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

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HiSLAC SYNOPSIS

The HiSLAC project is funded by the NIHR-Health Services Delivery Research Programme in response to their commissioned call 12/128 on the organisation and delivery of 24/7 healthcare, *Assessing the effectiveness & cost-effectiveness of different models of organising acute care at nights & weekends*. The project was launched in February 2014 and underwent a major revision in June 2014 to reflect the rapidity of health policy changes in this area.

The rationale for the HiSLAC project is that research in diverse health systems demonstrates 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 working group on seven-day services which has now mandated that all Trusts must meet 10 standards for 7-day services by 2018. 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 this fundamental change in service delivery. We will also assess the health economic impacts of improving specialist cover over weekends. HiSLAC will help to inform national policy development.

Our proposal evaluates High-Intensity Specialist-Led Acute Care (HiSLAC) to improve the care of acutely ill adult 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 changes over time.
- Prospectively evaluate the effect of changing specialist intensity on differences in quality of care between patients admitted at weekends *vs* weekdays through a causal and cost-effectiveness model.
- 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.
- Develop a health economic model with data derived from the project to estimate the cost-effectiveness and budget impact of increasing specialist intensity.

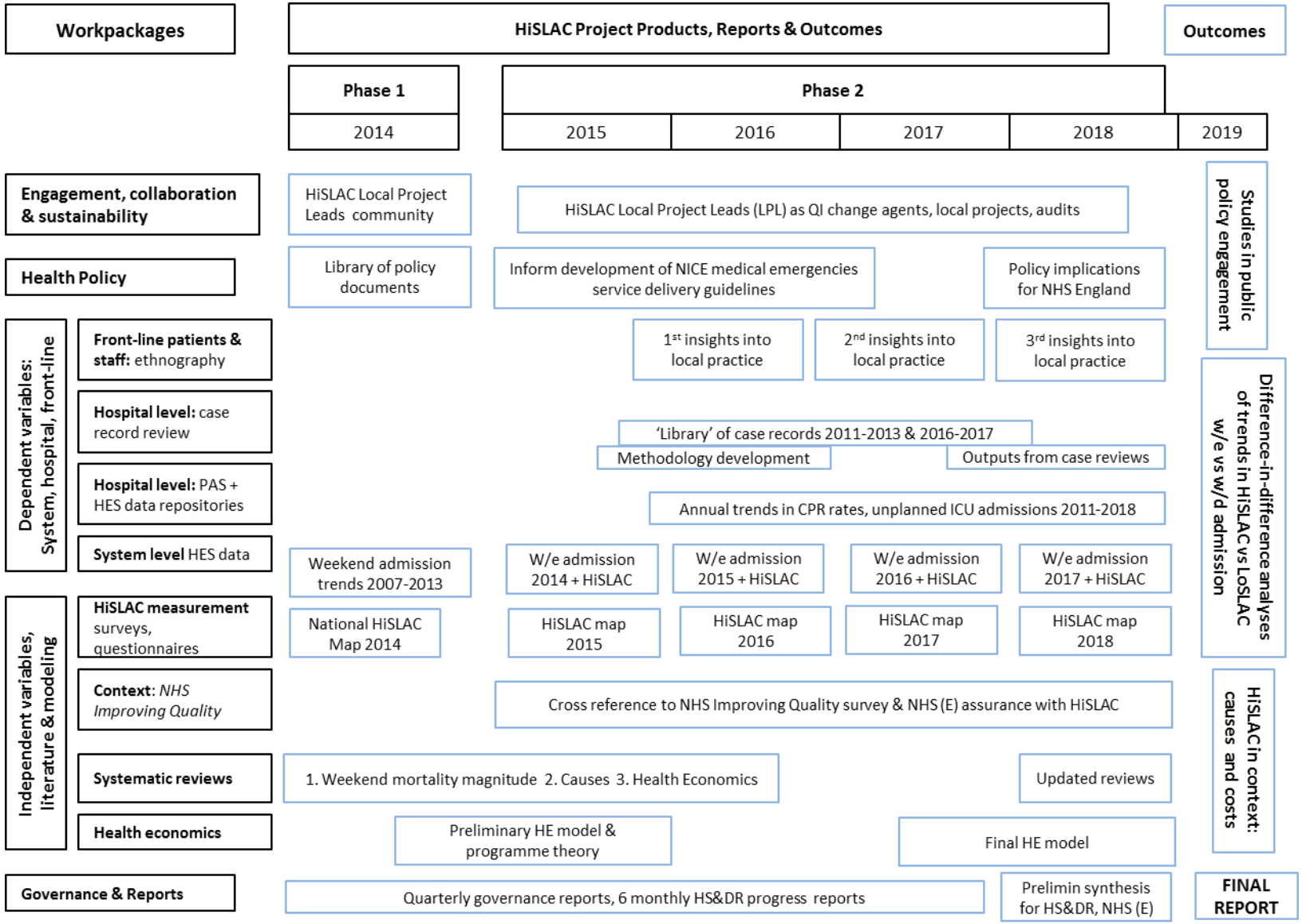
We will do this using a phased approach **(Fig 1)**.

