Evaluation of the Impact of High-Intensity Specialist-Led Acute Care (HiSLAC) on Emergency Medical Admissions to NHS Hospitals at Weekends.

Protocol

(HSDR application form 'Detailed Project Description')

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"Due to recent bed pressures patients are often sent from the Acute Medical Unit to the wards without a consultant review, and in some cases without a registrar review".

"On the wards it is 'pot luck' whether the patient is seen by a consultant the following day or a few days down the line".

"Once the patient is identified under the correct team it depends on which day a consultant does their ward rounds, which means a delay up to 5-6 days".

"The patient was an outlier; no one knew the patient and wanted to take any responsibility".

Reflections of a Foundation Year 1 trainee
January 2013

Chapters & Sections

THE RESEARCH TEAM	
MEMBERS	**ROLES**
PROJECT MANAGEMENT COMMITTEE: Study design, direction, progress, analysis, support and outcomes	
Chief Investigator	
• Prof Julian Bion	Professor of Intensive Care Medicine, University of Birmingham
PPI representative	
• Mr Peter Rees	Public and Patient Involvement representative. Member of the Academy of Medical Royal Colleges Patient Liaison Group, The Royal College of Anaesthetists' Patient Liaison Group, The Board of the Faculty of Intensive Care Medicine.
Clinical Reps	
• Prof Julian Bion	Chief Investigator. Professor of Intensive Care Medicine, University of Birmingham and Hon Consultant in ICM at Queen Elizabeth Hospital Birmingham. Past-Dean of Faculty of Intensive Care Medicine. Co-chair of AoMRCs 7 day working subgroup.
• Dr Chris Roseveare	President of the Society for Acute Medicine. Principal author of the RCPL Acute Care Toolkit on 7 day working on the AMU, co-chair of AoMRCs 7 day working subgroup.
• Prof Tim Evans	Professor of Intensive Care Medicine, Imperial College London. Senior Fellow, Future Hospital Commission, and Academic Vice-President, Royal College of Physicians. NIHR Senior Clinical Investigator (2010-2013)
• Dr Mark Temple	Physician Nephrologist, Birmingham Heartlands Hospital; Acute Care Fellow, Royal College of Physicians
• Dr Mike Clancy	President, College of Emergency Medicine. Past chair of research committee. Masters in Health Services Research.
Birmingham Academic Health Partners	**Research Design & Methodology Advisors, Clinical trials & Analysis**
• Prof Richard Lilford	Professor of Clinical Epidemiology, Vice-Dean Applied Health Research, University of Birmingham; NIHR Senior Investigator Award: 2008-2011 & 2012-2013; Chair - MRC/NIHR Methodology Advisory Panel: 2012 on; Chair - NIHR Research for Patient Benefit (RfPB) Regional Funding Committee, West Midlands Region 2011-12
• Mr Alan Girling,	Reader in Medical Statistics.
• Prof Russell Mannion	Professor of Health Systems, Health Services Management Centre, UoB. Previously Director, Centre for Health and Public Services Management (CHPSM), University of York until 2009. Member, NIHR HS&DR Commissioning Board.
• Dr Gavin Rudge	Research Fellow, Department of Health and Population Science; data scientist & expert on informatics.
University of Leicester:	**Ethnography**
• Dr Carolyn Tarrant	SAPPHIRE group: Department of Health Sciences. PhD social scientist. Qualitative methods in health care research.
Brunel University	**Health Economics**
• Dr Joanne Lord	Reader in Health Economics, Health Economics Research Group, Brunel. Economic evaluations and economic modelling.
Project Support	**Project management**
• Dr Cassie Aldridge	PhD: HiSLAC Project Manager
• Research nurse	Ms Amunpreet Boyal, Research Fellow
• Ms Carol Sheppard	Liaison Officer Academy of Medical Royal Colleges
• *Ethnographer*	*University of Leicester*
• *Health Economics*	*Assistants, Brunel University and University of Warwick*
STEERING COMMITTEE: Oversight & Governance	
• Professor Sir Michael Rawlins	Chairman, National Institute of Clinical and healthcare Excellence. Honorary Professor London School of Hygiene and Tropical Medicine. Chair of the Executive Committee of the RCP's Future Hospital Commission.
• Dr Jennifer Dixon	Director of the Health Foundation. PhD in health services research. Previously

	Director of Policy at the King's Fund, Director of Nuffield Trust
• Mr Peter Lees	Director, Faculty of Medical Leadership & Management. Previously specialist neurosurgeon (Southampton) and national roles in healthcare management.
• Mr Paddy Storrie	Member NICE Tech Appraisals Committee D; Member Academy of Medical Science Working Group on Regulation and Governance of Medical Research; Member MHRA Patient and Public Engagement Expert Advisory Group. Past member Citizen's Council of NICE. Headmaster of state comprehensive school.
• Mr Alastair Henderson	Chief Executive, Academy of Medical Royal Colleges
SCIENTIFIC ADVISORY BOARD: Guidance and support on specific scientific, professional or managerial issues	
• Prof Terence Stephenson	Chairman, Academy of Medical Royal Colleges; Professor of Child Health, University of Nottingham; President, Royal College of Paediatrics and Child Health
• Prof Mary Dixon-Woods	Professor of Medical Sociology & Wellcome Trust Senior Investigator, SAPPHIRE group: Department of Medical Sociology, University of Leicester
• Prof Derek Bell	Professor of Acute Medicine, Imperial College London. Academic research focuses on quality and organisation of acute healthcare.
• Dr Anne Driver	Head of Programmes, NHS Improving Quality
• Dr Andrew Goddard	Director of the Medical Workforce Unit, Royal College of Physicians, London
• Prof Mike Grocott	Director of the National Institute for Academic Anaesthesia Health Services Research Centre. Professor of Anaesthesia and Critical Care at the University of Southampton.
• Prof Kathy Rowan	Director of the Intensive Care National Audit and Research Centre (ICNARC). Health Services Research and Clinical Trials in intensive care.
• Dame Julie Moore	Chief Executive, Queen Elizabeth Hospital Birmingham NHSFT and honorary Professor at Warwick University. NHS Future Forum lead on Education and Training.
• Simon Bennett	DoH NHS Medical Directorate 7 Day Services programme. Deputy Director, Head of Clinical Governance, Clinical Audit and Patient Safety. (alt: Deborah Williams)
• Prof Keith Willett	National Clinical Director for Acute Episodes of Care, NHS England
• Dr Mike Durkin	Director of Patient Safety, NHS England
• Dr Jerry Nolan	Member, Executive Committee of the Resuscitation Council (UK).
• Mrs June Leatherdale	PPI representative
• David & Kay Schofield	PPI representatives
ADMINISTRATION: Institutional Research Governance Support, and Finance Officers	
University of Birmingham:	Dr Eliot Marston: Mr David Windridge
QE Hospital Birmingham	Dr Chris Counsell PhD; R&D Manager, QEHB.
Uni of Leicester:	Sarah Stokes
Southampton	Michelle Cawte, R&D Finance Manager, University Hospital Southampton NHS FT.
HoEFT	Dr Sarah Pountain, Research Portfolio Manager
Brompton	Dr Angela Cooper, Associate Director of R&D.
Brunel	Mr Hugh Cunning
HSDR Programme Manager	Dr Sue Pargeter PhD
Declarations of Potential Competing Interests	
Russell Mannion	Member of the NIHR HS&DR Commissioning Board.

SYNOPSIS

This research proposal responds to the NIHR-Health Services Delivery Research Programme's commissioned call 12/128 on the organisation and delivery of 24/7 healthcare. The proposal focuses on the second of four evidence gaps: *Assessing the effectiveness and cost-effectiveness of different models of organising acute care at nights and weekends*.

The rationale for this proposal is based on research in diverse health systems demonstrating poorer outcomes for patients admitted to hospitals at weekends. In the UK, four recent initiatives to address this problem include the Academy of Medical Royal College's publications '*Benefits of Specialist-Delivered Care*' and the Academy's standards document '*Seven Day Specialist-Present Care*'; the Royal College of Physicians *Future Hospital Commission* to examine new ways of providing specialist care; and NHS England's (Commissioning Board) working group on implementing seven-day services. Changing long-established working patterns is challenging. We will combine quantitative analysis with qualitative (ethnographic) research to measure quality of care and to explore cultural and behavioural aspects of a fundamental change in service delivery. We will also assess the health economic impacts of improving specialist cover over week-ends.

Our proposal evaluates High-Intensity Specialist-Led Acute Care (HiSLAC) to improve the care of acutely ill medical patients admitted as emergencies to English hospitals, with a particular emphasis on weekend admissions. Specifically we will:

- Develop a measure of the intensity of specialist provision at weekends.
- Measure the current intensity of specialist-led care and how this has changed over time.
- Evaluate the effect of specialist intensity on differences in quality of care between patients admitted at weekends *vs* weekdays, and any effect of HiSLAC in reducing these differences.
- Improve understanding of factors facilitating or impeding the uptake and effectiveness of HiSLAC, using ethnographic exploration.
- Determine the effects of HiSLAC on hospital-level measures such as length of stay.
- Construct a health economics model to estimate the cost-effectiveness and budget impact of increasing specialist intensity.

We will do this using a phased approach **(Fig 1)**.

In Phase 1 we will develop metrics for HiSLAC, map current levels of 'penetration', and determine how this has changed over the preceding years.

Phase 2 examines the impact of HiSLAC on emergency non-operative admissions to acute hospitals at weekends. There are two workstreams. The first is an NHS-wide comparison of HiSLAC penetration with NHS performance and outcomes currently and over the preceding three years using Hospital Episode Statistics (HES) data. The second is a detailed quantitative and qualitative study of 10 HiSLAC and 10 low-intensity (LoSLAC) hospitals supplementing routine data from HES & local healthcare databases with case note reviews of quality of care, and on-site ethnographic exploration.

A Phase 3 may subsequently be proposed if we find that uptake is still low in many hospitals, but set to change over the coming years.

This research is important for patients and for NHS strategy because it offers an unique opportunity to evaluate the impact of the transition to seven-day working, and to understand factors likely to impede or enhance the effectiveness of this change in practice.

Fig 1:RESEARCH PLAN FLOWSHEET FOR HIGH INTENSITY SPECIALIST-LED ACUTE CARE (HiSLAC)

<table>
<tr><th>Mo</th><th>Phase</th><th>Clinical Themes</th><th>Economics & Ethnography</th><th>Outputs, Analyses</th></tr>
<tr><td>1
2
3
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9</td><td>Phase 1: Develop</td><td>1. HiSLAC Measurement:
Workshop on measurement; pilot, refine.
2. Survey of all English NHS acute Trusts:
HiSLAC penetration; models, current & past 3 yr
3. Case record review:
Criteria, training package development
4. HES/ONS data acquisition
Set up, preparation, ‘dry run’</td><td>5. Health economics
Update systematic review
Workshop: Subject expert elicitation
Develop Model structure & QA
Populate with Bayesian priors
6. Ethnography
Researcher training in clinical environment
Institutional approval for ethnography</td><td>HiSLAC measurement methods (high, medium, low-intensity).
HiSLAC map across English NHS
Case note review framework
Preliminary Economic model
HES database, search terms & fields
Online collaborative workspace</td></tr>
<tr><td>10
12
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34
36</td><td>Phase 2: Observe, associate</td><td>Workstream A: System-wide analysis of unplanned non-op admissions to all English NHS acute Trusts.
HES/ONS data: current and 3-yr retrospective analysis: Weekend vs weekday adjusted mortality rates; length of stay; readmissions
Workstream B. Detailed cross-sectional study of non-op admissions to 20 English NHS acute hospitals: 10 HiSLAC vs 10 Low-intensity (LoSLAC) hospitals
Hospital-level metrics (PAS) to supplement national (HES/ONS) data: HiSLAC staffing; CPRs; unplanned ICU admissions; absenteeism; PROMs
Case note reviews of 50 weekend vs 50 weekday admissions to each Trust:<ol type="i">
Implicit review of quality of care
Explicit (criterion-referenced) analysis of best practice adherence</td><td>Health Economics
Model verification & validation
Repopulation of model with empirical data
— Effectiveness parameters
— Cost-drivers
Feedback to subject experts (‘synthetic posterior’)
Ethnography
Observe delivery of weekend care
Identify contextual & social factors
Interview staff
Interview patients & relatives</td><td>Workstream A:
NHS-level case mix-adjusted mortality, length of stay & 7-day readmission rates, by:
— HiSLAC status
— Weekend vs weekday
— Change over time
— Difference-in-difference-in difference
Workstream B:
Local (PAS) data by HiSLAC/LoSLAC status and weekend/weekday
Quality of weekend vs weekday care by HiSLAC/LoSLAC status
Ethnography
Characterise reality of HiSLAC
Determine barriers, facilitators
Health Economics
Final model estimates of cost-effectiveness and budget impact</td></tr>
<tr><td colspan="5">Analytical phase: Triangulation of systems level and local level quantitative metrics with ethnographic findings and health economics. Determine need for and feasibility of Phase 3.</td></tr>
<tr><td colspan="5">Phase 3 (Test): Decision Gate for new application. Options include: 1. No Phase 3: HiSLAC already widely adopted in NHS England. 2. Natural experiment: if ~50% adoption of HiSLAC across NHS. 3. Step-wedge cluster RCT if <50% adoption and sufficient number of hospitals willing to introduce HiSLAC.</td></tr>
</table>

PROJECT OVERVIEW

Background to this application

This application responds to the NIHR-HSDR commissioned call 12/128 for research proposals examining the organisation and delivery of 24/7 healthcare. We propose to focus on the second of the four 'evidence gaps' identified in the call, focussing on *the assessment of the effectiveness and cost-effectiveness of different models of organising acute care at nights and weekends*. However we will need to at least partially close the first gap (*Mapping and evaluating existing models of care and activity for different staff groups*) in order to design the study in our phased approach. We wish to focus primarily on one specific model of organisation: specialist-led acute care. We refer to specialists (rather than consultants) to mean any doctor who has successfully completed specialist training, as this encompasses the wider range of current NHS employment models.

We take 'acute care' to mean acutely ill patients, including unscheduled hospital admissions and those who develop acute complications during an elective pathway. Acutely ill patients represent around 50% of all hospitalised patients and are high risk, high cost, and compete with elective admissions for access to health system resources. The acute illness 'phenotype' challenges conventional models of service provision. The context of care of these patients is not ideal. Acute illness challenges the traditional model of disease-specific disciplines, in that effective management requires competence in managing both the underlying medical condition ('diagnosis') and in supporting failing organ systems ('fixing the physiology'), requiring integration of care across disciplines and over time.

Patients admitted to hospital at weekends have a higher rate of death and less reliable care than apparently similar patients admitted on weekdays. In separate studies, a favourable ratio of specialists to patients overall also appears to be associated with improved outcomes. Combining those two findings leads to the hypothesis that increasing specialist input at weekends will improve care. This we will test by:-

1) Describing current provision (which we have reason to believe is very variable), how it has evolved, and what future plans entail.
2) Carefully comparing the quality of care in hospitals that have high specialist cover over weekends with those that have lower levels.
3) Developing a health economics model to estimate the costs and health outcomes (QALYs) associated with increased intensity of specialist provision.

Our study uses 'mixed-methods', supplementing observations of patient outcomes and care processes with in-depth observation on the ward to help explain the findings and factors which might undermine or improve the success of enhanced service provision.

The study will proceed in two phases (**Fig 1, above**), together with parallel ethnographic and health economic studies:

PHASE 1 (developmental).

HiSLAC measurement and mapping: we will use a consensus method to devise a questionnaire to measure provision of specialist activity over weekends. This form will be used to survey all English hospital trusts receiving emergency medical admissions. The questionnaire will elicit current provision and how this has changed over the preceding three years, and will also request information on planned changes for the future. In this way we will map previous, current and proposed specialist provision over the country. We will also identify high and low provision hospitals (at each end of the distribution) for Phase 2.

We will also refine and pilot a method to evaluate the quality of care, using both implicit and explicit (criterion-referenced) case record review. Implicit (or global) measures of quality will be based on a 10 point scale using the reviewer's expert judgement. Explicit criteria will be derived from current best practice management guidelines for each of the 10 most common primary admitting diagnoses.

Health economics: We will construct a cost-utility model from a health and personal social service perspective, extending the approach recommended by NICE for the evaluation of health technologies. During Phase 1 the model will be constructed and populated with data from the literature and prior estimates of key parameters from experts. Preliminary estimates of the incremental cost per Quality Adjusted Life Year (QALY) gained through the use of high-intensity rather than low-intensity specialist care will be derived. In addition, we will estimate the budget impact of implementation of high-intensity care at local and national levels.

Ethnography: the ethnographer will need some experiential training in the acute care environment, becoming familiar with clinical practice variation through the week. Following site selection, institutional approval for ethnographic observations will be needed.

PHASE 2 (observational).

Phase 2 consists of two workstreams:

Workstream A: NHS-System-level analyses. We will correlate the provision ('dose') of specialist provision at weekends with dependent variables collected routinely from hospitals (eg: standardised mortality rates, length of stay) across the NHS in England. Building on previous work, we will compare differences in outcomes by intensity of provision, the difference in these differences between weekends and weekdays, and the difference in this difference over time.

Workstream B: Cross-sectional mixed methods comparison of 10 high and 10 low provision hospitals which will supplement the NHS-level data in workstream A with detailed analysis of the following:-

i. **Patient outcomes** collected routinely in hospitals but not via HES nationally (need for emergency life support & cardiopulmonary resuscitation, unplanned ICU admissions). We

will also collect national level data but note that the standardised mortality rates (SMR) must be interpreted with caution because it is a small signal that may not show up statistically even if trends are favourable in a sample of only ten versus ten hospitals.

ii. **Assessment of quality of care** and incidence of adverse events based on expert review of clinical case notes using a method developed and tested in a previous large scale study. Statistical calculations show that the review of 100 case notes (50 for weekend admissions and 50 for weekday admissions) from each of 10 high and 10 low provision hospitals is sufficient to detect plausible and important differences. Each set of case records will be reviewed independently by two expert reviewers, to permit assessment of reliability – how much observers agree (beyond that expected by chance). The case notes will be photocopied and categorised at source before being transferred to the research unit where they are digitised and then reviewed, as in our previous research. The case notes will be 'scrambled' (like a pack of playing cards) before review so that the effect of 'learning' and 'fatigue', which we have demonstrated in separate research, cannot bias the results.

iii. **Ethnography**: The above statistical studies will be complemented by in-depth observations and by interviews with staff, patients and relatives in the admission wards of the participating hospitals. This will identify factors that are likely to promote or impede successful implementation of high-intensity specialist-led acute care (HiSLAC).

