patients, their families and practitioners. Written project information for participants will also be available and will follow NREC guidelines relating to consent and right to withdraw.

Practitioners recruitment and consent:

- Researchers will be in each setting at pre-arranged times (They will have NHS ID and honorary contracts and will be CRB checked).
- Written consent will be taken for pre-arranged formal interviews with key practitioners (decision-makers), such as acute physicians, consultants, AGPS. Interviews will be conducted with 8-10 key practitioners. Each interview will be approximately 1 hour long.
- Practitioner consent-taking will be viewed as a process rather than a one-off event (Lawton, 2001; Wiles et al 2005). Avoiding burdening of practitioners in a busy emergency department environment is crucial, balanced alongside the need for transparency and Information and consent to take part. Prior to commencement of observation, timely information will be given about the study, the nature of observational research and how the data will be used. Written consent will be taken for interviews at appropriate times, taking account of the emergency environment. Practitioners will be reassured that they can talk to researchers about any concerns they may have about the study.

Patient/Family recruitment and consent:

- Researchers will be positioned at admission points within the settings once familiarisation has taken place.
- Practitioners or research network nurses will seek verbal permission from patients and families for a researcher to approach a patient. This will be recorded by the researcher.
- Researchers will approach patients/family members and verbally explain the study: including issues of confidentiality, privacy and the right to withdraw.
- Written information about the study will be given.
- Where possible, patients and family members will be given time to consider their involvement.
- It will be made clear that participants have the right to withdraw their personal data from the study at any time.

- Researchers will repeat explanations about the study as requested.
- Verbal consent will be taken from patients during organisational level observation, and a record made that this has been done. In every case, written information about the study will be given to patients, which will include researcher contact details and an invitation to contact the researcher to discuss the study and their data. Researchers will check that written information about the study is available in a variety of formats (eg, large script). Written consent will be taken from patients (at appropriate time depending on event) for observations and interviews during mini-case patient journeys.
- The researcher will engage in participant observation, talking informally to and supporting participants at potentially distressing times, which may entail changes to experience and outcomes; researchers will receive training to ensure they cause minimal disruption and can point people in the direction of appropriate help where necessary.
- Participants will be sent the initial analysis if they wish, and encouraged to provide feedback and reflection. Patient involvement throughout will also help address ethical issues.
- Emergent ethical concerns will form one thread of discussion for the learning sets.

7. Contribution to collective research effort and research utilisation

This research will contribute to understanding the needs of patients and the NHS, by providing a systematic investigation of three innovative and one traditional settings and a detailed assessment of the ways in which they contribute to improved outcomes, defined in terms of both reduction in avoidable admissions, and in a qualitative analysis of patient experience. Study findings will contribute to our understanding which components of care are likely to lead to the improved organisation and delivery of unscheduled care.

The outputs of the research will include: 1) A rich "thick" description of patient journeys, the decision making process and team work in the acute admissions process, which will enable practitioners at all levels of skills and experience to improve practice by increased awareness of the outcomes of decisions, and thus develop alternative ways of working; 2) An understanding of the key processes and mechanisms underpinning novel approaches to decision making in admission, and how different processes relate to admission decision outcomes; 3) Developing provisional hypotheses about how organisational models (pathways, skill mix, roles), and clinician-patient interactions can safely contribute to reducing avoidable admissions; 4) embedded cost analysis.

The project will consider how individual practitioners from a range of professional backgrounds and professional experience can develop new roles and ways of working in order to contribute to safely avoiding unnecessary admissions. As well as providing benefit to the South West healthcare community during the project, this research will be of immediate use to the wider NHS, supporting NHS managers and lead clinicians in developing new models and new roles for professionals in the area of acute care.

This research project will also contribute to the NIHR and NHS research process by:

1) Complementing other areas of research within this call which focus on organisational aspects, such as commissioning and control of admissions;
2) Informing the development of models of acute care suitable for further evaluation using experimental or other methodologies;
3) Contributing to methodological development, in particular to the use of realistic evaluation and theories of change methodology to examine decision making; together with an observational (focused ethnographic) approach in health services research;
4) Highlighting which aspects of initiatives appear to work, and from whose perspective;
5) Providing a detailed description of how decisions are made in the context of changing organisations and new initiatives;

6) Providing guidance on the factors influencing unnecessary admissions, and on which methods of delivery facilitate better outcomes;
7) Providing detailed description of the variety of patient journeys and how patient pathways, clinicians' skills and models of care interact.