- In Phase 1 we will develop metrics for specialist intensity and measure levels in acute Trusts across England. We will also start development on a programme theory of causal mechanisms behind the weekend-weekday mortality gap to inform our systematic reviews, ethnography framework and health economic model.
- Phase 2 is a prospective natural experiment of HiSLAC on adult emergency non-operative admissions to acute hospitals at weekends. There are two workstreams: an NHS-wide comparison of HiSLAC penetration with NHS performance and outcomes using Hospital Episode Statistics (HES) data; and a detailed quantitative and qualitative study of 10 HiSLAC and 10 low-intensity (LoSLAC) hospitals which combines data from HES & local healthcare databases with case note reviews of quality of care, and on-site ethnographic exploration.

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

Mo	Phase	Clinical Themes	Cross-cutting Themes	Deliverables: Outputs, Analyses
3 6 9 12	**Phase 1: *Developmental***	**HiSLAC Measurement:** • Workshop on measurement; pilot, refine **Survey of all English NHS acute Trusts:** • HiSLAC penetration; models, current & past 3 yr **HES/ONS data acquisition** • Set up, preparation, 'dry run' **Systematic Review of weekend mortality** • Elicit focus group opinion to inform reviews into mechanisms and costs of weekend effect	**Health economics** • Start development of causal model **Ethnography** • Researcher training in clinical pathways • Institutional approval for ethnography	• National collaboration – local project leads with Trust senior management buy-in • HiSLAC measurement methods (HiSLAC, LoSLAC) • HiSLAC map across English NHS • HES database, search terms & fields • Online collaborative workspace • Focus group opinion elicitation to frame systematic reviews.
15 18 21 24 27 30 33 36 39 42 45 48 51 54 57	**Phase 2: *Natural experiment prospective study***	**Workstream A: System-wide analysis of unplanned non-op admissions to all English NHS acute Trusts.** • **HES/ONS data:** 7-yr retrospective and 4-yr prospective analysis (2007-2018) • Comparison with other national datasets (UK, USA, Aus) **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** (e.g.: PAS; ICNARC-CMP) to supplement national (HES/ONS) data • **Case record reviews of 50 weekend vs 50 weekday admissions to each Trust:** 2 epochs, 4000 case records i. Implicit review of quality of care ii. Evaluate explicit (criterion-referenced) analysis of best practice adherence **Link with concurrent national quality initiatives:** • NICE-Service Delivery Standards for acutely ill patients • NHS Improving Quality projects	**Health Economics** • Develop model structure & QA • Populate with Bayesian priors • Model verification & validation • Repopulate model with empirical data — Effectiveness parameters — Cost-drivers • Feedback to subject experts ('synthetic posterior') **Ethnography** (annual visits years 2-4) • Observe delivery of weekend care • Identify contextual & social factors • Interview staff, patients & relatives • Explore diagnostic pathway precision **Track 7-day services implementation**: • Annual surveys via Local Project Leads • Triangulation with NHS-IQ: NHS(E) standards for 7-day services • Compile library of public and policy documents on 7-day services	**Workstream A:** NHS-level case mix-adjusted mortality, length of stay, 7-day readmission rate by: • HiSLAC status • Weekend vs weekday • Change over time — *Difference-in-difference* **Workstream B:** As workstream A, plus… • Local (PAS) data analyses: CPR rates, unplanned ICU admissions; absenteeism; satisfaction rates • Quality of weekend vs weekday care – two epoch comparison exploring change over time **Ethnography** • Characterise fidelity of HiSLAC over time • Determine mechanisms, barriers, facilitators **Health Economics** • Final model estimates of cost-effectiveness and budget impact
60		**Analytical phase: Triangulation** of systems level and local level quantitative metrics with ethnographic findings and health economics.		

Fig 2: HiSLAC project work packages, timelines, products, reports and outcomes



PROJECT

Background to this application

The aim of the HiSLAC project is to determine whether increasing the intensity of specialist-led care at weekends improves outcomes for patients admitted to hospital as emergencies at weekends.

This application responds to the NIHR-HSDR commissioned call 12/128 for research proposals examining the organisation and delivery of 24/7 healthcare. We have focused on the second of the four 'evidence gaps' identified in the call, *the assessment of the effectiveness and cost-effectiveness of different models of organising acute care at nights and weekends*. We will also 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 with a Certificate of Completion of Training (CCT) or equivalent, 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, as patients cross speciality boundaries and transit between locations. For our Phase 2 in-depth study we have chosen to study specifically medical, that is non-operative, adult patients, as this group has no generic best practice pathway, contains many frail elderly patients, and challenges health systems to provide reliable, patient-centred, integrated care in both community and hospital settings, particularly at a time of major reorganisation and financial constraints.