Health Economics

The model developed in Phase 1 of the study will be updated during Phase 2 as information accrues from HES and OPCS national datasets and from the case note review. The model will be used to estimate the cost-effectiveness and budget impact of increased specialist intensity.

PHASE 3 (Interventional).

Phase 3 will be proposed if there are enough hospitals committed to increasing specialist cover at weekends from a low baseline at the end of Phase 2. Similar metrics will be used as in Phase 2, but with the added value of tracking hospitals over time as they increase the intensity of specialist cover. This phase will only be invoked if such hospitals can be identified and if phase 2 identifies an observable difference between high and low provision hospitals. The precise details of phase 3 will be worked out when phase 2 is complete, and would be subject to a new application.

Summary:

At the end of the study we will be able to test whether care at the weekends is worse in low than in high provision hospitals and whether the difference between weekdays and weekends is also greater in the low provision hospitals. Anchoring the difference at weekends in the weekday performance offers protection against bias over and above that which statistical control alone can provide. We hypothesise that we will find:-

1) Very variable practice around the country with respect to weekend specialist cover.

2) Differences between high and low provision hospitals with respect to outcomes (e.g. need for resuscitation) and the quality of clinical care determined by case record review.
3) A bigger difference between weekday and weekend performance in low than in high provision hospitals.
4) Improvement in 2) and 3) above as we track roll out of improved provision over the preceding three years.
5) While the national budget impact of implementing HiSLAC will be substantial, the additional labour costs will be to some extent offset by savings associated with better quality care.
6) Overall HiSLAC will be a cost-effective use of NHS resources, as the additional cost will be justified by health improvements (QALYs gained).
7) New insights about the likely effect of context on effectiveness of enhanced specialist cover from the ethnographic study.

LITERATURE SYNTHESIS & RESEARCH RATIONALE

LITERATURE SYNTHESIS & RESEARCH RATIONALE

Key points:

- Acutely ill patients are the largest patient population in hospitals, and the highest risk.
- Weekend admissions to hospital have a higher standardised mortality than weekday admissions.
- Quality of care has also been documented to be lower on average over week-ends.
- Association studies suggest that the increased weekend mortality is related to suboptimal intensity of predominantly daytime specialist care of acutely ill patients.
- Studies of generic non-specialist interventions (outreach, hospital-at-night) have been unable to identify strong evidence of effectiveness.
- We hypothesise that specialist-led acute care will improve processes of care and outcomes for patients undergoing emergency admission to hospital.
- To test this hypothesis, we propose a two-phase study to determine whether high-intensity specialist-led acute care (including daily specialist ward rounds) is cost-effective.
- Our study combines rigour with pragmatism by triangulating quantitative and qualitative measures of process and outcome. At the end of Phase 1 there will be a decision gate to ensure that we are able to make measurements of the intensity of weekend specialist-led care.

Literature Search Strategy

We have accessed both primary and secondary research, assessing quality and relevance through the search terms (below) and those which contained clearly defined outcomes, clear process measures, prospective studies, or large scale studies using high quality observational databases. We also made use of the recently published systematic literature review of the impact of specialists on clinical outcomes by the Academy of Medical Royal Colleges, 'Benefits of Specialist Delivered Care' [AoMRCs Jan 2012]. The report employed standard electronic searches using MEDLINE, EMBASE, HealthSTAR, AMI/InformitHealth collection, Scott's medical database, Google Scholar, PubMed, EThOS, and GreySource to identify published evidence. The literature on the impact of weekend versus weekday admissions was sourced using the following key words: hospital mortality, length of stay, levels of staffing, medical admissions units, outcome assessment, readmission rates, weekday admission, weekend admission; relevant articles are presented in Appendix 1. Expert opinion was additionally obtained from professional organisations via the Academy. In addition, we identified studies which attempted to determine explanatory mechanisms, provided context-sensitive interpretations of models of 24/7 care, and those which specifically and prospectively tested higher-intensity specialist-led care. The selection criteria for articles were based on standard identification by key words applied to UK and international papers, written in English (1991-2011).

What is the 'Weekend Effect'?

The driver behind the HSDR programme commissioned call is a growing body of international evidence suggesting that case mix-adjusted mortality rates are higher for patients admitted to hospital 'out-of-hours', with most research focussing on weekends [Freemantle 2012, Mohammed

2012, Cram 2004, Cavallazzi 2010, Aylin 2010, Aylin 2013, Kruse 2011, Buckley 2012, Barba 2006; Bell 2001; Kostis 2007; Hamilton 2003; McGaughey 2007, James 2010, Fang 2012, Ricciardi 2011, Worni 2012, De Cordova 2012, Deshmukh 2012, Palmer 2012, Niewada 2012]. Six studies report no adverse effects from weekend admission [Byun 2012; Kazley 2010; Myers 2009; Orman 2012; Worni 2012; Schmulewitz 2005]. Of these studies, five focus on specific and well-defined diagnostic entities (liver disease and transplantation, stroke and appendectomy), and only one [Schmulewitz 2005] reports unselected emergency admissions in a single centre study of 3,244 patients, which is likely to be underpowered. The weekend effect is not confined to emergency admissions: Mohammed et al identified a higher case mix-adjusted mortality at weekends for elective admissions than for emergencies [Mohammed 2012]; and case mix-adjusted mortality rates for patients undergoing elective surgical procedures increase with increasing proximity of the procedure to the following weekend [Aylin 2013].

Mortality rates and other outcome differences for patients admitted at weekends compared with weekdays are summarised in **Appendix 1**. Different approaches to reporting adverse outcomes and variation in selected diagnostic groups make it difficult to report an aggregated effect size. The surplus mortality for unselected emergency weekend admission ranges from an odds ratio of 1.0 to 1.4, and from 1.0 to 5.2 for selected diagnostic groups. The reported absolute difference in percentage mortality in the studies of unselected emergency admissions excluding Schmulewitz et al ranges from 0.3% to 1.2% (mean 0.5%).

Causation: structure and process:

Structural factors contributing to increased mortality may include inadequate numbers or inadequate input of skilled staff [Kane 2007, Cho 2008, Kane 2007, Martin 2007, Needleman 2002, Pronovost 2002, Wallace 2012, Kim 2010, Aiken 2002, Penoyer 2010, Dr Foster 2012, Goddard 2012], lack of organisation and structure for care delivery [Anderson 2012], and reduced access to specific interventions [Kostis 2007, Deshmukh 2012, Jneid 2008, Palmer 2012]. The Royal College of Physicians' specialists' survey [RCP 2010] found that only 19% of responding hospitals reported having a formalised rapid response team for acutely ill patients, only 20% of specialists were available at weekends for periods exceeding 8 hours, and 18% reported no weekend attendance at hospital, while 73% of acute physicians did not work at weekends. Only 39% of specialists working in acute medical units reported having protected time for this work free of other duties, and providing care for blocks of time greater than a single day. The largest gap in terms of specialist input (and in reliable information on current practice) would therefore appear to be in the care of patients on their journey through the AMU and ordinary wards.

Unreliable or inexpert care processes are a major public health problem for all health systems [McGlynn NEJM 2003, Runciman MJA 2012]. Error rates are more common at weekends with an incident rate ratio of 2.74 [Buckley 2012]. Misdiagnosis is particularly common (30% of potentially preventable deaths [Hogan 2012]). In a longitudinal case record review study in the Netherlands [Baines 2013] adverse events related to diagnostic errors were associated with the highest mortality rate (21.7%) and considered to be the most preventable (79.7%). Contextual factors include poor organisation of care, failures in critical thinking, and undisciplined treatment strategies [Anderson 2012]. Patients admitted to hospital at nights or weekends are more likely to experience unplanned

admission to intensive care [Tam 2008] as a consequence of failure to detect physiological deterioration and of errors in management [McQuillan 1998, Braithwaite 2004, Vlayen 2011]. Suboptimal specialist input was identified in the NCEPOD audit of deaths following emergency hospital admission [NCEPOD 2007]: at 12 hours following admission, 40% of patients had not been seen by a consultant, and in 12.4% there was no documentary evidence of consultant review. In 95 cases in which the assessors considered the delay in consultant review to have been unacceptable, the delay was considered to have adversely affected the accuracy or timeliness of diagnosis in 32.6%, and may have contributed to the adverse outcome (ICU admission, worsening prognosis or death) in 49.5%.

Patients admitted to hospital out-of-hours are exposed to greater risk of error and adverse events because they experience multiple transitions in the location of care (for example, from the Emergency Department to the Acute Medical Unit to general acute wards, or to the Intensive Care Unit (**Fig 3**)), each transition involving discontinuities and gaps in communication. In the Royal College of Physicians' specialist survey, 28% reported that they considered continuity of care to be poor in their own hospital [RCP London 2012 (2)]. The impact of poor process control is amplified at weekends because of reduced specialist input and lack of supporting resources, particularly in ordinary acute wards.

The putative week-end effect can thus be plausibly explained by suboptimal specialist staffing of hospitals out-of-hours and during the continuum of care after acute admission.

Rationale and challenges for higher intensity specialist led care as the 'solution':

The deficiencies in structure and care processes described above are those over which specialists can exert the greatest effect – diagnosis, critical thinking, organisation of care, and access to timely investigation and treatment. The study by Baines et al (2013) that greatest avoidable harm came from diagnostic errors adds weight to the principle of specialist-led care. It is notable that acute care interventions which have been specifically designed to substitute for specialist involvement such as critical care outreach [McGaughey 2007] and 'hospital at night' [Hospital at Night 2010] have not impacted strongly on patient outcomes. The 'weekend effect' may be diminished when the disease process has a well-defined care pathway likely to include 7-day specialist input [Byun 2012; Kazley 2010; Kevin 2010; Myers 2009, Smolina 2012, Al-Lawati 2012, Jneid 2008, McKinney 2011] (**Appendix 1**). The Royal College of Physicians (RCP) evaluation of specialist input into acute medical admissions [Lambourne 2012] found that amongst the 61% of responding Trusts, case mix-adjusted mortality rates were lower in hospitals with specialists dedicated to the on-call work, working in blocks of several days, and offering two formal patient reviews a day. A single centre study has shown that improving structures and processes by integrating the medical assessment unit with the emergency department to permit higher intensity specialist-led care is associated with a sustained and significant reduction in overall hospital standardised mortality ratios [Boyle 2012].

Two intensive care studies give some insight into the concept of 'dose' of the intervention by examining the impact of daytime versus resident night-time specialist cover; night-time intensivist staffing was associated with reduced case mix-adjusted mortality, but only in ICUs with low-intensity intensivist staffing during the day [Wallace 2012]; while no benefit from resident night-time

intensivists was identified in a prospective Canadian study [Garland 2012] in which both centres had day-time intensivist staffing. A study of specialist input in acute medical units (AMU) in England has reported lower case mix-adjusted mortality rates and lower 28-day readmission rates in AMUs providing more than 4 hrs of consultant staffing per day [Bell 2013].

Contextual and cultural factors

These require detailed evaluation through ethnographic enquiry. Specialists do not function in isolation, but as team-leaders and controllers of care pathways supported by other services across secondary and primary care. Local variations in cultures and norms of behaviour will influence the adoption and impact of quality improvement interventions [Mannion 2005]. If available during the lifetime of the current project, insights gained from the SDO-funded study 'Effective Board Governance of Safe Care' (http://www.netscc.ac.uk/hsdr/projdetails.php?ref=10-1007-02) will be incorporated in the analysis.

Specialists as a professional group have a key role in influencing organisational culture and productivity [Bate 2000, Mannion 2005, Kreindler 2012]. Changing specialist practice will therefore require professional buy-in as well as institutional and systems-wide support. We will therefore triangulate quantitative measures with ethnographic evaluation to gain qualitative insights into the interaction between specialists, patients and their relatives, in particular addressing the matter raised by Angela Coulter in the Kings Fund reports on medical leadership [Coulter 2012]: *"...there has been much less emphasis on tackling the quality of everyday interactions between individual patients and the clinicians who form the front line of the service. Yet it is this face-to-face contact that most of us care most about when we are patients."*

The ethnographic component of the study will involve non-participant observation, interviews and documentary analysis. It will aim to characterise the features of weekend care in both HiSLAC and LoSLAC hospitals and how the organisation and delivery of care varies across both HiSLAC and LoSLAC hospitals. It will identify the key components of HiSLAC, the mechanisms through which it has an impact on patient outcomes, and the contextual and social factors that modify its implementation.

The ethnographic work will enable us to gain a deep understanding of how HiSLAC systems operate 'on the ground', the variation between systems, and the features that make them more effective, acceptable and sustainable. We will explore, for example, the extent to which HiSLAC involves direct specialist review, or whether in practice specialist review is replaced by or supplements ward rounds by trainees. The ethnographic study will also permit insights into how handovers are managed within HiSLAC systems, and the extent to which patients are directed along specific, well-designed trajectories.

Introducing working patterns is not simply a technical or logistical issue. It also involves changes in social practices and long-established norms and role expectations within the setting of local history and established systems and processes. We will use the ethnographic research to explore the contextual, cultural and behavioural aspects of change, how they act as barriers and facilitators to the implementation of HiSLAC, and how they are addressed in settings where HiSLAC is successfully implemented. We will focus particularly on issues of staff attitudes, acceptance and resistance, and

executive support. This work will be of value to future efforts to implement HiSLAC, as well as other significant changes to working patterns.

Triangulating qualitative results with quantitative observations has been shown to yield important insights [Benning et al 2011]. The ethnographic study will be of value in informing the interpretation of the quantitative data by providing an assessment of the extent to which HiSLAC or LoSLAC is really delivered, in evaluating factors which facilitate or impede the capability of hospitals to implement HiSLAC, and the coping strategies adopted at weekends. It will also be invaluable in shedding light of the particular features of the organisation and delivery of weekend care that are associated with improved patient outcomes, and better staff and patient experiences, across both the HiSLAC and LoSLAC sites. This will enable the definition of HiSLAC to be refined, and the impact of 'dose' to be assessed.

Why is this research needed?

This research is important because of the large number of patients who stand to benefit and because the research literature indicates the need for a large-scale study to provide secure evidence about the best way to improve care out of hours. There are however obvious practical and financial implications of increased specialist intensity at the weekends. It is important to establish whether diverting NHS resources from alternative uses is justified by improvements in patient outcomes and/or savings in later care costs.

Acutely ill patients represent a major challenge for health services in terms of volume, risk, safety, costs, and impact on elective care pathways. They also cross traditional disease-specific boundaries of specialist practice as many have multiple co-morbid diseases. As stated above, they experience multiple transitions and discontinuities in care. The acutely ill patient pathway is presented conceptually in **Fig 3** with approximate numbers of patients and outcomes.

Emergency admissions are estimated to cost the NHS around £11bn per year [Blunt 2010]. In 2008-9 there were 5m emergency admissions to hospitals in England, a rise of 11.8% since 2004/5, and representing 35% of all hospital admissions [Blunt 2010]. This has increased to 5.2M emergency admissions for 2010 and 2011 [Hospital Episode Statistics 2011-2012]. Given the additional (unquantified) numbers of elective hospital admissions who become acutely ill during their hospital stay and require urgent or enhanced levels of care (such as admission to intensive care units), the acutely ill patient population is the single largest group of patients in NHS hospitals. The overall mortality rate at hospital discharge or 30 days is 0.7% for elective hospital admissions but a recent report from the Information Centre for Health and Social Care, reported that the 30 day mortality rate following non-elective (urgent and emergency) admission was approximately 3.7% in the period 1 April 2011 to 31 March 2012. Of these deaths, 75.7% occurred in hospital and the remainder after discharge [Information Centre 2013]. Mortality risk is much higher for specific conditions such as myocardial infarction (12.5% mortality for hospitalised patients with acute MI) [Smolina BMJ 2012], stroke (around 20%) [McKinney 2011], fractured proximal femur (10%) [Wu 2011], and septic shock (30-40%) [Levy 2010].

In summary, the majority of studies show that weekend admission to hospital is associated with an increased case mix-adjusted mortality risk and more errors in care. The impact may be even more adverse for patients perceived initially as low-risk who subsequently deteriorate, either from misdiagnosis or systemic failure to track physiology and trigger a prompt response. The feature which distinguishes hospitals at nights and weekends from weekdays is the reduction in intensity of specialist input.

Why this research is needed <u>now</u>

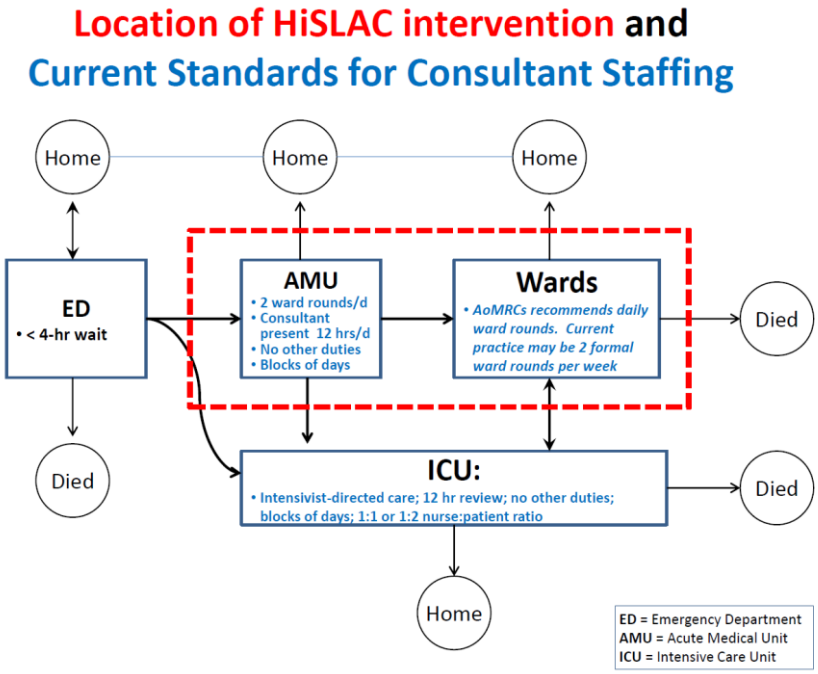
Four national policy initiatives in 2012 address these perceived deficiencies: the Department of Health's promotion of seven-day working [NHS Improvement]; the Royal College of Physicians' (RCP) Future Hospital Commission; the Academy of Medical Royal Colleges' (AoMRCs) review of the benefits of specialist-delivered care; and the Academy's recently published national standards for seven-day consultant-present care.