Dissemination will utilise traditional research means, such as journal papers and presentations at conferences, but will also involve conferences aimed at redesign within the NHS. A website will be developed during the life of the project, both to support the ongoing learning sets and to showcase models as they emerge, as well as to allow rapid and effective dissemination of the results as they emerge.

8. Project management

8.1 The project is managed by Prof. Jonathan Pinkney and Dr. Richard Byng, who is leading the acute admissions programme and have taken overall charge. A core research management group will also include Prof Jonathan Benger leading the UWE site, Dr. Siobhan Sharkey and Prof. Ruth Endacott leading on methods and the research co-ordinator. The co-ordinator will have responsibility for day to day work and the core group will meet regularly by tele-conference or one to one, monthly or twice monthly depending on the progress and phase of the project. This core management group will ensure that key milestones are kept; alternative strategies are implemented if required and will ensure high quality data collection and analysis.
8.2 A number of sub-groups will exist with varying responsibilities. A northern sites group will include Prof Jonathan Benger, the research fellow based at University of West of England, Dr Sarah Purdy and support from Dr. Siobhan Sharkey. Individual sites will have an implementation group which will include the comprehensive research network nurse researcher, one or more local managers, a learning set member, either Prof Jonathan Pinkney, Dr. Richard Byng or Prof Jonathan Benger, and Dr. Siobhan Sharkey or Prof. Ruth Endacott and the researcher for that site. Mike Williams, former NHS Chief Executive and current NHS Senior Research Fellow, University of Exeter Business School (Organisational theory, systems and management expertise) will offer organisational theory advice throughout the project. A wider study group will include all the applicants and researchers and will provide detailed advice and support when required as well as strategic direction.
8.3 The learning sets will be run by Prof Peta Foxall with support from one of the clinician researchers, Prof Jonathan Pinkney, Dr. Richard Byng and the co-ordinator.
The ethnographic component of the data collection and analysis will be lead by Dr. Siobhan Sharkey working closely with Prof. Ruth Endacott and the co-ordinator and supported by Richard Byng. Ruth and Siobhan together will ensure the researchers are fully trained and supervised on a weekly basis. The patient representative will be part of this group to ensure ethical considerations are taken into account and to support data collection planning and interpretation. If possible a member of the learning set will also be part of this group.
8.4 The quantitative research will be overseen by Prof Jonathan Pinkney and Dr. Richard Byng, supported by Dr Rob Anderson, Dr Martin Pitt, the research co-ordinator and Dr Richard Byng to ensure integration of the mixed methods.
8.5 The PI and the research team will be supported by collaborators comprising: Rod Sheaff, Professor in Health Service Research, University of Plymouth (Commissioning expertise), Dr Martin Pitt, Director of PenCHORD (providing Operational Research expertise), Dr Mike Allen (PenCHORD VSM expert), Professor Peta Foxall, PCMD (learning sets), Dr Peter Rudge, Acute GP lead and NHS Plymouth PEC Chair (Clinical and acute GP expertise). and Dr Simon Walford, University of Wolverhampton (best practice design of urgent care systems), formerly Senior Medical Advisor to the Department of Health. **8.6** An External Advisory Committee will be brought together to steer the project, ensure methodological rigour and represent key stakeholders (2 patient representatives, commissioners/SHA, external academics, policy experts).

10. Service users/public involvement

Patients will be involved throughout, drawing on the PenCLAHRC Patient Involvement Group (PenPIG), which advises PenCLAHRC on all aspects of user involvement. Its members include service users, carers and members of the public. Group members were involved in the initial prioritising of the project topic within PenCLAHRC and have also met with researchers to discuss the writing of this proposal. They have commented on the draft and identified key areas where they feel that user involvement will strengthen the project. These suggestions have been incorporated into the proposal. Others may emerge during the course of the project. There is strong support for the approach taken.

It is important that user involvement is appropriate to the research. To this end initial involvement of PenPIG members will be, supplemented by a broader group of patients and carers with experience of unplanned admissions. Local service user input will be recruited and supported via Patient and Public Involvement mechanisms within each site. User involvement will be tailored to emerging research findings.

If particular condition specific groups emerge as a concern, relevant subgroups will be set up. They, along with members of PenPIG, will be invited to contribute to the project in a number of ways.