Professional standards and best practice statements focussed on the role of consultants and the reconfiguration of acute services have been endorsed by NHS England which has set out 10 standards for 7-day working in the health service (Table 1). An important driver for 7-day services has been the mortality difference between weekend versus weekday admission to hospital. 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. The HiSLAC project will test this hypothesis by:-

1) Describing current provision (which we have reason to believe is very variable), and mapping changes in provision over time.
2) Using multiple methods to compare the quality of care in hospitals with high levels of 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.

The HiSLAC 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**), together with parallel ethnographic and health economics studies:

PHASE 1 overview (developmental).

The aim of Phase 1 is to establish the feasibility of, and create the tools for, Phase 2. The work includes creating a collaborative community of Trusts and local project leads, undertaking or updating systematic reviews, developing metrics for measuring HiSLAC, undertaking surveys of HiSLAC, and begin development of a programme theory of mechanisms behind the weekend mortality gap.

Collaborative community: We will invite Trust Chief Executives and Medical Directors in England to nominate a local project lead to work with the project team on survey work. This group also has the potential to function as a quality improvement network.

Systematic review: of the weekend-weekday mortality difference to characterise possible causes, confirm effect size, evaluate the impact of case mix, and possible modifiers.

HiSLAC measurement and mapping: We will use a consensus workshop to develop the survey methodology to determine provision of specialist activity over weekends in acute admitting hospitals in England. The methods will include the following components:

- A point prevalence survey of all specialists in all acute admitting hospitals in England: to determine the number of specialists physically present in the hospital and providing care for acute admissions on a specified Sunday and the following Wednesday. No personal data collected at a local level will be transmitted to the project team.

- Local project leads will be asked to direct a questionnaire to clinical service leads and managers to elicit more detailed provision on specialist input. The questionnaire may be supplemented by recorded telephone interviews with a member of the project team to clarify any terms and to capture perceptions of the extent to which 7-day working standards are being achieved.

HiSLAC Map: Through HiSLAC measurement we will map current specialist provision in acute Trusts throughout England. We will also identify high and low provision hospitals (at each end of the distribution) for Phase 2.

Ethnography: Contextual factors profoundly influence the impact of service delivery interventions. We will use ethnographic methods to study local context. The ethnographers 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 overview (prospective natural experimental study).

The aim of Phase 2 is to determine whether increasing the intensity of specialists at weekends closes the weekend-weekday admission mortality gap. We will do this by comparing differences in specialist intensity with differences in weekend-weekday admission mortality, and examining the difference in those differences over time as HiSLAC is implemented.

Phase 2 consists of two workstreams:

Workstream A: NHS-System-level analyses. We will study the weekend-weekday mortality difference retrospectively 7 years (2007-2013) to quantify secular trends, and track changes in staffing intensity prospectively from 2014 to 2018 to observe associations between mortality and staffing differences over these five years. We will correlate the provision ('dose') of specialist provision at weekends with dependent variables collected routinely from hospitals (e.g.: 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. Data will be cross-referenced with NHS Improving Quality's survey of all Trusts in England to determine their adoption of NHS England's 10 standards.

Workstream B: Prospective 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 (rates of 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. These outcomes will be tracked over time from 2014 to 2018.
ii. **Two-epoch 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. Case records will be obtained for two epochs, 2011-2013 and 2016-2017, to capture pre-intervention and post-intervention periods of specialist staffing. Statistical calculations show that the review of 100 case notes in each epoch (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.

iii. **Ethnography**: The above statistical studies will be complemented by annual 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: 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. A preliminary 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 implementing high-intensity care at local and national levels. The work will include developing a programme theory of the mechanisms by which specialists might promote better patient outcomes at weekends; these causal mechanisms will be used in the health economics model, in the methodology for case record review, and in training the ethnographers. The preliminary model will be updated as information accrues from HES and OPCS national datasets and from the case note review.

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. Implementation of this prospective study will enable us to monitor and evaluate in real time the effect of increased specialist-led care at weekends. 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 weekday-weekend difference in low than in high provision hospitals.
4) Improvement in 2) and 3) above as we track roll out of increased specialist intensity.
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

Please note that this literature synthesis will be updated during the project.

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 reduced 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.
- We are testing this hypothesis by exploring associations between weekend admission mortality and changes in specialist intensity over five years.

Literature Search Strategy

An initial search was undertaken 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**. We included studies which attempted to determine explanatory mechanisms, provided context-sensitive interpretations of models of 24/7 care, and those which specifically and prospectively testing 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). During the project we will build on and revise this initial search, and undertake a formal systematic review of the literature (see page 25).