Of the projects on 7-day working reported by NHS Improvement, the majority are focussed on increasing senior staff at weekends and nights. The Health Foundation's Safer Clinical Systems programme is also currently evaluating quality improvement methodologies in clinical handovers, and in prescribing [Safer Clinical Systems 2012]. Seven day specialist working is being considered by Medical Education England's *Shape of Medical Training* [MEE 2012a], by the Centre for Workforce Intelligence's *Shape of the Medical Workforce* [CfWI 2012], and is being piloted as part of *Better Training, Better Care* [MEE 2012b] following the Temple Report [Temple 2010]. These now form RCP-endorsed standards for the AMU [RCP Standards document 2011], now adopted by London Health care for commissioning [NHS London Health Programme 2011]. The Society for Acute Medicine has defined standards for the staffing and organisation of acute medicine units [WMQRS-SAM 2012; Lees 2012] which emphasise the importance of the supporting infrastructure which surrounds specialist-led care in the AMU. This year the Royal College of Physicians has launched the *Future Hospital Commission* [RCP London 2012 (3)] to produce recommendations for the reconfiguration of hospital services particularly those focussed on acute care. The Academy of Medical Royal Colleges (AoMRCs) has published an evidence review showing the benefits of consultant-delivered care, and has called for more robust research [AoMRCs 2012 (2)]. The Academy's multi-college committee on seven-day acute services [AoMRCs 2012 (1)] has proposed that all hospitalised patients should receive a minimum of a once-daily specialist review unless the care pathway specifies that this is not necessary.

We hypothesise therefore that better outcomes may be achievable through enhanced specialist-led care along treatment pathways [NICE 2007], and detecting departures from that pathway using, for example, the RCP's National Early Warning Score [RCP London 2012 (1)]. The most important element in managing those pathways – the key 'delivery device' - is the clinical team, led by an experienced clinician, usually a specialist or a senior nurse. The evidence we have presented indicates that closing the weekend daytime gap and enhancing the weekday continuum in the intensity of specialist-led care may be a cost-effective use of limited NHS resources.

The nature of the intervention

Fig 2: Location of the HiSLAC interventions, and current national standards for consultant (specialist) staffing.



The intervention is high-intensity specialist-led acute care (HiSLAC). We define a specialist as any doctor who has successfully completed specialist training.

There are two recently-published UK standards for HiSLAC:

- The Society of Acute Medicine and the RCP recommend (Jun24e 2012) twice daily formal specialist ward rounds, no other concurrent duties when on emergency call, specialist presence 12 hours a day, and specialists working in blocks of several days to promote continuity of care for patients in acute medical units (AMUs). This does not apply to hospital care once patients have been transferred from the AMU to general wards. [http://www.acutemedicine.org.uk/images/stories/pdf/wmqrs-sam%20am%20qss%20v2%2020120610%201.pdf]
- The Academy of Medical Royal Colleges' subcommittee on 7-day acute care has recommended (December 2012) that all hospitalised patients should be reviewed formally at least once a day by a specialist unless the care pathway identifies that this is not required. [http://www.aomrc.org.uk/publications/reports-a-guidance/doc_details/9532-seven-day-consultant-present-care.html] Two additional standards focus on support services in hospital and community.

HiSLAC is a 'systems-level' complex intervention whose effects may vary according to how the intervention is delivered, and the context in which delivery occurs. The competence of the specialist to provide accurate, timely and appropriate diagnosis and treatment, the capacity of the system to support the specialist as the leader of a clinical team with access to information, to diagnostic and

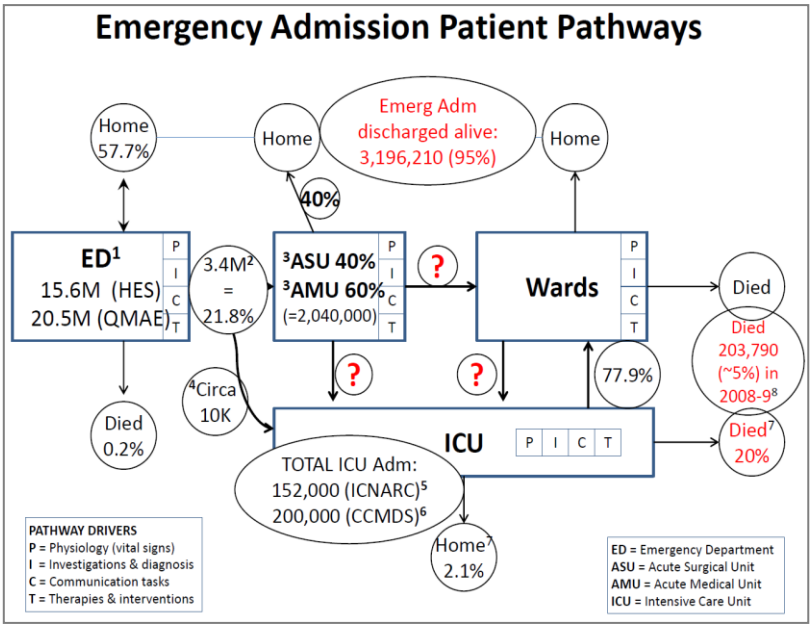
therapeutic services, and the availability of community services at the time of patient discharge may all affect the effectiveness of enhanced specialist provision

We emphasise here that HiSLAC does not mean an atomised individual working in isolation, but as part of a team of individuals and support services. In Phase 1, in addition to the measures of consultant presence, we will collect information on the nature of the team and support that is available - for example, the availability of laboratory and radiology services, the provision of physician assistants, and the number and grade of doctors in training. The ethnographic study in Phase 2 will observe how these factors affect the specialists' work.

The target population: Patient level

The target patient population is the acutely ill hospitalised medical patient, that is, those undergoing unplanned (urgent or emergency) admission with a primary non-operative diagnosis. The pathway starts following admission from the Emergency Department, and will usually include the acute medical unit (AMU) for a variable period (12-48 hrs) followed by transfer to standard acute wards. Discharge, death, and cardiopulmonary resuscitation may occur at any point on this pathway (**Fig 3**).

Fig 3: Emergency Admission Patient Pathways



Source References for Fig 3:

1. HES data; higher figure comes from Quarterly Monitoring of Accident and Emergency (QMAE) http://www.ic.nhs.uk/pubs/aandeattendance0910
2. HES data
3. Southampton data (personal communication Prof Mike Clancy, VP-CEM)
4. http://emj.bmj.com/content/22/6/423.full
5. Data courtesy of Intensive Care National Audit and Research Centre
6. http://www.ic.nhs.uk/statistics-and-data-collections/hospital-care/critical-care/adult-critical-care-data-in-england--april-09-to-march-10-experimental-statistics
7. ICNARC case mix programme.
8. Nuffield Trust report on Emergency Admissions 2010:

Inclusion/Exclusions

The location of the intervention will be acute medical units (AMUs) and ordinary wards caring for patients undergoing emergency admission to hospital. Emergency Departments and intensive care units (ICUs) are not the primary focus of the intervention as these areas already provide consultant-present care for a substantial proportion of the working day. Data from ICUs about unplanned admissions will be included in outcomes.

We will build an algorithm to filter out surgical (operative) patients (including primary operative diagnosis and procedure code) as these patients are currently the subject of a separate application to the HSDR programme (*Enhanced Peri-Operative Care For High-Risk Patients (EPOCH) Trial. A Stepped Wedge Randomised Cluster Trial Of An Intervention To Improve Quality Of Care For Patients Undergoing Emergency Laparotomy. Reference: 12/5005/10*). The HiSLAC and EPOCH projects are complementary studies.

For Phase 3 (either natural experiment or step-wedge cluster-randomised trial) hospitals will be included if they are willing to implement high-intensity specialist-led care. Hospitals will be excluded if they are not acute admitting centres (no emergency department). We will not study paediatric hospitals.

Difference between current and planned care pathways

Current practice in the continuing care of acutely ill patients can be identified from the RCP survey [Royal College of Physicians of London 2012], which identified that only 19% of responding hospitals reported having a formalised acute response team for acutely ill patients, only 20% of specialists were available at weekends for periods exceeding 8 hours, 18% reported no weekend attendance at hospital, and 73% of acute physicians did not work at weekends. Once patients have been transferred from the AMU to the ordinary wards they may be seen by a specialist only twice a week.

Appendix 2 is a preliminary list of 28 hospitals which we understand have implemented various forms of HiSLAC, of which 17 focus specifically on emergency medical admissions. There is little objective data about ordinary ward care, most of the research referring to the AMU. We therefore anticipate that this project will provide objective information about the gap between current and ideal practice in specialist-led care of acutely ill hospitalised patients.

METHODS

METHODS

Introduction

Initially conceived as a three phase project, we will focus here on the first two phases. Phase 3 would be proposed as a new application if certain progression criteria were to be met. Project progress will be monitored by the independent Steering Committee chaired by Professor Sir Michael Rawlins, who will invite a representative of the HSDR programme to join the Steering Committee. The SC is responsible to, and will make decisions for ratification by, the HSDR Programme, not the investigators. This is consistent with the principle of iterative commissioning [Lilford et al, J Health Serv Res and Policy 1999 4 164-167].

The intervention being studied is High-intensity Specialist-Led Acute Care (HiSLAC). We define 'specialist' as a doctor who has obtained a certificate of satisfactory completion of specialist training. This will include specialists, staff-grade and non-consultant career-grade doctors. Timelines are described in the Gantt Chart (**Fig 4**) .

PHASE 1 (Developmental). 9 months.

Phase 1 consists of four Clinical Themes, a Health Economics theme, and preparation for the ethnographic theme.

We will:

1. Develop, pilot and refine a method to measure the intensity of specialist-led acute care and characterise its variations from high-intensity (HiSLAC) to low-intensity (LoSLAC). The questionnaire will collect data on how specialist care is delivered and on context.
2. Undertake a national mapping exercise to measure current and previous levels of specialist-led acute care across all acute hospitals in England.
3. Develop a tool and a training package for standardising the approach to case record review in Phase 2.
4. Develop an algorithm to acquire HES/ONS data for acute (unplanned) admissions to NHS England acute Trusts; set up database.
5. Develop a health economics model to estimate the cost-effectiveness and budget impact of HiSCLAC.
6. Provide the ethnographer with experiential learning in the acute care environment

1. Develop a tool to measure specialist intensity

We will convene a stakeholders' workshop to bring together professional organisations, patient and public representatives, and front-line clinicians and managers with experience of 24/7-working to identify the critical features that might affect the effectiveness of specialist weekend care and to develop a form to measure HiSLAC. This will enable us to measure the 'dose' of the intervention

and characterise supporting facilities. Workshop participants will be accessed via partner organisations.

2. Map current HiSLAC penetration

We will map current HiSLAC penetration and how this has changed over the preceding three years, the likely rate of change, and obstacles to change through a web-based survey of all acute hospitals in England. An invitation to participate in the survey will be sent to the Chief Executive and the Medical Director of each acute NHS Trust in England, with the request that it be directed to the divisional director of medical services for formal response. Through the collaboration we will seek the support of professional and managerial networks in order to maximise response rates. Non-responders will be followed up by phone. The survey will be parsimonious, trialled before implementation, and submitted to the Review of Central Returns (ROCR) http://www.ic.nhs.uk/rocr for prior approval. From this survey we will measure the intensity of specialist-led acute care. We will also seek the participation of 10 HiSLAC and 10 LoSLAC hospitals from the extremes of the distribution for Phase 2.

3. Case record review

This will follow the approach by Benning et al [2011], using both explicit (criterion based) and implicit (holistic) approaches since they identify a different spectrum of errors [Lilford 2007]. Implicit review is essential to this study since specialist care is most likely to impact on selecting the correct clinical pathway through accurate diagnosis rather than adhering to that pathway once identified, which is where explicit review has its focus. We will develop a training package to harmonise the way different reviewers evaluate the case records. We will construct a framework for categorising generic and disease-specific best practice based on clinical standards published by professional organisations and by the National Institute for Health and Clinical Excellence. Generic measures will include factors such as timeliness of clinical review or response to abnormal vital signs. Disease-specific indicators will be based on the ten most frequent primary admission diagnoses.

4. Hospital Episode Statistics (HES), Office for National Statistics, and Patient Administration Systems data acquisition

There are three principal sources of routinely collected data that map the patient's progress through an in-patient pathway (**Fig 5**):

First, when patients present as an emergency they will typically go through the Emergency Department. The Accident and Emergency commissioning minimum data set (A&ECDS) captures clinical variables such as diagnosis and procedure rather poorly, but it does capture time and mode of arrival which are important pathway variables. Also in the event of hospital admission it captures the time the patient left the Department; thus the total delay in reaching a ward from presentation can be determined. A&ECDS is captured on a local system using a standard field specification and is uploaded to the Information Centre (IC) periodically. The IC will clean and process these data and release them as a part of Hospital Episode Statistics (HES).

Second, when the patient reaches a ward (which could be the ultimate ward of treatment or an intermediary or assessment ward), an 'episode of care' is created. Technically this occurs where the responsibility for the patient is transferred into the care of a Consultant on a ward rather than the A&E Consultant. The episode, the period of time spent under the care of a given consultant, is the building block of HES data. Unlike the A&ECDS it contains much more clinically relevant data including coded diagnosis and procedures. Like A&ECDS, this is captured in local systems to a prescribed data structure and uploaded to the IC. The local system is typically called a patient administration system (PAS). The time delay between PAS and HES which consists of several iterations of cleaning, could be an issue for the project. It is more timely to collect PAS data directly from participating centres. There are also some variables on local PAS systems that are not part of the HES data set. The most important of these is time of arrival. HES captures only the date on which episodes start and end which makes it impossible to calculate the total time over which processes happen accurately.

Third, there are mortality data. Mortality is also quick and easy to capture where death occurred in hospital, as it is clearly recorded on PAS and HES. HES additionally capture mortality up to thirty days after discharge by linking death certification data from the Office for National Statistics (ONS) to HES retrospectively through a national linkage process. Ninety day mortality is also captured for performance monitoring but is not used as a flag on the finished HES data set that is released to research users. Where a longer delay between discharge and death is needed, a separate process is required where the research team would have to perform the linkage themselves using raw ONS data following a separate research governance procedure. It is not envisaged that this longer retrospective linkage would be required in this study.

HES data (approximately 500 million rows) will be uploaded to a server in the UoB Department of Public Health, Epidemiology and Biostatistics, and subject to a system-level security policy in line with current governance requirements, with off-site back-up to the University severs. Analysis will be conducted using the Enterprise Edition of SQL.

5. Health Economics

HiSLAC is a generic service delivery intervention, which in many respects are more challenging to evaluate than the more familiar type of intervention evaluated in Health Technology Assessments.[Lilford 2010] The effects of service interventions are highly diffuse – they may impact on a very wide range of outcomes across many patient groups. In addition, there is often greater uncertainty over key parameters, notably over the effectiveness of the intervention, due to the difficulty of conducting controlled studies. Nevertheless, we believe that service interventions should be evaluated in a way that is commensurate with evaluations of health care technologies in order to inform prioritisation decisions over the efficient use of NHS resources.

Model Development – Phase 1

We will therefore construct a cost-utility model from a health and personal social service perspective, building on the approach recommended by NICE for the evaluation of health technologies.[NICE 2013] A modelling approach will be used to estimate the incremental cost per Quality Adjusted Life Year (QALY) gained through the use of high-intensity rather than low-intensity

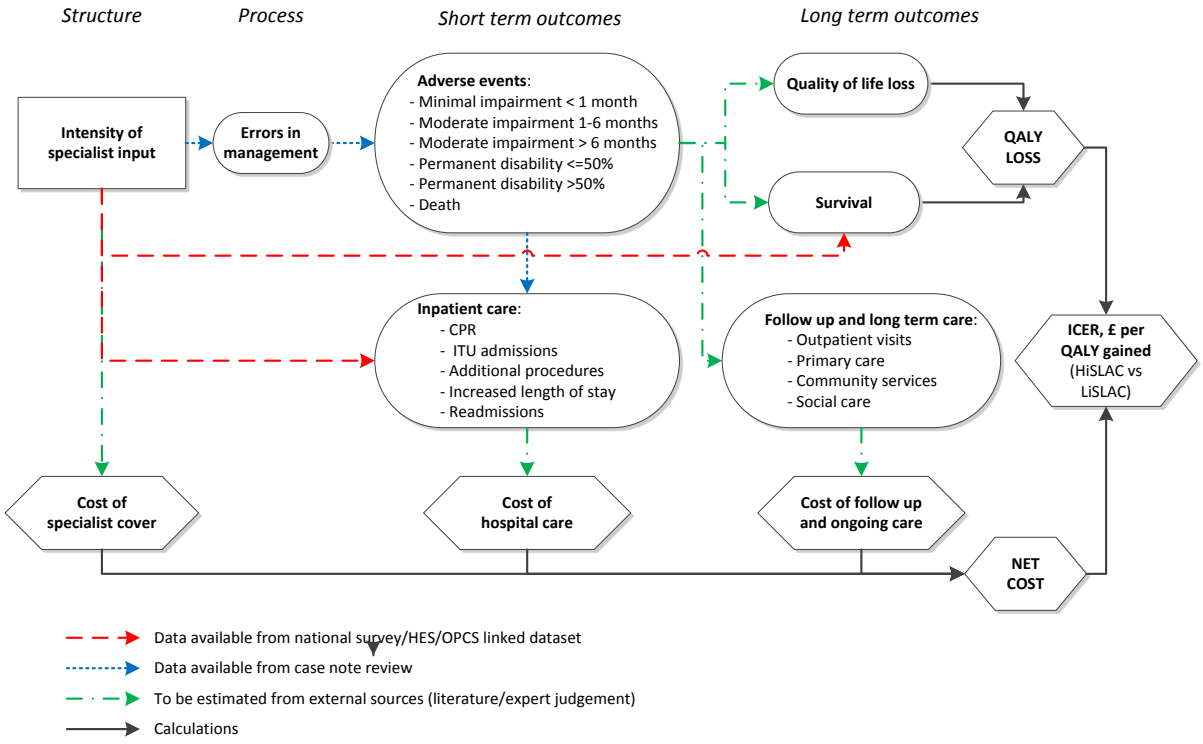
specialist-led acute care at weekends in NHS hospitals in England. In addition, we will estimate the budget impact of implementation of high-intensity care at local and national levels. The model will be developed in Phase 1 of the study, informed by prior estimates of key parameters elicited form experts and by data from the literature. In Phase 2, the model will be updated with information from the HES and OPCS national datasets and from the case note review.