The project will involve engaging with members of the public at a potentially critical moment. This will need to be handled sensitively. The process of engagement, obtaining consent and carrying out interviews will therefore be piloted with the involvement of service users and carers to support development of the research instruments (e.g. the interview schedule) and ensure that these address service user and carer perspectives. Service users and carers will be invited to contribute to learning sets to ensure that their perspective is heard by practitioners and academics. Service users and carers will also be invited to comment on initial data analysis. This will provide an important additional perspective on the emerging issues and themes. Costs for training, support, time and travel will be met partially through PenCLARHC and the research budget. Given the geographical dispersal of case study sites, a number of meeting formats will be explored as appropriate. These may include face-to-face meetings, tele-conferencing and video conferencing. A minimum of two representatives will be on the project advisory group. Patient Involvement in the project and the provision of appropriate training and support will be coordinated by Dr Andy Gibson and Dr Siobhan Sharkey.

11. Expertise and justification of support required

This project is the first in depth study of the avoidable acute admissions making process in the UK and possibly worldwide and justifies a high quality approach, with a relatively simple research proposal. We will employ an experienced researcher at 1.0 FTE for two years in the Peninsula to co-ordinate daily activity, collect data in three sites and conduct analysis. A 0.7 FTE experienced researcher will be employed for one year in Bristol to collect data for two sites in the north of the region. Two senior researchers with experience of comparative qualitative case studies and ethnographic methods will be employed 0.2 FTE each to provide supervision, support and analysis. A research assistant (1.0 FTE, 3 months) will help with ethics approval and governance set-up. A quantitative analyst will be employed for 3 months to work on the quantitative analysis.

Additional support will be provided by senior clinical researchers, a patient involvement researcher and advisors. The NHS trusts involved have each agreed to contribute eight days of clinician and manager time for the research project and learning set. Travel will be minimised by keeping the project regional and locating researchers near sites. NHS costs are limited to the consequences of having a researcher observing the acute care setting.

We have ensured that the skills and expertise required for this project are available in the following way: Secondary care clinical (MD, JP, JB); urgent care from a primary care perspective (RB, SP, PR, JC); redesign of acute care (SP, MD, JB, SL, EH, PR); professionalism and new roles (RC, RE, SS); business planning (SL, EH, MD, RA); commissioning (RS, RB, PR); governance (MD, RB), system redesign (CG, MD, EH, RB, SL), research

project management (RB, JB, RE) qualitative methods (SS, RB, RE, SP); practitioner patient communication (RB, SS, RE); ethnography (SS, AG); patient involvement (AG, JS, SS, RB); Realistic Evaluation (RB, SS, RA, RE); health economics (RA) and organisational theory (MW, RS).

12. Data Handling and Record Keeping

12.1 Case report Forms

Case report forms will be filed in a study file and will be kept in a locked cupboard within the Plymouth University Peninsula Schools of Medicine and Dentistry. The data will be transcribed onto an electronic password protected document on the Plymouth University Peninsula Schools of Medicine and Dentistry Department shared drive (to prevent data loss in the event of hard disk failure).

12.2 Records Retention

All records will be stored for 7 years at Plymouth University Peninsula Schools of Medicine and Dentistry secure storage facility. Electronic medical
s will be stored on a password protected computer within the schools' shared drive. Computer drives are securely and professionally erased when disposed of.

12.4 Quality Control and Quality Assurance Procedures

The study will be conducted in accordance with the current approved protocol, ICH GCP, relevant regulations and the Trust standard operating procedures.
Data will be evaluated for compliance with the protocol and accuracy in relation to source documents by the Principal Investigators.

12.5 Regulatory Considerations

The Investigator will ensure that this study is conducted taking into account the principles of the Declaration of Helsinki.
The Investigator will ensure that this study is conducted in full conformity with relevant regulations and with the ICH Guidelines for Good Clinical Practice (CPMP/ICH/135/95) July 1996.
This study will adhere to the principles outlined in the NHS Research Governance Framework for Health and Social Care (2nd edition). It will be conducted in compliance with the protocol, the Data Protection Act and other regulatory requirements as appropriate.

12.6 Approvals

The protocol, informed consent form, participant information sheet and any proposed advertising material have been submitted to an appropriate Research Ethics Committee (REC) and host institution(s) for written approval.
The Investigator will submit and, where necessary, obtain approval from the above parties for all substantial amendments to the original approved documents.