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 4**), 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 weekend 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]. 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, supported by detailed observation of 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."* Triangulating qualitative results with quantitative observations has been shown to yield important insights [Benning et al 2011].

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 4** 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 now

Four recent national policy initiatives addressed 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. Royal College of Physicians launched the *Future Hospital Commission* [RCP London 2012 (3)] to produce recommendations for the reconfiguration of hospital services particularly those focussed on acute care, and reported in 2013 [RCP 2013]. 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)] recommends that all hospitalised patients should receive a minimum of a once-daily specialist review unless the care pathway specifies that this is not necessary. Following this work, NHS England published 10 standards for 7-day services (Table 1). These standards emphasise the importance of specialist-led care of patients every day of the week. NHS England now requires Trusts to introduce seven day working 'at scale and pace' and to provide draft plans assuring commissioners that they will be able to comply with all the clinical standards by 2016/17. The standards are 'backed by incentives, rewards and sanctions'.

As part of this process the government has announced the creation of the Better Care Fund, which will redirect £3.8Bn of existing NHS funding into a common pool for improving the integration of

patient care between secondary and primary (community) care as well as implementing seven day services. Costs of implementing seven day services have been evaluated by the Healthcare Financial Management Association (HFMA) in a report commissioned by NHS Services Seven Days a Week Forum. The report was based on an analysis of data from eight Foundation Trusts; two Trusts were in London and had already substantially introduced seven day working including enhanced consultant and diagnostic services. The HFMA estimated that (excluding London) the costs of implementing seven day services were typically 1.5% to 2% of total income, equivalent to a 5% to 6% increase in the cost of emergency admissions. The main cost driver was recruitment of additional consultants, though costs could be reduced by sharing emergency provision across Trusts, and by use of non-consultant-based models of service delivery. The HFMA concluded that "*A rapid expansion of full seven day services across the whole NHS would be expensive and probably impractical given the number of additional consultants required. Some degree of seven day services, negotiated locally, would be more clearly cost-effective in the short term*". However, "*If the clinical case for seven day services is strong, internal NHS obstacles should not be allowed to prevent it*" [Knowles (undated)].

Given the rapidity of change, the opportunity to study systems in flux, the uncertainties surrounding the cost-effectiveness of seven-day working in relation to local context, and the importance of informing policy with evidence [Walshe 2010], the original study design was modified to undertake a substantially prospective study tracking changes in specialist intensity and patient mortality as Trusts adopt NHS England's 10 standards for seven day services.

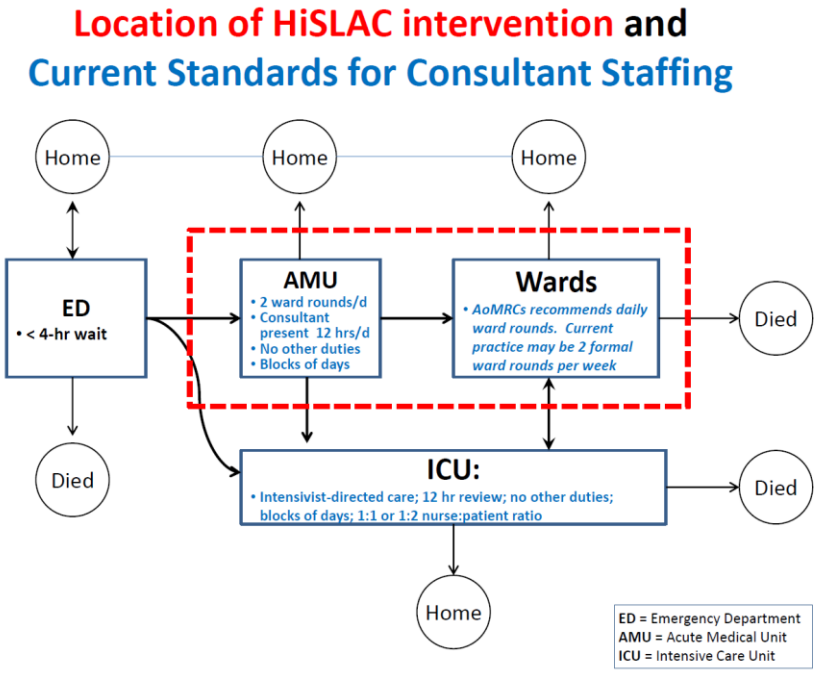
The evidence we have presented indicates that closing the weekend daytime gap and enhancing the weekday continuum of specialist-led care may be a cost-effective use of limited NHS resources.