Conceptualisation of model structure

Recommendations for good practice in model development suggest that an explicit process should be followed to define an appropriate model structure and to agree simplifications and assumptions in advance of programming or quantitative analysis.[Roberts 2012] The final structure of our model will be agreed by the research team (and signed off by the Steering Committee) during Phase 1 of the study, following a process of consultation with subject experts at the stakeholders' workshop. We will use influence diagrams or other simple graphical methods to illustrate our understanding of key aspects of the decision problem and to provide a framework for discussion within the research team, and with clinicians and managers attending the workshop. A written record will be kept to document the process and the decisions made.

Figure illustrates a possible structure for the model. It assumes a relationship between the intensity of specialist input and the incidence of errors in medical management and associated adverse events. There are many different types and severities of errors and adverse events that could be related to inadequate specialist cover at the weekend. For simplicity, we anticipate using the categorisation of adverse events from the famous Harvard Malpractice Study,[Brennan 1991] which members of our research team have used previously in an economic evaluation of a service delivery intervention.[Yao 2012] This classification defines six types of adverse event (**Fig 6**) according to the duration and severity of impairment and which can be related to expected survival and impacts on quality of life. This would provide a mechanism to estimate long-term QALY loss attributable to adverse events. The illustrated model distinguishes three types of cost: the direct cost of providing additional specialist input at the weekend; any inpatient costs which are contingent on adverse events (including unplanned admission into ICU, the number of tests, procedures or episodes of care, length of stay, and re-admissions), and follow up care and treatment of adverse events themselves (in particular those with permanent sequelae).

Figure 6. Illustration of possible structure for health economic model



There are a number of ways in which this initial conceptualisation of the model structure might be modified following discussion with stakeholders. For example, an alternative categorisation of adverse events could be adopted, such as that used by Hoonhout et al.[Hoonhout 2009]

Preliminary parameter estimates

When the structure of the model has been finalised, it will be implemented and populated with prior parameter estimates obtained from the literature and/or elicited from experts. This will provide preliminary results at the end of Phase 1, which will then be updated when data becomes available in Phase 2. This explicitly Bayesian approach has a number of advantages:

i. The data collected will be determined by the model, rather than vice-versa;
ii. The value of information will be explicitly modelled based on Bayesian 'priors'.
iii. The model will be quality assured and submitted for peer-reviewed publication.
iv. Health economic results will be available soon after the statistical analysis, thereby providing timely information for policy-makers.

We will update a systematic review [Yao 2012] to identify possible data sources to inform key model parameters: including 'background' event rates for medical errors and adverse events, and the relationship between such events and health outcomes and costs. For example, a large longitudinal case note review in the Netherlands provides evidence on 'background' rates of adverse events and related costs and outcomes.[Hoonhout 2009; Baines 2013; Zegers 2009]

Prior estimates of the effect of increased consultant cover (from the 10th centile on the national survey to the 90th centile) on different classes of adverse events will be elicited from experts. The effectiveness parameter will be couched in terms of a relative risk reduction (as used in our previous work, [Yao 2012; Hemming 2012; Lilford 1994; Lilford 1995; Latthe 2005; Johnson 2006; Girling 2007; Kreif 2013] rather than separately for the intervention and control "conditions,"[Girling 2007] as recommended by O'Hagan [O'Hagan 2006]. The respondents will be experts in the general area of health services research, but not domain experts in the particular subject of consultant weekend working as recommended by Khalil.[Khalil 2010] The experts will be provided with background information in the form of the HiSLAC protocol and a summary of relevant literature on adverse event rates from the systematic review, so that they can familiarise themselves with this topic prior to the elicitation exercise.

Estimates of the impact of adverse events on health related quality of life ('utility') will be obtained from the literature, using methods recommended for NICE submissions.[Papaioannou 2010] We do not intend to collect primary quality of life data from patients in Phase 2, as this would be underpowered - a highly important 25% reduction in adverse events (say from 4% to 3%) would not show up in an EQ-5D utility score (since the change in the mean value would be small relative to the standard deviation). It will not be possible to obtain a utility for each and every adverse event. We will therefore categorise these events by severity and duration as in our previous study.[Yao 2012] Archetypical examples of events in each class will be defined and agreed with clinical experts. Utility values associated with these archetypes will then be identified from the literature. We are also currently exploring alternative methods to elicit utilities for various classes of adverse events (funded by the Engineering and Physical Sciences Research Council [EPSRC] Multi-disciplinary Assessment of Technology Centre for Health [MATCH] programme and the National Institute for Health Research [NIHR] Collaborations for Leadership in Applied Health Research and Care [CLAHRC]). The utilities associated with the adverse event classes will be compared with baseline utilities from the Health Survey for England data, to estimate a utility loss associated with the adverse events.[Ara 2013] These estimates of utility loss will then be converted to QALYs by multiplying them by the duration of disability and factoring in expected loss of life from adverse event-related mortality.

The cost of increasing consultant hours will be estimated from PSSRU estimates.[Curtis 2013] The marginal cost of increasing specialist cover will depend on whether we assume an increase in hours worked by existing consultants or an increase in the total number of consultants employed across the NHS. The capacity for extending existing consultant hours will be limited, and so some degree of expansion of consultant numbers might be necessary if high-intensity weekend care were to be implemented. A range of estimates will be made based on a number of alternative assumptions. Preliminary estimates of the additional cost of hospital care will be obtained from the Dutch case note review, reported by Hoonhout et al.[Hoonhout 2009] These estimates will be converted from euros to pounds sterling and updated to 2014 values using the Purchasing Power Parity approach.

There are some other potential cost impacts that will be difficult to estimate from the literature – including possible effects of consultant presence on test ordering behaviour which could go either way. We consider that those are likely to be small relative to both the labour costs for consultants and potential savings through reductions in length of stay, admissions to the ICU, and treatment of

adverse events. Moreover, collecting estimates of these costs in the case note review would not be trivial. However, we will, during Phase 1, model the contribution that test ordering could make and also ascertain the feasibility and indicative costs for collecting this data.

Model verification and validation

Quality assurance is an essential step in decision modelling.[Eddy 2012] The model and results of the Phase 1 analyses will be reviewed by an experienced health economist external to the research team. The Health Economics Research Group at Brunel has a quality assurance checklist used to verify and validate models. This includes a series of practical checks for the integrity of model inputs, verification of coding, tests for internal validity, face validity and (if possible) external validity model outputs.

The results of the prior economic analysis will then be made available to the steering committee who will advise the funder and research team as appropriate.

6. Preparation for ethnography

The ethnographer will need to gain familiarity with the clinical environment in hospitals at weekends in order to make optimal use of the observation periods in each of the 20 hospitals in Phase 2. This will include understanding emergency admission patient flows, identifying different grades of staff, and appreciating the variety of styles of practice in patient reviews.

The ethnographer will also need an understanding of the project as a whole, including how the intensity of specialist-led acute care has been characterised. This requires attendance at the workshops and project management committee meetings.

Institutional approval will be required for the ethnographer to gain access to the 20 hospitals participating in Phase 2. The approval process will start towards the end of Phase 1.

PHASE 2 (Observational) (27 months)

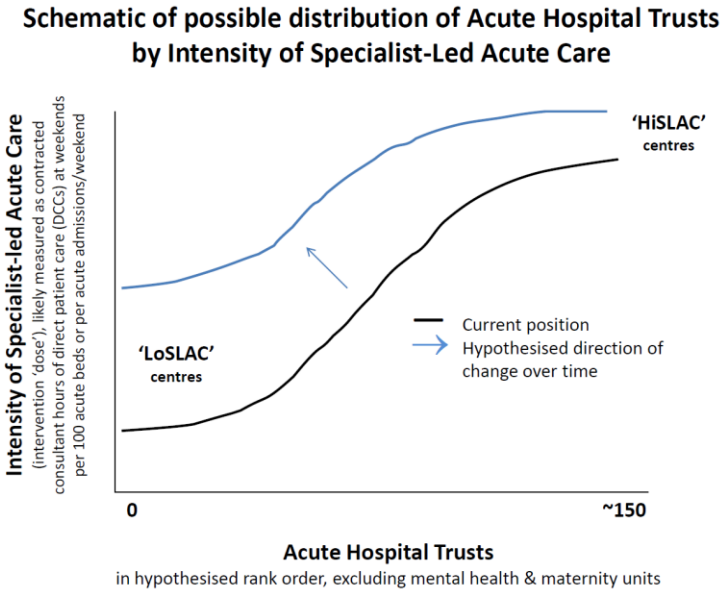
Study Design: Phase 2 consists of two major workstreams, in addition to the parallel themes of Health Economics and Ethnography. :

Workstream A: NHS System-level analysis of emergency (unplanned) admissions to all English NHS acute hospitals.

We will explore associations between intensity of speciality provision from the Phase 1 survey with outcomes data from HES/ONS for unplanned admissions at weekends and weekdays. Current data will be supplemented by anamnestic review of the previous three years, permitting an examination of changes over time. We will correlate the provision ('dose') of specialist provision at weekends with dependent outcome variables collected routinely from hospitals (eg: standardised mortality rates, length of stay), and with differences in outcome between weekends and weekdays. Changes in weekend outcomes and in weekend/weekday differences will be mapped over time. Analyses will be performed with and without adjustment for potential confounding variables (see Statistical analysis section).

Workstream B: In depth hospital comparison study. A detailed cross-sectional mixed methods analysis of emergency non-operative admissions to 10 HiSLAC hospitals and 10 low-intensity (LoSLAC) hospitals.

Selection of Trusts: Trusts at either end of the specialist-intensity spectrum (**Fig 7**) will be invited to participate in Phase 2 of the project. We plan to select hospitals from the extremes of the range rather than to match on variables such as hospital size. We are concerned that size and ability to provide specialist cover may be on the same causal pathway. However, the final decision on this point will be based on further discussion and a steering committee decision at the end of Phase 1.



We will use two investigative tools:

- **Hospital-level metrics**:

Local data will be extracted from patient administration systems (PAS) to supplement that submitted to HES. Comparisons will be made between HiSLAC status and length of stay (using time of admission from PAS system – not collected for HES); Cardiopulmonary Resuscitation (CPR) rates, unplanned ICU admissions (ICNARC case mix programme dataset); hospital readmission within 7 days; staff absenteeism rates; and patient-reported outcome measures of satisfaction (PROMs). We will record weekend and weekday admission case mix-adjusted hospital mortality rates, but at a single hospital level the small difference between weekend and weekday mortality (0.5- 1 percentage points) prevents this from being used as a primary outcome measure.

- **Case record reviews of 50 weekend vs 50 weekday admissions to each Trust**:
  - Implicit review of quality of care
  - Explicit (criterion-referenced) analysis of best practice adherence

We will utilise 100 randomly sampled case records (50 weekend, 50 weekday admissions) from each hospital (masked, photocopied, anonymised & digitised). Selection of cases and controls will be based solely on HiSLAC status. Case records will be sampled in proportion to the 10 most common primary diagnoses associated with emergency admission (HES) across the entire sample, and within each primary diagnosis by allocating equal proportions either side of median age for the entire sample.

At least 10 reviewers will contribute to each phase to improve 'calibration' ie; to reduce the effect of any outlier ('hawk' and 'dove') reviewers. Case records will be shuffled (presented in random order) and assessors will be blinded to level of intensity of specialist care (and time epoch in Workstream A), to diminish bias from reviewer variation, learning, unblinding or fatigue [Benning 2012]. The reviewers will not be aware of which sites are intervention or control (Phase 2) or which epochs are which (phase 3). Each case record will be assessed independently by two reviewers to permit averaging of global measures of quality and to measure inter-observer agreement (which we know will be lower for implicit than for explicit criterion-referenced review).

Implicit and explicit review will be performed by senior specialist trainees or consultants, who will determine adverse events, serious errors ('near-misses'), and quality of care. A list of explicit criteria will be formulated in Phase 1 to describe best practice care for the 10 most common primary diagnoses. Global assessment of care will also be made by the assessors using a ten-point scale.

Subsequent analysis will examine whether quality of care varies by admission period and the degree of HiSLAC implementation. We will look for a difference in difference i.e. a difference in the difference between weekdays and weekends across low and high intensity hospitals. In this way each hospital acts as its own control. Preventable adverse events and major errors not associated with adverse events ('near misses') will be recorded, with a hypothesised reduction in avoidable adverse event rates from 3% to 2%.

Health Economics

Repopulating the model with empirical data (Phase 2)

Phase 2 is the data collection phase based on:

1. Correlation of survey/HES/OPCS data (approximately 150 hospitals).
2. Comparison of 20 hospitals sampled from the extremes of the "dose" range – hospital comparison study.

In Phase 2 the model developed in Phase 1 will be repopulated with empirical data from Workstreams A and B. The data inputs for the model are summarised in Table 1. Recommendations for statistical methods for cost-effectiveness analysis using observational data will be followed [Kreif 2013], including assessment of the 'no unobserved confounding' assumption. Probabilistic Sensitivity Analysis (PSA) will be used to estimate the extent of uncertainty over the prior model results. In addition, a series of deterministic sensitivity analyses will be used to explore structural uncertainty over the model design and data sources.

Table 1. Data-sources for parameters required in the Decision Matrix.

	Data Type	Study Type Hospital Comparison (Workstream B)	National Correlation (Workstream A)
Effectiveness parameters	Mortality	+	+
	Errors	+	–
	Adverse events	+	–
	CPR rates	+	–
Parameters that drive costs and that are contingent on effectiveness	Length of stay	+	+
	Unplanned ICU admissions	+	+
	Hospital Readmissions	+	+
	Long-term care costs	–	–

Deaths and adverse events will be measured in the study. However, severe, permanent adverse events are rare and many of these (especially those due to misdiagnosis) will come to light beyond our observation period. These are the type of adverse event where consultant cover may be particularly effective. We will use sensitivity analysis to investigate the potential consequences of rare adverse events using data from the literature. We have experience in this type of modelling from our recent NIHR progressive grant study on e-health [Sheikh et al, NIHR grant]

Interpretation of findings and impact

Towards the end of Phase 2 we will assemble all those who took part in the original elicitation exercise (substituting where necessary). The purpose is fourfold:

1. To show them the data, quantitative and qualitative, and ask them what patterns they perceive, and what general tendencies and theoretical constructs they discern.
2. To ask them what meaning they attach to the data in terms of the policy implications in England and internationally.
3. To repeat an elicitation exercise to derive a form of "posterior" driven by a holistic assessment of the data from the index study (including the ethnographic work) and from other relevant research elsewhere. We will call this a synthetic posterior – it is a new approach that we are piloting in the NIHR programme grant on ePrescribing. It represents in effect, a quantitative elaboration of Pawson and Tilley's "realist synthesis,"[Pawson 1997] and the philosophical basis of this approach was laid down in our previous article concerning an "inconvenient truth".[Lilford 2010] While this approach is not standard, it does provide a

method to obtain a parameter estimate for use in models, where multiple data have to be 'triangulated.'[2] This is analogous to collating lots of data from different sources relating to climate change to form a best estimate of the future rate of global warming.

The final results will be fed-back to the Steering Committee and stakeholder meeting before the end of the study. The final parameter estimates will be used to recalculate true market cost effectiveness and to conduct sensitivity analyses.

Ethnographic evaluations

Ethnographic work will be conducted in the 20 hospitals – both HiSLAC and LoSLAC - participating in the hospital comparison study (Workstream B). It will aim to:

- Systematically describe the features of the organisation and delivery of weekend care to emergency medical admission patients in HiSLAC and LoSLAC hospitals;
- Identify the contextual and social factors that underpin variations in practice;
- Explore the experiences of staff of arrangements for weekend care, and their views on how these arrangements impact on staff and patients;
- Explore the experiences of patients and relatives of the care they receive on weekdays and at weekends in HiSLAC and LoSLAC hospitals;
- Identify the features of systems for weekend care that contribute to their effectiveness, feasibility and acceptability to staff;
- Identify the challenges involved in implementing HiSLAC systems, and what influences successful implementation.

The ethnographic study will be conducted in all 10 HiSLAC and all 10 LoSLAC sites. This will involve researchers visiting sites and conducting observations and informal chats with staff and patients. Each site will be visited twice, to account for seasonal effects and differences between the styles of different consultants; visits will be conducted at least 3 months apart. The observation visits will be conducted between Friday morning and Monday evening. A range of medical acute admitting wards will be included.

The data collected will consist of fieldnotes from observations and informal chats with hospital staff, and collection of documents related to the implementation of HiSLAC such as meeting notes and blank handover forms. A structured observation guide will be developed. This will detail the aims of the observations and the topics and issues on which data should be collected during observations, and will be informed by the definition of HiSLAC developed in Phase 1. Researchers will focus on observing weekend staffing levels and how staffing is managed, the functioning of ward teams and other teams that support specialist-delivered care, and the nature of formal reviews and handovers. The researcher will also aim to collect data on salient features of the local systems, social factors, and organisational context that may impact on implementation of HiSLAC. Through debriefing sessions with researchers, we will ensure that the data collection remains focused on core topics, and that emerging themes are explored and used to inform subsequent data collection.

Semi-structured interviews will be conducted with 3-5 members of staff (including those in a range of clinical and managerial roles) in each participating hospital. Face-to-face interviews will be

conducted during site visits; telephone interviews will be arranged with staff who are not available during the visit, or who would prefer a telephone interview. Staff interviews will explore: current weekend working patterns and views on the reasons for these patterns; their experiences of differences between care organisation and delivery on weekdays and at weekends and the impact of this on staff and patients; and barriers and facilitators of efforts to introduce HiSLAC. Each interview will be tailored to the individual staff member's role, and will also explore issues that arise during observations.

We will also conduct up to 60 semi-structured interviews with patients and/or their relatives about their experiences of receiving care in HiSLAC and LoSLAC hospitals. During observational visits, patients who are in hospital over the weekend (or their relatives if appropriate) will be approached with an invitation to participate in an interview. Interviews will be conducted during the patient's stay. Patient/relative interviews will explore their experiences of care in the hospital on week days and weekends: the extent to which care was prompt, attentive, and met their needs; how easy it was to get their questions answered; how often they saw a doctor, whether they saw junior or senior doctors, and whether this was something they are aware of/concerned about. They will also be asked about their overall views of the quality and safety of the hospital.