12.7 Participant Confidentiality

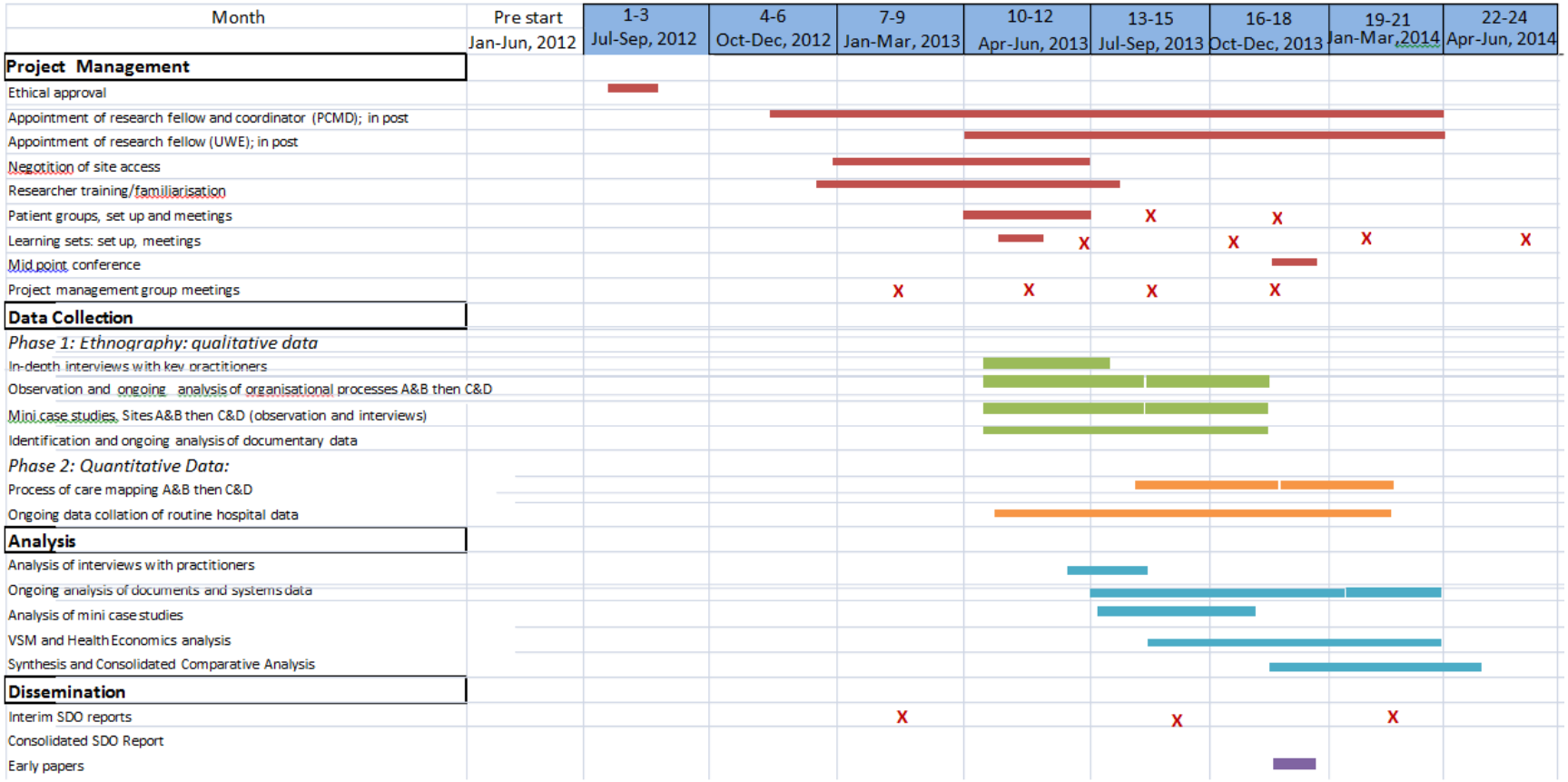
The trial staff will ensure that the participants' anonymity is maintained. The participants will be identified only by initials and a participants ID number on the CRF and any electronic database. All documents will be stored

securely and only accessible by trial staff and authorised personnel. The study will comply with the Data Protection Act which requires data to be anonymised as soon as it is practical to do so.

13. Publication policy

Articles submitted for scientific publication will be reviewed by at least one of the study supervisors. All members of the study management team involved in the product of scientific work will appear as named authors. Acknowledgements will be made to others involved in the project but not directly contributing to the articles.