NHS Services, Seven Days a Week: Clinical Standards **NHS England Board Paper NHS121315** http://www.england.nhs.uk/wp-content/uploads/2013/12/brd-dec-13.pdf
Standard 1: Patients, and where appropriate families and carers, must be actively involved in shared decision making and supported by clear information from health and social care professionals to make fully informed choices about investigations, treatment and on-going care that reflect what is important to them. This should happen consistently, seven days a week.
Standard 2: All emergency admissions must be seen and have a thorough clinical assessment by a suitable consultant as soon as possible but at the latest within 14 hours of arrival at hospital.
Standard 3: All emergency inpatients must be assessed for complex or on-going needs within 14 hours by a multi-professional team, overseen by a competent decision-maker, unless deemed unnecessary by the responsible consultant. An integrated management plan with estimated discharge date and physiological and functional criteria for discharge must be in place along with completed medicines reconciliation within 24 hours.
Standard 4: Handovers must be led by a competent senior decision maker and take place at a designated time and place, with multi-professional participation from the relevant in-coming and out-going shifts. Handover processes, including communication and documentation, must be reflected in hospital policy and standardised across seven days of the week.
Standard 5: Hospital inpatients must have scheduled seven-day access to diagnostic services such as x-ray, ultrasound, computerised tomography (CT), magnetic resonance imaging (MRI), echocardiography, endoscopy, bronchoscopy and pathology. Consultant-directed diagnostic tests and completed reporting will be available seven days a week: • Within 1 hour for critical patients • Within 12 hours for urgent patients • Within 24 hours for non-urgent patients
Standard 6: Hospital inpatients must have timely 24 hour access, seven days a week, to consultant-directed interventions that meet the relevant specialty guidelines, either on-site or through formally agreed networked arrangements with clear protocols, such as: • Critical care • Interventional radiology • Interventional endoscopy • Emergency general surgery
Standard 7: Where a mental health need is identified following an acute admission the patient must be assessed by psychiatric liaison within the appropriate timescales 24 hours a day, seven days a week: • Within 1 hour for emergency care needs • Within 14 hours for urgent care needs
Standard 8: All patients on the AMU, SAU, ICU and other high dependency areas must be seen and reviewed by a consultant twice daily, including all acutely ill patients directly transferred, or others who deteriorate. To maximise continuity of care consultants should be working multiple day blocks. Once transferred from the acute area of the hospital to a general ward patients should be reviewed during a consultant-delivered ward round at least once every 24 hours, seven days a week, unless it has been determined that this would not affect the patient's care pathway.
Standard 9: Support services, both in the hospital and in primary, community and mental health settings must be available seven days a week to ensure that the next steps in the patient's care pathway, as determined by the daily consultant-led review, can be taken.
Standard 10: All those involved in the delivery of acute care must participate in the review of patient outcomes to drive care quality improvement. The duties, working hours and supervision of trainees in all healthcare professions must be consistent with the delivery of high-quality, safe patient care, seven days a week.

Table 1 - NHS Services, Seven Days a Week: Clinical Standards (edited).

Characteristics and location of the intervention

Fig 3: 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 a CCT or equivalent.

There are three recently-published UK standards for HiSLAC:

- The Society of Acute Medicine and the RCP recommend (June 24 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 [WMQRS-SAM, 2012].
- 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 [AoMRCs 2012a]. Two additional standards focus on support services in hospital and community.
- NHS England has published 10 standards for 7 day services which include timely consultant review.

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

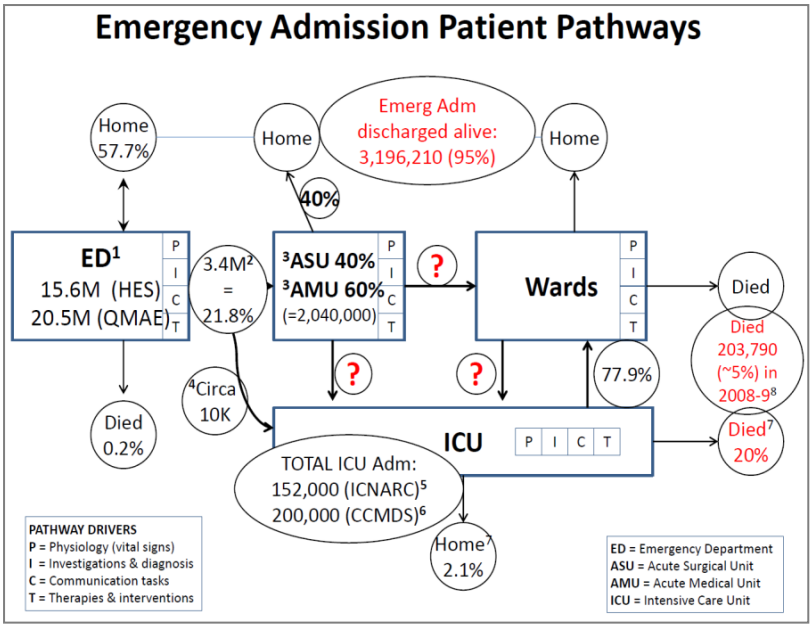
therapeutic services, and the availability of community services at the time of patient discharge may all affect the effectiveness of enhanced specialist provision.