Analysis of data will be on-going over the course of the fieldwork period. Interviews and field notes will be transcribed verbatim and coded using NVivo. Analysis will draw on elements of grounded theory, in particular, the constant comparative approach. Our analysis will remain grounded in the data, but will be guided by analytic themes or sensitising concepts arising from the work conducted in Phase 1.[iii] We will use techniques developed through our experience of conducting large scale ethnographic studies to enable us to manage the large amounts of data generated, and to move quickly from data to interpretation. These include: regular group debriefs; the production of summaries of data across sites organised by research questions and emerging themes; and charting of characteristics of individual sites on a set of core features. The latter approach will be of particular value to this study: we will develop a framework of key features of the delivery of weekend care drawn from the definition of HiSLAC generated in Phase 1. Informed by this, we will integrate data from observations and staff and patient interviews to produce a concise description for each site of the organisation and delivery of weekend care to emergency medical admissions patients. These case studies will be used to assess fidelity, and to inform the interpretation of the quantitative findings.

OUTCOMES AND DELIVERABLES

Proposed Outcome Measures

PHASE 1

- **HiSLAC Metrics:** The workshop will incorporate insights from managers, clinicians and PPIs in order to determine the most appropriate measure as well as the best approach to obtaining this information through the survey. One approach might include a numerator based on the consultant contract with denominators reflecting patient volumes or bed days. We will also elicit opinion on the intervention and on contextual factors that might affect the effectiveness of a given 'dose' of specialist presence. .
- **A national map** of all English NHS acute Trusts to determine the intensity and nature of specialist-led acute care now and over the preceding three years.
- **Case record review framework:** A scoring template will be developed for implicit (global) and explicit (criterion-referenced) review. Criteria will be derived from analysis of best practice guidance developed by professional organisations and agencies such as NICE, relating to the ten most common primary emergency admission diagnoses.
- **A Preliminary Health Economics Model** to determine the cost-effectiveness and budget impact of increasing the intensity of specialist input.
- **An online collaborative workspace and web page** hosted by the Academy of Medical Royal Colleges to describe the project and provide communication tools.

PHASE 2

Workstream A:

At whole-NHS-level we will measure case mix-adjusted mortality, length of stay & 7-day readmission rates. These will be analysed by HiSLAC status, weekend vs weekday, and changes over time, using a difference-in-difference-in difference approach [Sutton 2012].

Workstream B:

- **Hospital-level outcome measures** will include adjusted mortality, CPR rates, unplanned ICU admissions; absenteeism; and patient-reported outcome measures, in addition to the NHS_level data above. We will not over-interpret a null result given the likely signal-to-noise ratio (see statistics section).

- **Case record Review:** Quality of Care will be assessed by implicit and explicit case record review. Global assessment of quality of care (implicit review) will be quantified using a 10-point rating scale. We will look for a difference in difference i.e. a difference in the difference between weekdays and weekends across low and high intensity hospitals. In this way each hospital acts as its own control. Preventable adverse events and major errors not associated with adverse events

('near misses') will be recorded, with a conservatively estimated hypothesised reduction in potentially avoidable adverse event rates from 3% to 2% [Buckley 2012, Zegers 2009, Baines 2013, Hogan 2012, Vlayen 2012, Yao 2013]. A list of explicit criteria will be formulated in Phase 1 to cover common errors in addition to explicit criteria based on best practice guidelines for the 10 most common emergency admission diagnoses.

- **Health Economics:** The results will be presented in the form an Incremental Cost-Effectiveness Ratio (ICER) - the 'cost per QALY' – for HiSLAC compared with LoSLAC. Based on the NICE benchmarks for cost-effectiveness, high-intensity provision would be cost effective if the estimated ICER is below about £20,000 per QALY gained. In addition we will estimate the national and local budget impacts of implementation. Measures of uncertainty over the economic results and the value of information associated with further research will also be presented.

Ethnographic 'deliverables' will include:

- Characterisation of the features of the organisation and delivery of weekend care to emergency medical admission patients in HiSLAC and LoSLAC hospitals. This will take the form of individual case studies for each site;
- A grounded, theoretically sophisticated analysis of the contextual and social dynamics underpinning variations in practice for delivering weekend care;
- Insight into the impact of HiSLAC and LoSLAC on the experiences of staff, patients and relatives;
- A description of the features of systems for providing HiSLAC that contribute to their effectiveness, feasibility and acceptability to staff and patients;
- A description of the barriers and facilitators of the implementation of HiSLAC.

Assessment & Follow-up

As the study does not use patient-identifiable information there is no opportunity to follow up individual patients from the participating hospitals. Seven-day readmission rates will be recorded, truncated at this point because the proportion of preventable readmissions falls rapidly thereafter.

DISSEMINATION

The main research outputs will include:

- Information on current provision of specialist-led care throughout NHS acute hospitals in England, the extent of national variation, the use of physician 'extenders', and plans for change.
- National standards and definitions of quality of specialist-led care, and measurement metrics.
- Development of a generic framework for acutely ill patient pathways
- Novel data on the relationship between specialist-led care and specific patient outcomes, for example on CPR rates or length of stay.

- A better understanding of the interplay between weekend and weekday admission and the intensity of specialist-led care.
- Insights into the mechanisms for the link between weekend admission and suboptimal outcomes.
- An economic model to determine whether the impact of the intervention justifies or even fully offsets the workforce costs.
- An estimate of the national and local budget impact of increasing specialist intensity, which will help to inform policy-makers and managers about implementation.
- A more detailed and nuanced understanding from the ethnographic study of the relationship between contextual factors and innovation uptake.
- Evidence for improvement in patient outcomes with the introduction of higher-intensity specialist-led care during national roll-out, if Phase 3 is realised.

These outputs will be presented through the collaborating NHS, professional and public organisations to their respective constituencies and networks through regular reports, peer-reviewed scientific publications and presentations at scientific meetings. We will translate information on the link between process quality and outcomes into generalisable learning and sustained change in practice through the competency-based training programmes for acute care medical specialities. An example of this approach is the international training programme for intensive care medicine (www.CoBaTrICE.org) the development of which was led by a member of the research team (JB).

The impact of these research outputs will be of value to health service policy makers and funders, patients and the public, the professions, and to quality improvement and human factors scientists. The findings will be of interest internationally as well as in the UK. We have ensured that the key constituencies are represented in the project team, including PPI reps, the clinical communities and professional organisations, the Department of Health and Medical Directorate, health services and sociology researchers, and groups focussed on promoting professional leadership (Faculty of Medical Leadership & Management).

The combination of objective and experiential data is a powerful method for engendering change. We expect to engender shared understanding between clinicians and managers of the barriers to and facilitators of major service reconfiguration through the triangulation of quantitative and qualitative data on process and outcome.

Generalisable experiential learning from the adopting hospitals lends itself to a peer-support model of diffusion and sustainability [Woolhouse 2012]. While not the immediate focus of this application, in contingent Phase 3 the Academy of Medical Royal Colleges may take the opportunity to develop a collaborative support network through the professional lead organisations and with the additional guidance of the Advisory Board, so that HiSLAC-Adopting hospitals will act as Promoters for others in their immediate proximity through the development of partnerships.

To enhance dissemination and impact, we will take into account the evidence synthesis published by the Health Foundation on challenges in quality improvement research [Dixon-Woods 2012]. We will invest substantial project time in stakeholder engagement, and in developing consensus on the correct metrics for measuring the impact of HiSLAC. We will minimise 'top-down' approaches to project management, capitalising on existing networks of clinicians with experience in front-line acute care and building on that community; and we will use ethnographic observations to promote reflective learning and to identify and minimise unintended consequences.

LIKELY BENEFITS OF THIS RESEARCH

The impact of these research outputs (above) will be of value to health service policy makers and funders, patients and the public, the professions, and to quality improvement and human factors scientists. The findings will be of interest internationally as well as in the UK.

The combination of objective and experiential data is a powerful method for engendering change. We expect to engender shared understanding between clinicians and managers of the barriers to and facilitators of major service reconfiguration through the triangulation of quantitative and qualitative data on process and outcome.

Generalisable experiential learning from the adopting hospitals lends itself to a peer-support model of diffusion and sustainability [Woolhouse 2012]. While not the immediate focus of this application, the Academy of Medical Royal Colleges may take the opportunity to develop a collaborative support network through the professional lead organisations and with the additional guidance of the Advisory Board, so that those Adopting hospitals which have been able to implement HiSLAC will act as Promoters for others in their immediate proximity through the development of partnerships.

Phase one itself will produce beneficial outputs, including refinement of methods for quality assessment in circumstances where explicit criteria are insufficient. The need for specialist input is just such a circumstance – if adherence to explicit criteria was all that was required then specialist deployment would not be the cost effective option. Phase 1 will also be directly useful to policy makers who need to understand current implementation of recommended practice and barriers to further roll out. Phase one will also yield a model that can help determine whether plausible benefits are likely to be cost effective or even cost releasing.

Success Criteria and Barriers

Success criteria include completion of the project as planned with a conclusive outcome. A conclusive outcome requires quantitative and qualitative evidence to point in the same direction, either in favour of HiSLAC or demonstrating no impact, with health economic modelling providing additional information on the cost-effectiveness and budget impact of the intervention at different levels of penetration.

Barriers to the project are organisational and methodological. Organisational barriers relate primarily to potential lack of engagement by hospital clinicians, managers or leadership. Lack of

engagement may be a consequence of competing demands during a time of health service reorganisation, or inability to fund the additional specialist staffing to implement HiSLAC at a time of financial constraints. We will use professional networks to maximise engagement.

Methodological barriers include the inability to detect a signal from the intervention because of background 'noise' from a health system experiencing multiple concurrent policy initiatives directly or indirectly targeting patient outcomes. We will minimise this risk by triangulating measures of impact, and through the study design incorporating an observational and then an interventional phase.

PATIENT AND PUBLIC INVOLVEMENT

PATIENT AND PUBLIC INVOLVEMENT

Both of our P&P representatives have important experience in education, public service and governance.

Mr Peter Rees is the PPI representative in the study management committee. He has experience of the health service as a user, as an observer of front-line care, and at national level as a member of the Board of the Faculty of Intensive Care Medicine and member of the Patient Liaison Group of the Royal College of Anaesthetists and the Academy of Medical Royal Colleges. He has used this experience to evaluate the protocol and to suggest possible quality indicators for high-intensity specialist led acute care and how they might be employed in the evaluation of the intervention.

Mr Paddy Storrie is the PPI representative in the Study Steering Committee, providing oversight and governance of the project, and will contribute as one of five members who will make recommendations to the HSDR Board on whether the project should proceed through the decision gates at each phase. He has experience of the health service as a user, and is also a member of the Citizen's Council of the National Institute for Health and Clinical Excellence, Member of the Academy of Medical Science Working Group on Regulation and Governance of Medical Research, and Member of the MHRA Patient and Public Engagement Expert Advisory Group.

All the professional organisations represented in this project have patient and public committees in their governance structures. We will invite these groups to offer their unique insights during the project and in particular to contribute to the developmental work of Phase 1.

The costs of all PPI collaborators and advisors will be met in full and are included in costs to the grant. A contingency is also included for educational opportunities for PPI representatives and the PPI representatives will be invited to interact in local forums for PPI involvement in Birmingham such as the NIHR CLAHRC PPI forum. We will ensure that at least two PPI collaborators are invited to all meetings. An induction programme will be organised for PPI representatives. We will seek their advice regarding all questionnaires produced at every stage of the programme, including the dissemination aspects.

The ethnographic work in Phase 2 specifically seeks the views of health services users – patients and relatives – through up to 60 semi-structured interviews with patients and/or their relatives about their experiences of receiving care in HiSLAC and LoSLAC hospitals.

STATISTICAL ANALYSIS

STATISTICAL ANALYSIS

For each measured outcome the analysis will be concerned both with the values achieved for weekend admissions (which may be directly associated with levels of weekend specialist care) and also with the difference between weekend and weekday admissions – "difference-in-difference" analysis – which may reflect differential performance across the week. Separate analyses will be conducted for each of these aspects. The analysis of weekend outcomes will incorporate covariance adjustment for the same outcome for weekday admissions. The difference-in-difference methodology mimics that adopted in a recent high-profile study (Sutton et al, (2012)).

Whole-system data (Workstream A)

Three years of data will be available from about 150 hospitals for Length of Hospital Stay (LOHS), Readmission Rates, CPR Rates and Mortality. Hospital-level analyses will be performed. Temporal trends over the whole system will be investigated using mixed effects models with random intercepts (hospitals) and slopes (hospital by time) using hospital level data. For each hospital a measure of weekend specialist intensity ('SLAC') – to be developed in phase 1 – will be collected for the first and third year. The impact of these measures on the slopes and intercepts will be investigated by introducing appropriate fixed effects into the models. Analyses will also be adjusted for: hospital type (Small acute trust, medium acute trust, large acute trust and acute teaching trust); hospital size (numbers of beds in the medical directorate); and for deprivation (the Income domain score of the indices of Multiple Deprivation 2010).

Case-note review data (Workstream B)

Quantitative analyses in Phase 2 will be designed to examine the association between the intensity of specialist engagement and the process and outcomes of care, in hospitals purposively sampled to represent opposite ends of the spectrum of specialist engagement. Analysis will use mixed effects logistic regression models (for binary outcomes) and mixed effects ordinary regression models (for continuous outcomes), with adjustment for age and sex. Variation between hospitals will be modelled in terms of random effects. Continuous outcome variables will be subjected to normalising transformations as appropriate. High intensity hospitals (HiSLAC) will be compared with non-adopting (low intensity, LoSLAC) hospitals with respect to: process data (quality of care) and clinical outcomes (length of stay, CPR rate, mortality) for weekend admissions; and differences in process and outcome (measured as odds ratios for binary outcomes and as numerical differences for continuous data) between weekend and weekday admissions.

Analysis of qualitative data from the ethnographic work will be based on the constant comparative method.

Power analysis

All calculations are based on 2-sided tests with P = 0.05.

Power for analysis of whole system data (Workstream A)

With 150 hospitals there will be 80% power to detect a correlation of 0.23 or greater between the SLAC measure of specialist engagement and any hospital level outcome. Such a correlation would imply that about 5% of the variation in the outcome is attributable to the level of specialist engagement.

This does not take account of errors in measuring levels of engagement. In general the detectable correlation is increased by a factor 1/r where r is the correlation between actual and measured levels of engagement. For example, if 25% of the variation in the SLAC measure was due to measurement error, then the correlation between measured engagement and actual engagement would be 0.87 (= r) rather than 1, and the detectable underlying correlation would be 0.27 (instead of 0.23).

Power of Comparative Study of 10 High-Intensity versus 10 Low-Intensity Hospitals (Workstream B)

The power calculations are presented as effect-sizes detectable at 80% and 90% power in Table 2. The calculations for length of hospital stay and mortality are based on 10,000 admissions per hospital per epoch, with 24% being admitted at weekends (Mohammed et al 2012); those for QoC use 100 case-notes per hospital, using a stratified sampling scheme to achieve equal numbers of weekend and weekday admissions. The calculations depend on the intra-cluster (hospital) correlation (ICC), estimates of which are obtained from Campbell et al (2005). For the analysis of differences between weekend and weekday outcomes the detectable effect-sizes depend also on the proportion of the ICC that is due to stable differences between clusters (hospitals), as opposed to transient changes within clusters. This proportion can be identified with the correlation between weekends and weekdays within each group of hospitals and corresponds to a "within cluster autocorrelation" (r_C) (Teerenstra et al. 2012). In the most favourable case ($r_C = 1$) the same hospital-level effect persists across the whole week – and indeed is eliminated entirely from the analysis of weekend/weekday differences. But the calculations are quite sensitive to this assumption and, in some cases, power can be considerably reduced if a lower value of r_C is assumed. (See table)

Results for continuous outcomes (length of hospital stay (LOSH) and Global quality of care (QoC)) are expressed as detectable differences from the baseline in terms of SD units. Plausible baseline levels are: LOSH mean 8.5 days, SD 1.3 days [Lambourne 2012]; QoC mean 5.8, SD 2.5 (Bishop & Lilford, in preparation). A difference of ½SD can always be detected with power at least 80% under all suggested analyses. Mortality calculations assume a base rate of 6% for weekend mortality (Mohammed et al (2012); Aylin et al (2010); Cram et al (2004)). According to these calculations, the study is not powered to detect plausible differences between hospitals in mortality for weekend admissions unless the mortality ICC proves to be substantially less than 3%. However (depending on the value of r_C) an absolute reduction from 7% to 6% may be detectable when the comparison is based on a contrast between Weekend and Weekday admissions within the same hospitals.

The risk of mis-interpreting a null result will be mitigated by conducting a supplementary Bayesian analysis in which the Bayesian priors collected in phase 1 will be updated [Hemming et al 2012].

Table 2: Detectable differences at given power for 2-sided tests with P = 0.05.

Variable	Within cluster autocorrelation (r_c)	**LOHS** Continuous outcome ICC = 0.04		**Mortality** Binary outcome (baseline rate = 6%) ICC = 0.03		**QoC** Continuous variable ICC 0.05	
		Difference (SD units)		Difference in rates (%)		Difference (SD units)	
Power		*90%*	*80%*	*90%*	*80%*	*90%*	*80%*
Comparison of weekend admissions between two groups of 10 hospitals		0.29	0.25	5.71	4.97	0.38	0.33
Comparison of weekend admissions between two groups of 10 hospitals with adjustment for week-day admissions	1 0.8 0.6	0.033 0.18 0.23	0.029 0.15 0.20	0.76 3.48 4.59	0.66 3.03 3.99	0.26 0.31 0.34	0.23 0.27 0.30
Comparison between weekend and weekday admissions within one group of 10 hospitals	1 0.8 0.6	0.024 0.13 0.18	0.020 0.11 0.16	0.56 2.73 3.81	0.49 2.36 3.30	0.20 0.25 0.29	0.17 0.21 0.25
Comparison of weekend vs weekday difference between two groups of 10 hospitals	1 0.8 0.6	0.033 0.19 0.26	0.029 0.16 0.23	0.79 3.85 5.39	0.69 3.33 4.66	0.28 0.35 0.41	0.24 0.30 0.35

Differences (for LOHS & QoC) expressed in units of Standard Deviation. Entries for Mortality expressed as absolute risk differences.