9. Plan of investigation and timetable (Gantt chart)



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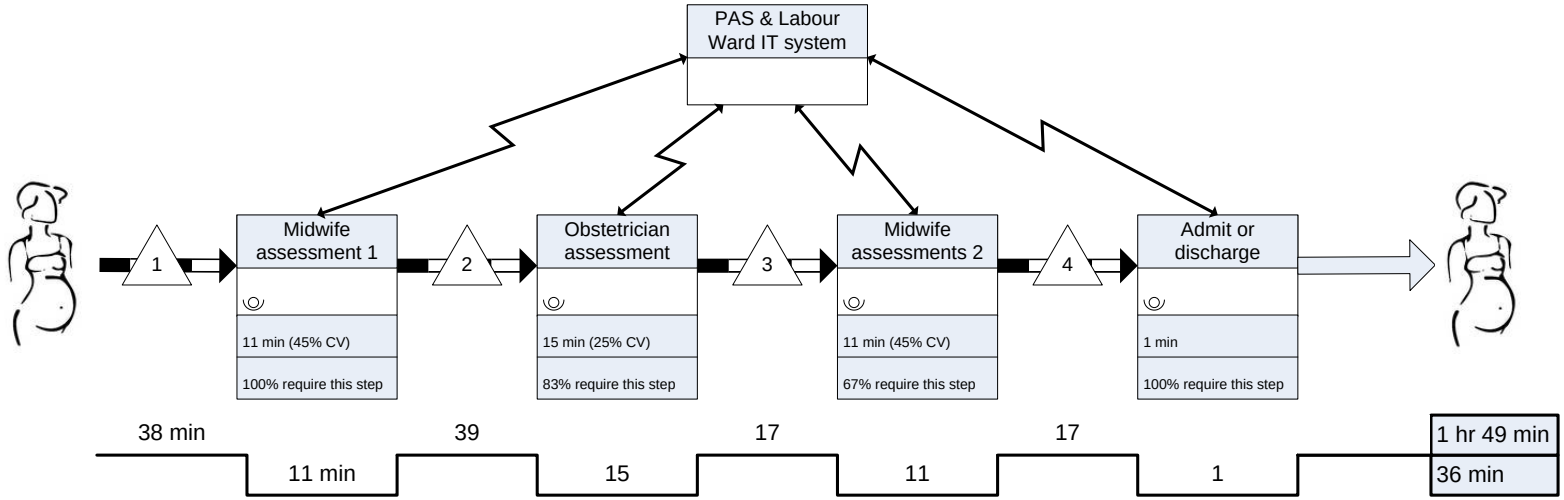
Labour Ward Admissions Value Stream Map



Value-adding time = 36 min out of a total time of 2 hr' 25 = 24%

Notes on wait times

Wait 1: 38 min (200% CV) waiting for free examination room and for midwife. Average waits were 13 min for examination room and then 23 min for midwife.

Wait 2: 83% patients were referred to see an obstetrician. There was an average wait of 39 min (60% CV).

Waits 3&4: 67% of patients have at least one subsequent assessment by a midwife. On average this adds 34 min wait time and 11 min assessment time before being discharged or admitted.

Value stream map based on observation of 30 women arriving at labour ward admission

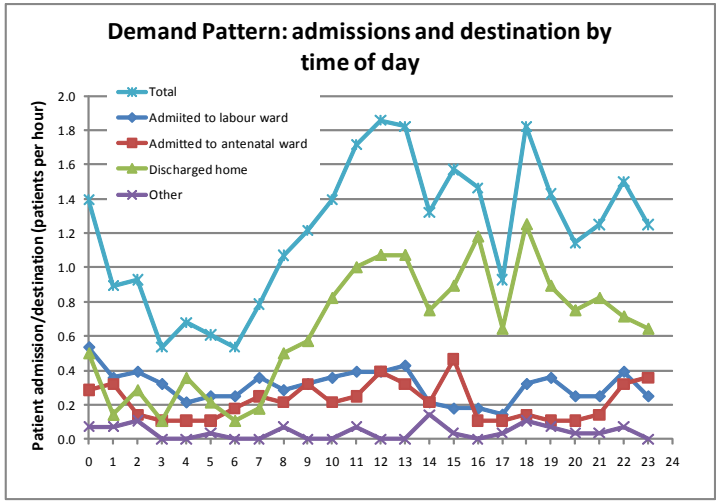


Figure 3. Example of a value stream map