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 2, 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 will observe how these factors affect the specialists' work.

The target population: Patient level

Workstream A (NHS–Systems level analysis) will include all unplanned admissions. Workstream B (mixed-methods comparison of 20 hospitals) will focus on 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 4**).

Fig 4: Emergency Admission Patient Pathways



Source References for Fig 4:

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:

The location of the intervention will be the in-hospital acute care pathway from the point of admission until discharge, including acute medical units (AMUs) and ordinary wards caring for patients undergoing emergency admission to hospital (Fig 3). Emergency Departments and intensive care units (ICUs) are incorporated in Workstream A but 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.

For the point prevalence survey we will request information from all hospital specialists regardless of discipline, in order to obtain a composite view of specialist intensity across the hospital. The directorate-level questionnaire will focus solely on specialists in the medical (non-operative) pathway.

Trusts will be excluded from the survey and subsequent analyses if they are not non-selective acute admitting centres (no emergency department). We will not study paediatric or maternity hospitals as patient volumes are likely to be too low to detect a weekend signal.

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. 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

HiSLAC is a two-phase project, the first developmental, and the second a prospective natural experiment. Both phases contain clinical and cross-cutting themes (**Fig 1**).

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 5)**.

Project progress will be monitored by the independent Oversight and Governance (Steering) Committee chaired by Professor Sir Michael Rawlins. The O&GC 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].

PHASE 1 (Developmental). 12 months.

In Phase 1 we will:

1. Plan and start two interlinked literature reviews exploring the magnitude, mechanisms of harm, and costs of the effect of weekend versus weekday admission on patient outcomes.
2. Develop, pilot and refine methods to measure the intensity of specialist-led acute care and characterise its variations from high-intensity (HiSLAC) to low-intensity (LoSLAC).
3. Undertake a national mapping exercise to measure current levels of specialist-led acute care across all acute hospitals in England.
4. Develop an algorithm to acquire HES/ONS data for acute (unplanned) admissions to NHS England acute Trusts; set up database.
5. Develop a 'Programme Theory' (influence diagram) as a causal model of the pathways through which HiSLAC may achieve (or fail to achieve) its objectives.
6. Prepare the ethnographers through experiential learning in the acute care environment.

1. Systematic Review

A systematic search of the literature will be undertaken. This will be informed by a preliminary model of the mediators and moderators of the weekend effect to identify relevant quantitative and qualitative evidence. First, high quality quantitative evidence will be synthesised to confirm the magnitude of the impact of weekend admission via a conventional systematic review and to identify possible moderators and mediators. Secondly, we will undertake an additional review using Framework synthesis methodology to explore the mechanisms of the weekend effect. This work will add to the literature already represented in this protocol.

The two literature reviews are complementary to each other. The reviews will initially be undertaken using one combined search strategy. The scope of the search will be informed by focus groups undertaken with clinicians and PPI representatives. Output will consist of two separate reviews with linked publications.

Review 1: The conventional systematic review will examine the magnitude of the weekend effect and has three main aims:

> (1) Do patients admitted to hospital during weekends experience worse outcomes compared to similar patients admitted during weekdays?
>
> (2) If such weekend effects exist, what is the magnitude of the effect and does it vary according to the type of patients, settings, outcomes and/or other factors?
>
> (3) Have any structure or process measures been shown to differ between weekends and weekdays and to be associated with weekend effects on health outcomes?

Review 2: The aim of the second review is to synthesise evidence on the mechanisms and contextual modifiers of the weekend admission effect via framework synthesis methodology. The review will explore the factors that are likely to impact on the weekend effect, considering structural factors (e.g. staffing levels; the intensity of specialist input) and processes (e.g. waiting time for procedures) and how these factors can contribute to negative outcomes for patients, as well as exploring contextual modifiers.

This review and synthesis will be framed in terms of a broad research question:

> *Question: What are the likely mechanisms through which differences in structure and process of care or in case mix (patient factors) between weekdays and weekends result in the increased mortality associated with weekend admission to hospital?*

We will generate, and iteratively revise, more focused research questions over the course of identifying and synthesising the literature. Bibliographic databases including MEDLINE, EMBASE, HMIC, AMED, Health Business Elite, CINAHL and the Cochrane Library will be searched from year 2000 onwards with no limit on language. Indexed terms will be informed by the focus groups. In addition, a search of the internet will be conducted via Google, and potentially relevant studies will be sought from subject experts via the Academy of Medical Royal Colleges. Reference lists of included studies will be checked to locate further studies.