The calculations for length of hospital stay and mortality are based on 10,000 admissions per hospital per epoch, with 24% being admitted at weekends (Mohammed et al 2012); those for QoC use 100 case-notes per hospital, using a stratified sampling scheme to achieve equal numbers of weekend and weekday admissions

Economic Modelling Analysis

It is possible that high-intensity specialist care might be cost saving – if the cost of the additional consultant input is outweighed by savings on hospital and/or long-term health and social care costs. If so, and assuming that high-intensity care is also health improving (that it does not actually increase the incidence of adverse events), it would clearly be cost-effective for the NHS to implement this change. However, if high-intensity care is more expensive overall, the results can be presented in the form an Incremental Cost-Effectiveness Ratio (ICER) - the 'cost per QALY' – for HiSLAC compared with LoSLAC. Based on the NICE benchmarks for cost-effectiveness, high-intensity provision would be cost effective if the estimated ICER is below about £20,000 per QALY gained.

Sensitivity analysis and value of information

A probabilistic sensitivity analysis (PSA) will be used to estimate the impact of uncertainty over the prior parameter estimates on the probability that the high-intensity intervention is cost-effective (at the NICE lower limit of £20,000 per QALY gained). Estimates of the variance and (where possible) correlations between input parameters will be collected from literature sources and from experts in the elicitation procedure. In addition, deterministic sensitivity analysis will be used to examine the impact of structural uncertainty over the modelling assumptions – for example, the impact of different methods used to calculate the marginal cost of increasing consultant hours at the weekends.

A ‘value of information’ approach will be used to estimate upper limits to the value of collecting further information about groups of input parameters - the ‘Expected Value of Partial Perfect Information (EVPPI). This will help to shape the design of the Phase 2 case note review form, and to target our research efforts on collecting data about which there is most uncertainty, and where the uncertainty has potentially large impacts on costs/QALYs. For example, the EVPPI for the impact on consultant test-ordering behaviour will help us to decide whether detailed information should be collected, as mentioned above.

MANAGEMENT, GOVERNANCE & ETHICS

PROJECT MANAGEMENT & GOVERNANCE

Research Management and Governance structures are described in **Fig 8**.

The project **Management Committee** will be responsible for the day-to-day conduct of the study. Monthly meetings will take place in person alternating with teleconference calls. The committee will report to the Steering Committee and the HSDR Board.

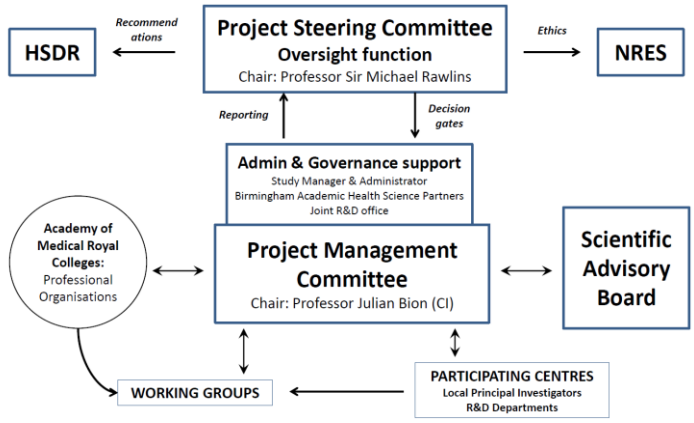
The project will be governed by the **independent steering committee** chaired by Professor Sir Michael Rawlins. The steering committee will monitor project progression and will make recommendations to the HSDR Board. The Steering Committee will receive 6-monthly progress reports from the Management committee and will meet either in person or by teleconference call (TCC) towards the end of each Phase and at least every 12 months.

The **Scientific Advisory Board** will receive progress reports from the Management Committee, and will be invited to participate in project workshops. Members will be asked to provide intermittent guidance and support on methodological and scientific issues

Investigator meetings with participating **hospital local leads** will take place approximately once every year. Each participating hospital will be visited individually by the project team (Chief Investigator and project manager, and one additional clinical member of the project team) at the start of Phase 2.

Communication with the various clinical constituencies represented in the project and reflected in the acute ill patient pathway will be via the Academy of Medical Royal Colleges and the stakeholder professional organisations (Colleges, Faculties, Societies, NHS Medical Directorate). We will develop an online collaborative workspace and web pages for the project, hosted by the Academy of Medical Royal Colleges, to aid project management, resource sharing, file exchange, and communication both within the project team and with the public. This resource will continue to be developed through the lifetime of the project and afterwards as a community resource.

Fig 8: Project Management and Governance



Work that has already commenced in the preparation of this research

We have undertaken preliminary and informal survey work through the Academy of Medical Royal Colleges' working group on standards for Consultant-present care, which shows that there are at least 28 Trusts which have implemented various forms of HiSLAC. Of these, 17 focus specifically on all or part of the acutely ill adult medical patient pathway (Appendix 2). While there may well be more than this, it is improbable that the NHS will reach HiSLAC saturation rapidly. In the unlikely event of doing so within the early stages of this project, the study will not proceed beyond Phase 1.

We have endorsement for this project by the stakeholder professional organisations represented in the Management Committee.

Clinical Trials Approval

We will apply through IRAS for ethics approval for the ethnographic component, as this is the only element which lies outside 'usual care' and may raise ethical issues [Bosk CL. What would you do? Chicago: University of Chicago Press, 2008]. Institutional approval will be required for the ethnographer to observe clinical practice. Staff will need to be informed that observation of practice is taking place, and will have the right to refuse observations if they wish. Information sheets will be provided for both staff and patients in the clinical areas in which the observations are taking place. The observations will be anonymised and following editing and coding will not be attributable to specific sites or individuals.

Ethical Review

According to our interpretation of current NRES/IRAS guidance (http://www.nres.nhs.uk/applications/guidance/research-guidance/?entryid62=66988) this project is a service evaluation (it evaluates an existing form of health care delivery, and the intervention is not a research treatment). No patient-identifiable data will be collected. The case note reviews will utililse masked and anonymised copies of the case records. Survey questionnaires are not mandatory.

Justification for use of questionnaires/ surveys

All acute NHS Trusts in England will be asked to complete a short voluntary web-based questionnaire concerning current or planned implementation of high-intensity specialist-led acute care. Ethnographic interviews with staff in the hospitals in Phase 2 will be voluntary and anonymous. Examples of information sheets are provided in **Appendix 3a** (patients) and **Appendix 3b** (staff).

INTELLECTUAL PROPERTY

None will be claimed, and all materials generated by the project will be made available to NHS hospitals

Research Timetable

This is a 36-month, two-phase parallel theme project (Gantt chart, **Fig 4**). **Preparatory period (months -4 to 0):** Given notification of a successful application in July 2013, we would expect to start the project officially between October 2013 and January 2014, thus utilising the summer period to recruit staff, engage professional organisations and prepare project materials.

Phase 1 (Developmental, months 1-9): During this time we will establish the workshops, develop the definitions and metrics, disseminate the survey and create the health economics model. The independent steering committee will monitor progress.

Phase 2 (Observational, Months 9-36): This consists of 24 months for data acquisition, and a three month analytical phase. During Phase 2 we will collate and analyse HES/ONS data from all acute English NHS hospitals (Workstream A), and conduct the mixed-methods cross-sectional observational study comparing ten HiSLAC hospitals with ten low-intensity (Workstream B). This will involve site visits, ethnographic observations, data acquisition from local and national databases, and case record reviews. Information from the NHS-systems wide analysis of HES/ONS data will be available within 2 years from project inception and will be reported to the HSDR Board.

In addition to reviewing progress, the independent steering committee will also consider the issue of whether the criteria have been met to justify Phase 3 (interventional study). The final three months will be used for data analysis and preparation of final reports and publications. The project will conclude around October-December 2016.

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FIGURES

Fig 1:RESEARCH PLAN FLOWSHEET FOR HIGH INTENSITY SPECIALIST-LED ACUTE CARE (HiSLAC)

<table>
<tr><th>Mo</th><th>Phase</th><th>Clinical Themes</th><th>Economics & Ethnography</th><th>Outputs, Analyses</th></tr>
<tr><td>1
2
3
4
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8
9</td><td>Phase 1: Develop</td><td>1. HiSLAC Measurement:
Workshop on measurement; pilot, refine.
2. Survey of all English NHS acute Trusts:
HiSLAC penetration; models, current & past 3 yr
3. Case record review:
Criteria, training package development
4. HES/ONS data acquisition
Set up, preparation, ‘dry run’</td><td>5. Health economics
Update systematic review
Workshop: Subject expert elicitation
Develop Model structure & QA
Populate with Bayesian priors
6. Ethnography
Researcher training in clinical environment
Institutional approval for ethnography</td><td>HiSLAC measurement methods (high, medium, low-intensity).
HiSLAC map across English NHS
Case note review framework
Preliminary Economic model
HES database, search terms & fields
Online collaborative workspace</td></tr>
<tr><td>10
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36</td><td>Phase 2: Observe, associate</td><td>Workstream A: System-wide analysis of unplanned non-op admissions to all English NHS acute Trusts.
HES/ONS data: current and 3-yr retrospective analysis: Weekend vs weekday adjusted mortality rates; length of stay; readmissions
Workstream B. Detailed cross-sectional study of non-op admissions to 20 English NHS acute hospitals: 10 HiSLAC vs 10 Low-intensity (LoSLAC) hospitals
Hospital-level metrics (PAS) to supplement national (HES/ONS) data: HiSLAC staffing; CPRs; unplanned ICU admissions; absenteeism; PROMs
Case note reviews of 50 weekend vs 50 weekday admissions to each Trust:
a. Implicit review of quality of care
b. Explicit (criterion-referenced) analysis of best practice adherence</td><td>Health Economics
Model verification & validation
Repopulation of model with empirical data
— Effectiveness parameters
— Cost-drivers
Feedback to subject experts (‘synthetic posterior’)
Ethnography
Observe delivery of weekend care
Identify contextual & social factors
Interview staff
Interview patients & relatives</td><td>Workstream A:
NHS-level case mix-adjusted mortality, length of stay & 7-day readmission rates, by:
— HiSLAC status
— Weekend vs weekday
— Change over time
— Difference-in-difference-in difference
Workstream B:
Local (PAS) data by HiSLAC/LoSLAC status and weekend/weekday
Quality of weekend vs weekday care by HiSLAC/LoSLAC status
Ethnography
Characterise reality of HiSLAC
Determine barriers, facilitators
Health Economics
Final model estimates of cost-effectiveness and budget impact</td></tr>
<tr><td colspan="4">Analytical phase: Triangulation of systems level and local level quantitative metrics with ethnographic findings and health economics. Determine need for and feasibility of Phase 3.</td></tr>
<tr><td colspan="5">Phase 3 (Test): Decision Gate for new application. Options include: 1. No Phase 3: HiSLAC already widely adopted in NHS England. 2. Natural experiment: if ~50% adoption of HiSLAC across NHS. 3. Step-wedge cluster RCT if <50% adoption and sufficient number of hospitals willing to introduce HiSLAC.</td></tr>
</table>

Fig 2: Location of HiSLAC intervention, and current standards for consultant staffing

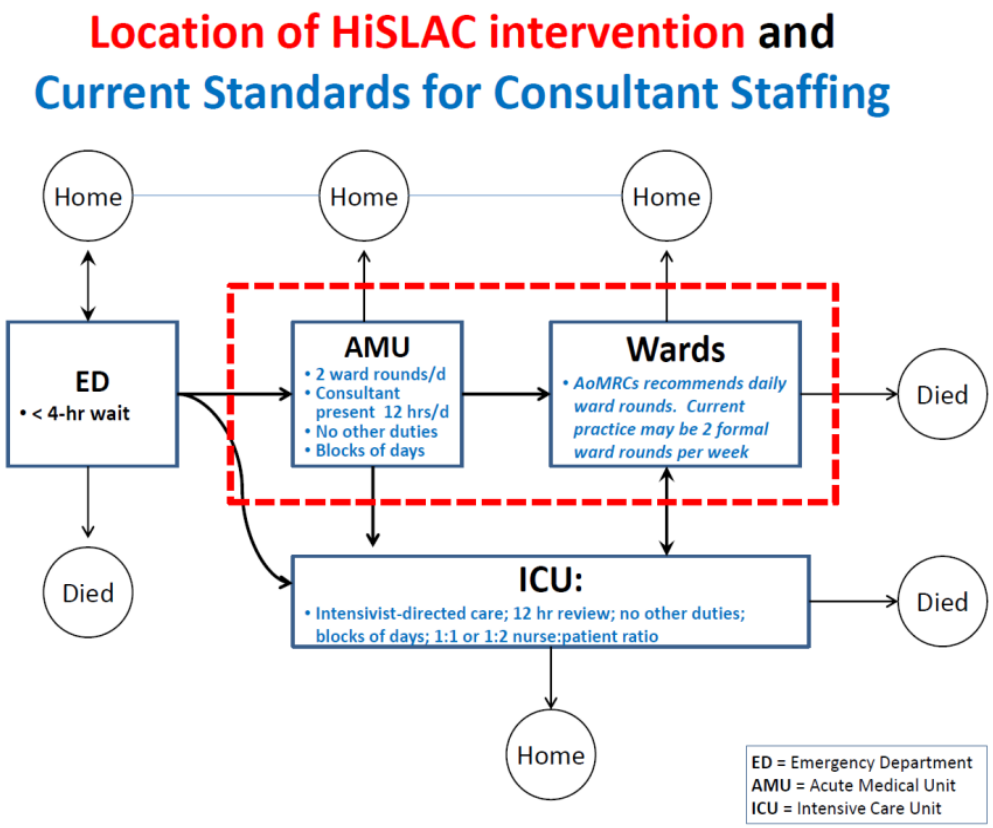


Fig 3: Emergency Admission Patient Pathways

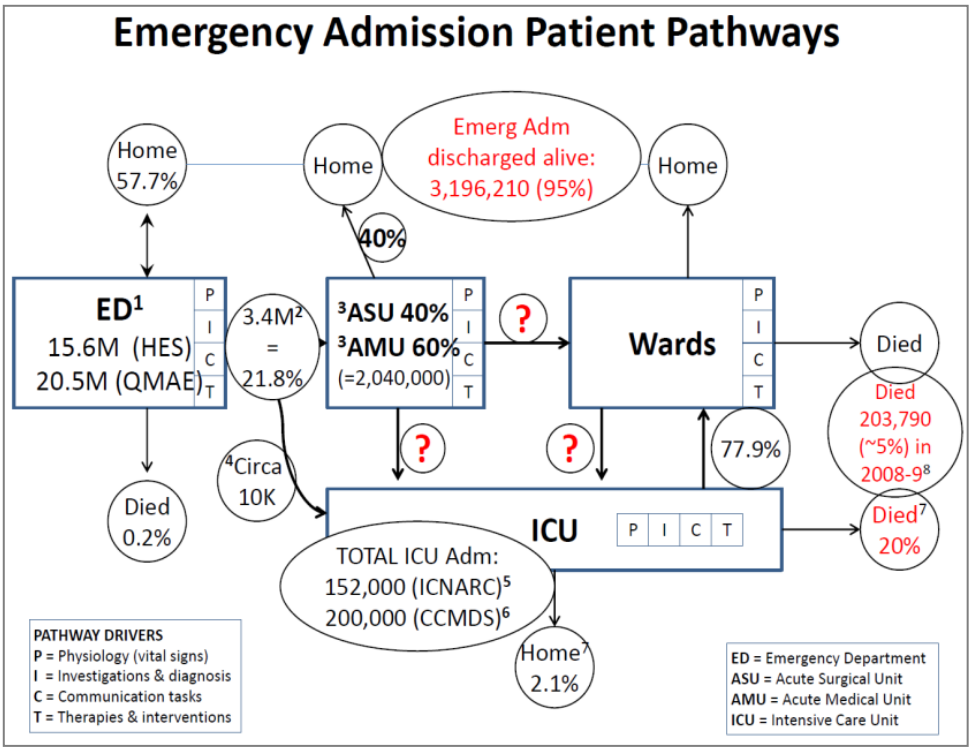
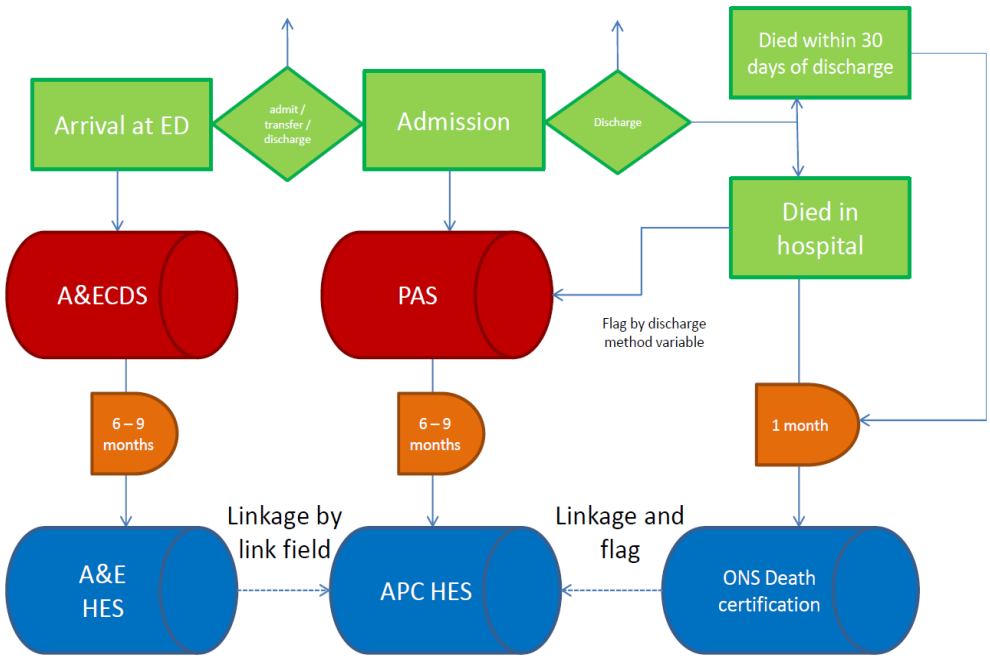
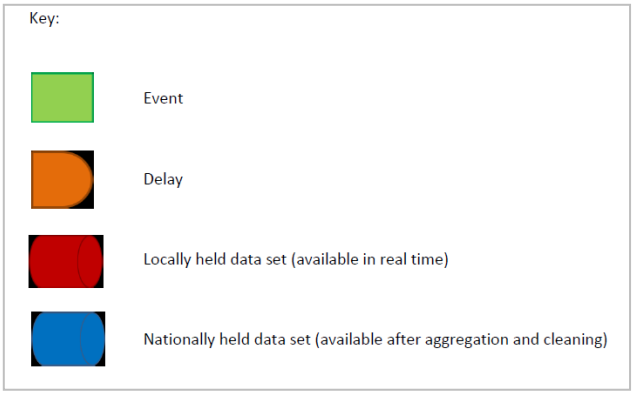


Fig 4: Gantt Chart High-intensity Specialist-Led Acute Care (HiSLAC) project, Phases 1 & 2

Phase, activity		Project Year	0	1												2												3											
		Project Month	-3	1		3			6			9			12						18						24						30						36
		Calendar month																																					
Developmental	**Standards, metrics, survey**	**PHASES**		**PHASE 1**												**PHASE 2**																						**ANALYSIS**
	Workshops; **C**ollaborator meetings			W								C									C						C						C					
	Develop HiSLAC Metrics																																					
	Survey, map HiSLAC penetration																																					
	HES/ONS data acquisition																																					
	Health Economics model development																																					
	Ethnographer training & set-up																																					
Observational	**Workstreams A&B, Parallel themes**																																					
	Recruit 10 HiSLAC & 10 LoSLAC sites																																					
	HES data analysis, interim **R**eporting																				R						R											
	Local PAS data analysis																																					
	Train case record reviewers																																					
	Case record reviews, 100 per site																																					
	Ethnographic evaluations																																					
	Health Economics model refinement																																					
Proj Man	**Governance**																																					
	Management Committee meet / TCCs																																					
	Steering Committee TCCs or meetings																																					
	Institutional approval for ethnography																																					
	Reports & Write-up																																					

Fig 5: Map of Routinely Collected Data Capture relating to an emergency admission and in-patient spell





ED	Emergency Department
PAS	Patient administration system. A locally managed hospital system capturing a national minimum data set
A&ECDS	Accident and Emergency Commissioning Minimum Data Set, captured locally
A&E HES	Accident and Emergency Hospital Episode Statistics, the national minimum dataset aggregating returns from all English Hospitals providing A&E or Minor Injury Unit services.
APC HES	Admitted patient care Hospital Episode Statistics, the national minimum dataset aggregating returns from all NHS-funded hospitals in England
ONS	Office of National Statistics

Figure 6. Illustration of possible structure for health economic model

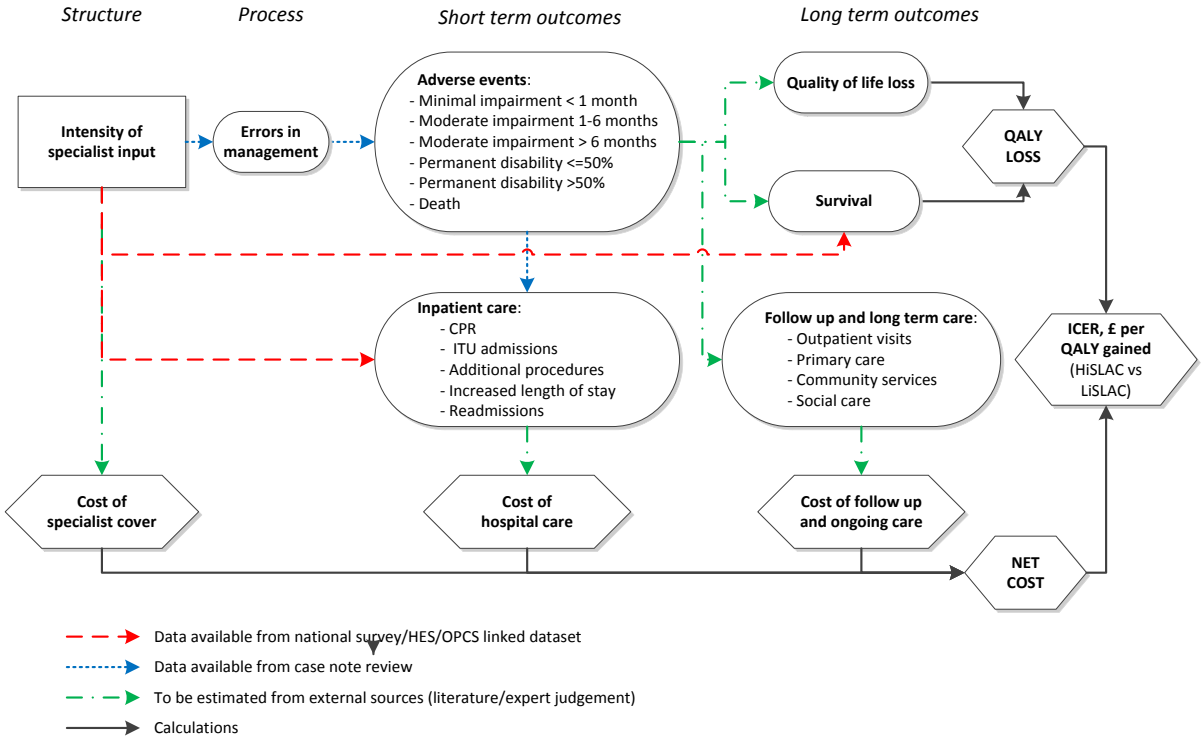


Fig 7. Schematic of possible distribution of Acute Hospital Trusts by Intensity of Specialist-Led Acute Care

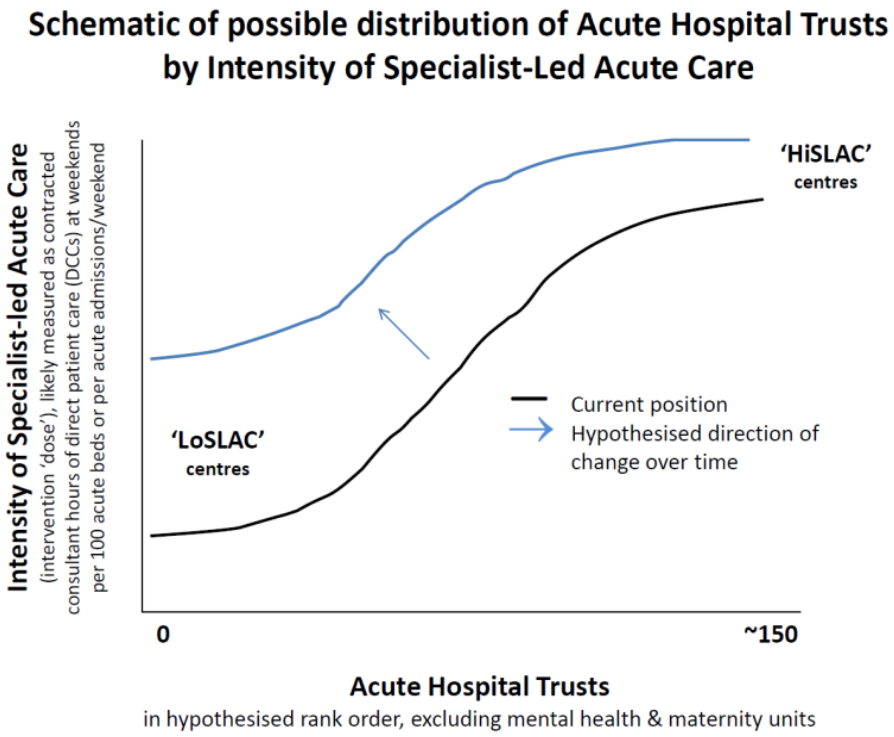
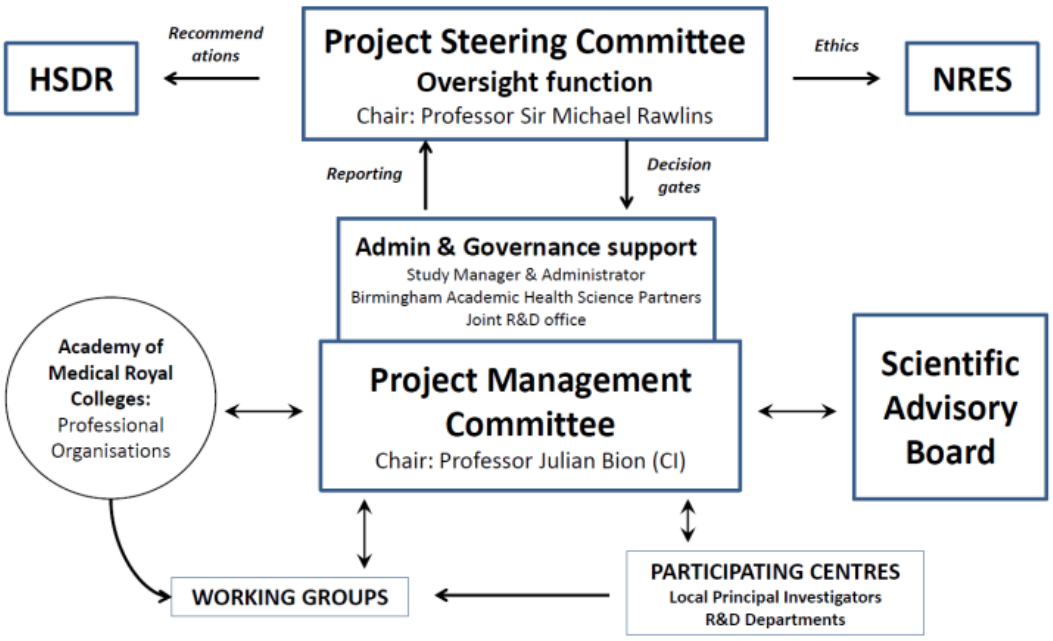
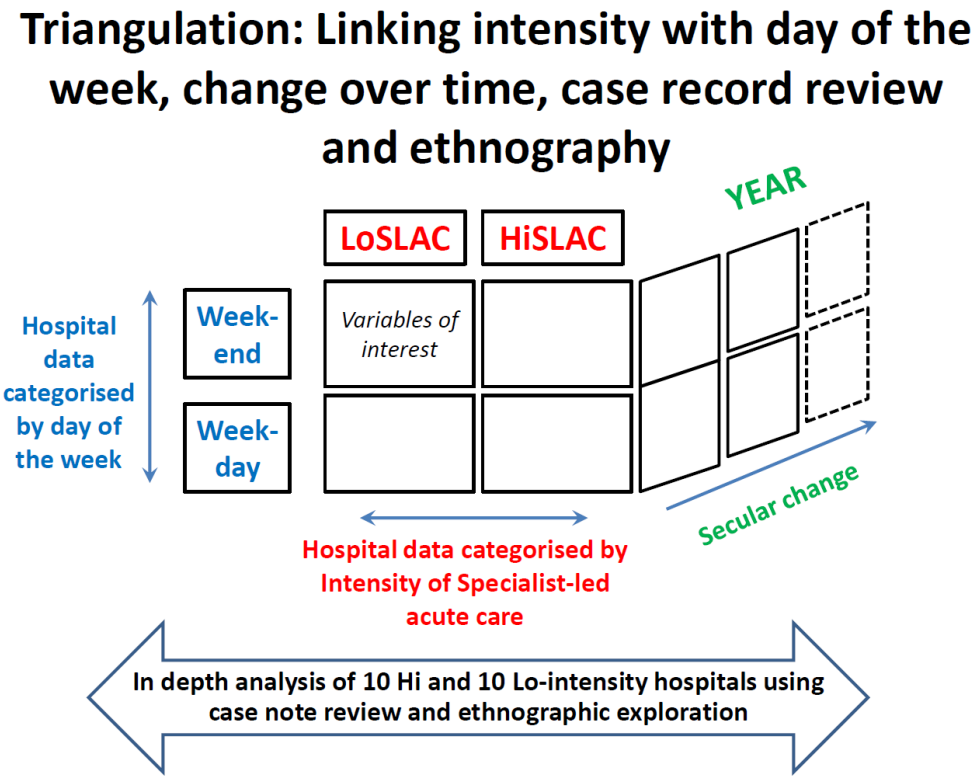


Fig 8: Project Management and Governance





APPENDICES

APPENDIX 1. Summary of publications examining impact of weekend admission on outcomes.

STUDIES REPORTING POSITIVE ASSOCIATION OF WEEKEND ADMISSION WITH HIGHER MORTALITY OR OTHER ADVERSE OUTCOME

	Ref	Where conducted?	Who were the patients?	How many?	Mortality Effect Size?				Any non-mortality effects reported?
	Reference	**Country**	**Study population**	**N (total)**	**Weekend crude mortality rates %**	**Weekday crude mortality rates %**	**Case mix-adjusted mortality (eg: OR, RR)**	**p**	**Morbidity or other outcome**
General unselected hospital admissions	Sharp AL, Choi H, Hayward RA. Don't get sick on the weekend: an evaluation of the weekend effect on mortality for patients visiting US EDs. Am J Emerg Med. 2013 May;31(5):835-7. doi: 10.1016/j.ajem.2013.01.006. Epub 2013 Mar 1.	USA	Adults admitted through the ED to hospital, from 2008 Nationwide Emergency Department Sample	4225973			Unadjusted: 1.073 (1.06-1.08) Adjusted: 1.026 (1.005-1.048)		Effect the same across all top 10 diagnoses.
	Freemantle N, Richardson M, Wood J, Ray D, Khosla S, Shahian D, Roche WR, Stephens I, Keogh B, Pagano D. Weekend hospitalization and additional risk of death: an analysis of inpatient data. J R Soc Med. 2012 Feb;105(2):74-84. Epub 2012 Feb 2.	England	All NHS Hospital Admissions	14217640 of whom 187,337 died	na	na	RR (HR) Sunday versus Wednesday 1.16 (95% CI 1.14 to 1.18) Saturday versus Wednesday 1.11 (95% CI 1.09 to 1.13)	P < .0001	
	Mohammed MA, Sidhu KS, Rudge G, Stevens AJ. Weekend admission to hospital has a higher risk of death in the elective setting than in the emergency setting: a retrospective database study of national health service hospitals in England. BMC Health Serv Res. 2012 Apr 2;12:87.	England	Elective and emergency admissions	1,535,267 elective admissions (0.54% died) 3,105,249 emergency admissions (6.67% died)	Elective: 0.77% Emergency: 7.06%	Elective: 0.53% Emergency: 6.53%	OR Elective: 1.32, (95% CI 1.23-1.41) emergency: 1.09, (95% CI 1.05-1.13)		
	Aylin P, Yunus A, Bottle A, Majeed A, Bell D. Weekend mortality for emergency admissions. A large, multicentre study. Qual Saf Health Care. 2010 Jun;19(3):213-7.	England	All emergency inpatient admissions	4317 866 (of whom 215054 died, = 5%)	5.2%	4.9%	OR 1.1 (95%CI 1.08-1.11)	P<0.001	

	Buckley D, Bulger D. Trends and weekly and seasonal cycles in the rate of errors in the clinical management of hospitalized patients. Chronobiol Int. 2012 Aug;29(7):947-54. Epub 2012 Jun 4.	Australia	63 Healthcare Facilities. Clinical incidents (critical incidents & adverse events)				The incident rate ratio for the weekend versus weekdays was 2.74 (95% CI 2.55 to 2.93)		Adverse events more common at weekends, and during Australian spring (case mix effect?).
	Cram P, Hillis SL, Barnett M, Rosenthal GE. Effects of weekend admission and hospital teaching status on in-hospital mortality. Am J Med. 2004 Aug 1;117(3):151-7.	California	Emergency department admissions to acute care hospitals	641,860 41,702 deaths (6.5%)	6.7%	6.4%	OR, 1.03 (95% CI, 1.01–1.06)	P<0.05	Weekend effect was greater in major teaching hospitals than minor or no teaching hospitals
	Barba R, Losa JE, Velasco M, Guijarro C, Garcı´a de Casasola G, Zapatero A. Mortality among adult patients admitted to the hospital on weekends. European Journal of Internal Medicine 2006;17:322–4	Spain	Emergency department admissions to hospital- mortality in first 48 hours	35,993	2.4%	1.7%	OR 1.40, (95% CI 1.18-1.62)	P<0.001	
	Ricciardi R, Roberts PL, Read TE, Baxter NN, Marcello PW, Schoetz DJ. Mortality rate after nonelective hospital admission. Arch Surg. 2011 May;146(5):545-51. doi: 10.1001/archsurg.2011.106.	USA	5 yr nation-wide sample 20 US community hospitals	29,991,621 emergency admissions; 6,842,030 (22.8%) at w/e	185,856 patients (2.7%)	540,639 (2.3%)	OR 1.1 (1.1-1.11) (Mortality 10.5% higher at w/e		w/e mortality higher for 15 of 26 (57.7%) major diagnostic categories. Higher co-morbidity score for w/e admissions
	Dr Foster Hospital Guide 2001-2011. http://drfosterintelligence.co.uk/wp-content/uploads/2011/11/Hospital_Guide_2011.pdf	UK	Not given	Not given	Circa 8.5%	Circa 7.3%	Not given	n/a	Hospital standardised mortality ratio (HSMR) higher for hospitals with fewer consultants per 100 beds

Studies reporting specific diagnostic categories

nosti c	**Reference**	**Country**	**Study population**	**N (total)**	**Weekend crude mortality rates %**	**Weekday crude mortality rates %**	**Case mix-adjusted mortality (eg: OR, RR)**	**p**	**Morbidity or other outcome**