Clinical reviewers include four registrars in acute and intensive care medicine, four academic researchers and one professor. Data extraction will be carried out independently by two reviewers and then compared. Discrepancies will be resolved by discussion between reviewers or be referred to the review team to reach a consensus.

2. Develop a tool to measure specialist intensity

A stakeholders' workshop was convened on February 11th 2014 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 were accessed via partner organisations.

Participants concluded that to acquire national information on specialist involvement in emergency care required a national collaboration of local project leads with the support of Trust Chief Executives and Medical Directors. The project leads would then be asked to support two information-gathering exercises. The first would be a national point-prevalence survey of direct involvement of specialists in the care of emergency admissions, focussed on a Sunday and a Wednesday. The second was a questionnaire inviting information from each Trust on contractual recognition for specialist emergency duties.

Definition of Specialist Led Acute Care:

We define Specialist Led Acute Care (SLAC) as the physical presence of the specialist in the clinical environment to direct the care of patients admitted as emergencies (unscheduled admissions). High-intensity (HiSLAC) will incorporate a range of formats, amongst which is a daily review 7 days a week by the specialist of each patient. Low-intensity (LoSLAC) would include the absence of routine daily specialist review at weekends, specialist review only when requested by resident junior doctor, or remote review (telephone-based).

3. Map current HiSLAC penetration

An invitation to participate in the project will be sent to the Chief Executive and the Medical Director of each acute NHS Trust in England, with the request that they appoint a local project lead (generally a senior physician) to join the project and assist with local data collection.

Current HiSLAC penetration will be mapped through the point prevalence survey and the directorate level questionnaire. Provided that these survey techniques prove feasible with an adequate response rate, we will repeat the survey annually. Where necessary the questionnaire will be supplemented by telephone enquiry.

i) The web-based point prevalence survey (**Appendix 2**) will be conducted covering a specified Sunday and the following Wednesday across all participating hospitals. Following piloting, project leads will be asked to send a standardised email to all specialists in the hospital explaining the background to the project and inviting them to complete the survey, relating to whether or not on that day they were present in the hospital and providing direct patient care to patients who had been admitted during that in-patient episode as an emergency. Respondents will be asked to identify the locus of their work (ED, AMU, acute wards, speciality wards, ICU, operating theatres etc), and their main speciality. Local project leads will be asked to record the number of specialists who were contacted (the denominator) in order to determine the response rate for each Trust.

ii) An electronic Directorate-level questionnaire (**Appendix 3**) will be sent to all local project leads asking them to provide aggregated contractual and staffing information from four acute medical care services (emergency medicine, acute medicine, general medicine and specialities, and intensive care medicine). Where necessary this will be supplemented by telephone enquiry to clarify what is likely to be complex information about specialist input. The telephone calls will be recorded digitally once verbal consent has been obtained by respondents. The digital recordings will provide both an additional level of security of data retention, and provide an important opportunity for verification of the data extraction process by allowing comparison of a sample of conversations between the primary data transcribers and independent observers. An external researcher (who is not part of the core team) will review a random sample of conversations to determine the quality and reliability of the data (to reduce researcher bias). From these two surveys we will develop measures of intensity of specialist-led acute care, and from the distribution of these measures we will identify 10 high intensity 'HiSLAC' and 10 low-intensity 'LoSLAC' hospitals for Phase 2.

We will distinguish high intensity from low-intensity hospitals using the following measures:

Measures of Specialist Intensity		
Source and type of data	**Point Prevalence Survey**	**Directorate-level questionnaire**
Quantitative	Ratio of: • Number of specialists delivering direct acute care on Sunday vs Wednesday • Number of specialists per 10 beds Sunday vs Wednesday • Number of specialists per 10 admissions Sunday vs Wednesday • Number of hours of specialist time per 10 admissions Sunday vs Wednesday	Ratio of: • Number of hours of specialist time per 10 admissions Sunday vs Wednesday

Qualitative	• Spread of specialities • Spread of locations	• Specialist working patterns: • Single day versus blocks of days • Daily review of patients • Consultant vacancies

We will undertake a correlation analysis between the quantitative measures, including the relationship between differences in specialist intensity with differences in weekend-weekday mortality. We will stratify Trusts from the intensity distributions, with the aim of selecting 10 HiSLAC and 10 LoSLAC Trusts. We will use the qualitative measures as further distinguishing characteristics to differentiate Trusts which have similar profiles on the quantitative measures.

Following review of these two approaches to collecting intensity data, we will select one method for annual measurement of specialist intensity to determine changes over time.