	Bell CM, Redelmeier DA. Mortality among patients admitted to hospitals on weekends as compared with weekdays. N Engl J Med 2001;345:663-8.	USA Selected diagnostic groups hypothesised to be susceptible (AAA, AE, PE) or non-susceptible (AMI, ICH, Hip #) to the weekend effect.	**Index cases**: Ruptured abdominal aortic aneurysm, acute epiglottitis, & pulmonary embolism. **Controls:** Myocardial infarction; intracerebral haemorrhage; Hip fracture	3,789,917 222,517 died (5.8%)	AAA = 42% AE = 1.7 PE = 13 AMI = 15 ICH = 44 Hip# = 6	AAA=36% AE = 0.3 PE = 11 AMI = 15 ICH = 44 Hip# = 7	OR 1.28 5.2 1.25 1.02 1.01 0.95	P<0.05	
	Deshmukh A, Pant S, Kumar G, Bursac Z, Paydak H, Mehta JL. Comparison of outcomes of weekend versus weekday admissions for atrial fibrillation. Am J Cardiol. 2012 Jul 15;110(2):208-11. Epub 2012 Apr 3.	USA	Admissions with atrial fibrillation	86,497	1.1%	0.9%	OR, 1.23 (95% CI 1.03 to 1.51)	p <0.0001	Cardioversion procedure use was lower at weekends
	Jneid H, Fonarow GC, Cannon CP, Palacios IF, Kilic T, Moukarbel GV, Maree AO, LaBresh KA, Liang L, Newby LK, Fletcher G, Wexler L, Peterson E; Get With the Guidelines Steering Committee and Investigators. Impact of time of presentation on the care and outcomes of acute myocardial infarction. Circulation. 2008 May 13;117(19):2502-9.	USA 379 hospitals coronary disease database 2000-2005	AMI patients	62,814 of whom 33 982 (54.1%) admitted out of hours			OR death 0.99 [0.93-1.06]	ns	Out-of-hours OR 0.93 [0.89 to 0.98] for coronary intervention; Longer door-to-balloon times (median 110 vs 85 mins).
	Al-Lawati JA, Al-Zakwani I, Sulaiman K, Al-Habib K, Al Suwaidi J, Panduranga P, Alsheikh-Ali AA, Almahmeed W, Al Faleh H, Al Saif S, Hersi A, Asaad N, Al-Motarreb A, Mikhailidis DP, Amin H. Weekend versus weekday, morning versus evening admission in relationship to mortality in acute coronary syndrome patients in 6 middle eastern countries: results from gulf race 2 registry. Open Cardiovasc Med J. 2012;6:106-12	6 middle-Eastern countries	AMI patients	4,616			OR= 0.88 [0.68-1.14]	ns	Lower utilisation of angiography at w/e
	Cavallazzi R, Marik PE, Hirani A, Pachinburavan M, Vasu TS, Leiby BE. Association between time of admission to the ICU and mortality: a systematic review and metaanalysis. Chest. 2010 Jul;138(1):68-75. Epub 2010 Apr 23.	Systematic Review of 10 cohort studies comparing Intensive Care admissions at nights or weekends versus weekday daytime.	ICU admissions	6 studies-total 180,600 patients	15.6%	11.1%	Weekend admission OR, 1.08 (95% CI, 1.04-1.13) Nighttime admission no effect: OR= 1.0 [95% CI, 0.87-1.17]	P < .001	

	James MT, Wald R, Bell CM, Tonelli M, Hemmelgarn BR, Waikar SS, Chertow GM. Weekend hospital admission, acute kidney injury, and mortality. J Am Soc Nephrol. 2010 May;21(5):845-51. Epub 2010 Apr 15.	USA	Admissions to acute care with primary diagnosis AKI	214,962 14,686 died (6.8%)	7.3%	6.7%	OR, 1.07, (95% CI 1.02 to 1.12)		Increases in mortality associated with weekend admission for AKI were most pronounced in smaller hospitals
	Worni M, Schudel IM, Ostbye T, Shah A, Khare A, Pietrobon R, Thacker JK, Guller U. Worse Outcomes in Patients Undergoing Urgent Surgery for Left-Sided Diverticulitis Admitted on Weekends vs Weekdays: A Population-Based Study of 31 832 Patients. Arch Surg. 2012 Jul 1;147(7):649-55.	USA	Admissions for acute diverticulitis	31 832					Weekend admission significantly higher postoperative complications (OR, 1.10; P = .005) and nonroutine hospital discharge (OR, 1.33; P < .001) compared with weekday admission
	Kostis WJ, Demissie K, Marcella SW, Shao Y-H, Wilson AC, Moreyra AE. Weekend versus Weekday Admission and Mortality from Myocardial Infarction. N Engl J Med 2007;356:1099–109	USA	Admissions for Acute MI	231164	12.9%	12%	HR (RR) mortality at 30 days 1.048 (95% CI 1.022- 1.076	p<0.001	Les frequent use of invasive cardiac procedures
	Hamilton P, Restrepo E. Weekend Birth and Higher Neonatal Mortality: A Problem of Patient Acuity or Quality of Care? JOGNN 2003;32:724–33	Texas, USA	Births to Teenage mothers	111749, of which 397 neonatal deaths	4.9 neonatal deaths per 1000 births	3.7 per 1000	OR = 1.42 (1.14-1.76),	p = 0.001)	Pronounced racial/social effect: surplus weekend mortality confined to African-Americans and Hispanics, not Caucasians
	Barnett MJ, Kaboli PJ, Sirio CA, Rosenthal GE. Day of the week of intensive care admission and patient outcomes: a multisite regional evaluation. Medical Care, 2002;40:530–9	USA	ICU Admissions	156136			OR 1.09 (95% CI, 1.04-1.15)	p<0.001	Length of ICU stay was 4% longer for Friday and weekends compared with midweek
	Palmer WL, Bottle A, Davie C, Vincent CA, Aylin P. Dying for the Weekend: A Retrospective Cohort Study on the Association Between Day of Hospital Presentation and the Quality and Safety of Stroke Care. Arch Neurol. 2012 Jul 9:1-7. doi: 10.1001/archneurol.2012.1030	England	Admissions with stroke	93 621	11%	8.9%	1.26 [95% CI, 1.16-1.37]		Performance poorer at w/e on 5 of 6 metrics (eg: Weekend same-day brain scans OR 0.83 [95% CI, 0.81-0.86]

	Niewada M, Jezierska-Ostapczuk A, Skowrońska M, Sarzyńska-Długosz I, Członkowska A. Weekend versus weekday admissions in Polish stroke centres -- could admission day affect prognosis in Polish ischaemic stroke patients? Neurol Neurochir Pol. 2012 Jan-Feb;46(1):15-21.	Poland, 72 stroke centres	National Registry 1 yr data 2004-5. Ischaemic stroke admissions	19667, of which 5924 (30.1%) at w/e	15.9%	14.1%	OR = 1.13		W/e admissions more severely ill
	Fang J, Saposnik G, Silver FL, Kapral MK; Investigators of the Registry of the Canadian Stroke Network. Association between weekend hospital presentation and stroke fatality. Neurology. 2010 Nov 2;75(18):1589-96	Canada, 11 stroke centres	Canadian Stroke Registry 2003-8	20,657	8.1%	7%	HR = 1.12 [1.0-1.25].		Admission to stroke unit, neuroimaging, and dysphagia screening same between w/e and w/d
	Aylin P, Alexandrescu R, Jen MH, Mayer EK, Bottle A. Day of week of procedure and 30 day mortality for elective surgery: retrospective analysis of hospital episode statistics. BMJ. 2013 May 28; 346:f2424. doi: 10.1136/bmj.f2424.	England	Elective surgical patients	4,133,346	Crude mortality & OR increase with proximity of day of operation to weekend		OR weekend 1.82	<0.001	
	STUDIES REPORTING NO IMPACT OF WEEKEND ADMISSION ON OUTCOME								
	Reference	**Country**	**Study population**	**N (total)**	**Weekend crude mortality rates %**	**Weekday crude mortality rates %**	**Case mix-adjusted mortality (eg: OR, RR)**	**p**	**Morbidity or other outcome**
	Snelder SM, Nauta ST, Akkerhuis KM, Deckers JW, van Domburg RT. Weekend versus weekday mortality in ST-segment elevation acute myocardial infarction patients between 1985 and 2008. Int J Cardiol. 2013 Sep 30;168(2):1576-1577. doi: 10.1016/j.ijcard.2013.01.053. Epub 2013 Feb 17.	USA	STEMI	6820					3 intervals examined. All ORs included 1.
	Byun SJ, Kim SU, Park JY, Kim BK, Kim do Y, Han KH, Chon CY, Ahn SH. Acute variceal hemorrhage in patients with liver cirrhosis: weekend versus weekday admissions. Yonsei Med J. 2012 Mar;53(2):318-27. doi: 10.3349/ymj.2012.53.2.318.	Korea	Admissions with principal or secondary diagnosis of esophageal variceal bleeding	294	23%	21.8%		p=0.87	
	Kazley AS, Hillman DG, Johnston KC, Simpson KN. Hospital care for patients experiencing weekend vs weekday stroke: a comparison of quality and aggressiveness of care. Arch Neurol. 2010 Jan;67(1):39-44.	USA	Patients admitted with acute ischaemic stroke	78 657 5413 died (6.9%)			OR 1.024 SE 0.032)		
	Myers RP, Kaplan GG, Shaheen AM. The effect of weekend versus weekday admission on outcomes of esophageal variceal hemorrhage. Can J Gastroenterol. 2009 Jul;23(7):495-501.	USA	Admissions for esophageal variceal hemorrhage	36,734 10.9% died	11.3%	10.8%	OR 1.05; (95% CI 0.97 to 1.14)		
	Orman ES, Hayashi PH, Dellon ES, Gerber DA, Barritt AS 4th. Impact of nighttime and weekend liver transplants on graft and patient outcomes. Liver Transpl. 2012 May;18(5):558-65. doi: 10.1002/lt.23395	USA	liver transplant operations	94,768 4% had died at 30 days			HR (RR)0.99 (95% CI 0.93-1.07) at 30 days		

	Worni M, Østbye T, Gandhi M, Rajgor D, Shah J, Shah A, Pietrobon R, Jacobs DO, Guller U. Laparoscopic appendectomy outcomes on the weekend and during the week are no different: a national study of 151,774 patients. World J Surg. 2012 Jul;36(7):1527-33.	USA	Laparoscopic appendisectomy in patients admitted for acute appendicitis	151,774	0.13%	0.09%	OR: 1.37, (95% CI 0.97–1.94)	p = 0.075	
	Schmulewitz L, Proudfoot A, Bell D. The impact of weekends on outcome for emergency patients. Clin Med. 2005 Nov-Dec;5(6):621-5.	Scotland	1 yr admissions for COPD, CVA, PE, CAP, GI bleed, & 'collapse'	3,244 of which 938 (28.9%) at w/e. Overall mortality 10.2%	9.2%	10.6%	OR across diagnostic groups = 0.5 to 1.65	ns	Small sample

APPENDIX 2. Hospitals where models of seven day *consultant present* care have been identified (not comprehensive, last updated 24 12 2012)

Site	Clinical Area	Description	Status	Contact	How identified	Interested in participating in research project?
Royal Wolverhampton Hospitals NHS Trust	Various	7 Day Working Across Medicine - 7 day on-site presence (Daily ward rounds)	Implementing	Jonathan Odum Jonathan.odum@nhs.net	Internet search for seven day working	Yes
Yorks & Humber	TBD	Consideration of Seven Day working	At desk-study stage to assess feasibility and potential pilots	Moira Livingstone Interim Medical Director Yorks and the Humber SHA Blenheim House Dunscombe Street Leeds LS14PL	Contacted Academy seeking to work alongside Academy Seven Day project	Yes
Northumbria	Acute hospital	Project to merge two sites and develop acute hospital with seven day consultant led care	Early days	Birju Rana Birju.rana@nhct.nhs.uk	Delegate at 7 Day Conference, Manchester, 14 Nov 2012.	Yes
Bradford Teaching Hospitals Foundation trust	TBD	Seven day working	Early days	Chris Bradley, divisional clinical director, medicine division, chris.bradley@bthft.nhs.uk; 07506 702412 Maria Neary, divisional general manager, maria.neary@bthft.nhs.uk	Delegate at 7 Day Conference, Manchester, 14 Nov 2012.	Yes
Wigan	Acute	40 bedded MAU. 8 wte acute physicians. February 2013 start 7day/12hr service on the MAU and Ambulatory assessment area.	Implemented	Sanjay Arya, Cardiologist Sanjay.arya@wwl.nhs.uk	Delegate at 7 Day Conference, Manchester, 14 Nov 2012.	Yes

Site	Clinical Area	Description	Status	Contact	How identified	Interested in participating in research project?
South Devon Healthcare NHS Foundation Trust	Various	Working Towards a Seven Day Hospital Service 7 day on-site presence	Implemented 2003	Paula Vasco-Knight, John Lowes, Kerri Jones, Peter Kember, Richard Seymour Paula.vasco-knight@nhs.net John.lowes@nhs.net Kerri.jones@nhs.net Peter.kember@nhs.net Richard.seymour@nhs.net	NHS Improvement Seven Day Case Study Emailed asking for status / assistance	Yes
Oxford Radcliffe Hospitals NHS Trust	Orthopaedics & Trauma	Consultant Led and Delivered Orthopaedic Trauma Service 7 day on-site presence (24 hours)	Implemented 1993	Keith Willett Keith.willett@ndorms.ox.ac.uk John McMaster Clinical Director for Trauma	NHS Improvement Seven Day Case Study	Yes
George Eliot Hospital NHS Trust	Various	Implement '7 day working' to ensure appropriate senior medical cover every day and improved access to diagnostics 7 days/wk	Mortality Report (29 February 2012)	Medical Director, Andy Arnold Andrew.arnold@geh.nhs.uk 02476 865072 Christine O'Brien Christine.obrien@geh.nhs.uk	Internet search Emailed	Yes
East Kent Stroke Network	Telemedicine	Telemedicine Supporting Seven Day Working Across a Range of Clinical Specialities 7 day on-site presence (4 hr weekend day)	Implemented 2008	David Hargroves David.hargroves@nhs.net	Internet search Emailed	Yes
Southampton	AMU	Seven day working – Acute medicine consultants on site 12 hours per day seven days per week	Implemented	Chris Roseveare	Co-Chair of Academy Sub-Group	Possibly

Site	Clinical Area	Description	Status	Contact	How identified	Interested in participating in research project?
Taunton & Somerset	TBD	Seven day working	Implemented	Cliff Mann	Member of Academy sub-group	Possibly
Harrogate	Stroke	Seven Day Stroke Service	In stroke – want to roll out wider - small DGH perspective	Claire Taylor, respiratory / general physician, Claire.taylor@hdft.nhs.uk	Delegate at 7 Day Conference, Manchester, 14 Nov 2012.	Possibly
Blackburn	AMU, short-stay unit and medical wards	Seven day working on AMU, short stay unit and medical words following merger of two hospitals	Implemented	Margaret Glew, clinical lead Acute medicine Margaret.glew@elht.nhs.uk	Delegate at 7 Day Conference, Manchester, 14 Nov 2012.	Possibly
Guernsey	Full hospital	Seven day consultant led service throughout hospital	Implemented for more than 10 years	Ed Freestone efreestone@hssd.gov.gg	Delegate at 7 Day Conference, Manchester, 14 Nov 2012.	Possibly
Royal Berkshire NHS Foundation Trust	Cardiac Care	Seven Day Acute Cardiology Service - 7 day on-site presence (M-F, 08.00 – 17.00, weekend ward rounds, 24/7 cover from home)	Implemented 2009	Carys Jones Research &Development Clinical Implementation Manager. Thames Valley CLRN representative on the NIHR Lead Nurses group Email: Carys.Jones@royalberkshire.nhs.uk	NHS Improvement Seven Day Case Study	Possibly
Heart of England NHS Foundation Trust	General Medicine	Seven Day Ward Rounds for General Medical Admissions - 7 day on-site presence (Daily 'golden hour' ward round)	Implemented (date unknown)	Mark Temple Robert.temple@heartofengland.nhs.uk	NHS Improvement Seven Day Case Study. Member HiSLAC management committee	Yes

Site	Clinical Area	Description	Status	Contact	How identified	Interested in participating in research project?
South Tees	TBD	Seven day working	TBD	Karen Rogstad, Karen.rogstad@sth.nhs.uk	Delegate at 7 Day Conference, Manchester, 14 Nov 2012.	Unknown
Gloucester	Radiology	Seven day consultant working in radiology across two sites	Implemented 2009	Frank Jewell, Frank.Jewell@glos.nhs.uk Medical Director, Sean Elyan, sean.elyan@glos.nhs.uk	Delegate at 7 Day Conference, Manchester, 14 Nov 2012.	Unknown
Doncaster & Bassetlaw	AMU	Seven day working in AMU with mix of acute and general physicians	Implemented	Nicholas Mallaband (acute physician) Nicholas.mallaband@dbh.nhs.uk	Delegate at 7 Day Conference, Manchester, 14 Nov 2012.	Unknown
Barnet and Chase Farm Hospitals	Paediatrics	Co-located consultant led assessment unit and paediatric A&E 7 day on-site presence (12 hours per day)	Business case in 2011 (current status unknown)	Richard Watson Richard.watson@bcf.nhs.uk	Internet search Emailed	Unknown
Stockport NHS Foundation Trust	Weekend Mortality Action Plans	7 day on-site presence (12 hours over weekend for Medicine; daily review of emergency admissions by surgical consultant at weekends	Weekend mortality	Dr James Catania, Medical Director	Internet search Emailed	Unknown
North Bristol NHS Trust – stroke network	Stroke	7 day one-stop TIA service 7 day on-site presence (level unknown)	Implemented (date unknown)	Neil Baldwin Neil.baldwin@nbt.nhs.uk	Internet search	Not asked

Site	Clinical Area	Description	Status	Contact	How identified	Interested in participating in research project?
East Sussex Healthcare NHS Trust & NHS Sussex	Surgery	Consultant led service for patients with general surgical and orthopaedic emergencies 7 day	Pre-consultation Business Case, 02 July 2012	?	Internet search	Not asked
NHS West Kent	A&E / Primary Care	Out of hours service integration 7 day on-site presence (Emergency primary care clinicians in A&E 24 hours per day)	Unknown	?	NHS Improvement Seven Day Case Study	Not asked
The Leeds Teaching Hospitals NHS Trust	Cardiac Care	Regional PPCI treatment by Consultant and specialist staff. 24/7 on-call out of hours	Dates not known	Dr Jim McLenachan / Darren Lee	NHS Improvement Seven Day Case Study	Not asked
Aneurin Bevan Health Board – Wales	Integrated Older Peoples Services	Pan Gwent Frailty Programme: Seven Day Rapid Response and Reablement Service	Implemented 2000	Pradeep Khanna Emma.griffiths3@wales.nhs.uk	NHS Improvement Seven Day Case Study	Not asked
Salisbury NHS Foundation Trust	Radiology	Seven Day Radiology Service 7 day on-site presence (M-F = until 20.00, S/S = 09.30 – 12.30)	Implemented (date unknown)	Katie Johnson Katie.johnson@salisbury.nhs.uk	NHS Improvement Seven Day Case Study	Not asked

Site	Clinical Area	Description	Status	Contact	How identified	Interested in participating in research project?
Northumbria Healthcare NHS Foundation Trust	Integrated System	A Consultant led and Delivered 7 Day Working Model Across a Geographically Challenged Trust 7 day on-site presence (Working day 08.00 – 22.00)	Implemented 2004	David Evans Dave.evans@northumbria-healthcare.nhs.uk	NHS Improvement Seven Day Case Study	Not asked

APPENDIX 2a and 2b: Ethnography Information Sheets for Patients & relatives (2a) and staff (2b).

Separate pdf files