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:

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 timelier 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. 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, and possible 'mechanisms of action' through the development of the programme theory and influence diagram. 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 (A Prospective Natural Experiment) (48 months)

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

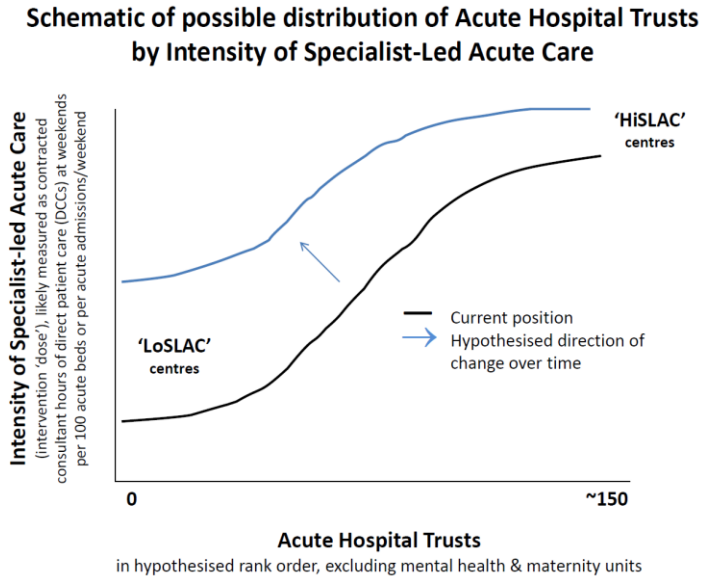
Workstream A: NHS System-level analysis of emergency (unplanned) admissions to all English NHS acute hospitals.

We will explore associations between intensity of speciality provision obtained from the specialist intensity surveys and outcomes data from HES/ONS for unplanned admissions at weekends and weekdays. This prospective analysis will take the form of a natural experiment made possible by the roll-out of increased intensity of specialist-led care as NHS England's standards are implemented between 2014 and 2017-18. We will therefore track changes in the weekend-weekday mortality gap in relation to changes in HiSLAC at weekends across all Trusts in England. It is reasonable to assume that roll-out of higher-intensity specialist input at weekends will not be simultaneous, and hence that the study can exploit 'natural' differences in uptake over time. We will also analyse the weekend-weekday mortality gap retrospectively to 2007 to determine secular trends. We will correlate the 'dose' of specialist provision at weekends with dependent outcome variables collected routinely from hospitals (e.g.: standardised mortality rates, length of stay), and with differences in outcome between admission at weekends and weekdays. Changes in weekend admission 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: hospital-level 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: To ensure representation of hospital types, Trusts will be grouped into quintiles based on size (number of beds). Within each group, Trusts will be stratified by specialist intensity distribution with the aim of selecting the highest and lowest intensity Trusts in each group. Wherever possible we will ensure that single and multi-sites trusts are matched and that both urban and rural centres are represented.

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



We will use two investigative tools:

- **Hospital-level metrics**:

Local data will be extracted from patient administration systems (PAS) annually 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. 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 during two epochs**:

We will develop a training package to harmonise the way different reviewers evaluate the case records. We will focus primarily on implicit, global assessments of quality of care including timeliness and accuracy of diagnosis. We will also examine the options for criterion-referenced review based on adherence to disease-specific best practice clinical standards published by professional organisations and by the National Institute for Health and Clinical Excellence. Disease-specific indicators, if used, will be based on the ten most frequent primary admission diagnoses.

Case record reviews will be conducted for two epochs: 2011-2013 and 2016-2017, to capture pre-intervention and post-intervention periods of specialist staffing. For each epoch, 100 randomly

sampled case records will be retrieved from each of 20 hospitals, 10 with high and 10 with low-intensity specialist led care (2000 case records for each epoch, 4000 case records in total). Half the records from each centre will be weekend admissions, half weekday. Selection of cases and controls will be based solely on HiSLAC status. Case records will be sampled with up to 10 of the 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. Case records will be masked, photocopied, anonymised & digitised before being presented to the reviewers.

At least 10 reviewers will contribute to each epoch to improve 'calibration' i.e.; to reduce the effect of any outlier ('hawk' and 'dove') reviewers. Each set of case records will be reviewed independently by two expert 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). 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. This follows 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]. The expert stakeholders used to develop the programme theory (causal model) may also provide insights into differences between clinical groups in their interpretations of care quality. 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.

Case records will be shuffled (presented in random order) and assessors will be blinded to level of intensity of specialist care and time epoch to diminish bias from reviewer variation, learning, unblinding or fatigue [Benning 2012]. Each case record will be assessed independently by two reviewers, using two approaches: an implicit global assessment of quality of care, and explicit (criterion-referenced) analysis of best practice adherence. 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 up to 10 of the 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 epoch 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, and a further difference between epochs. 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%.

Ethnographic evaluations: front-line-level analysis

Ethnographic work will be conducted annually (2015-18) 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 three visits to each site during 2015-2018. Ethnographers will record the views of staff about how specialist input has changed, and whether the other 7-day working standards have been implemented, by visiting each of the 20 hospitals each year over a three-year period. They will also conduct interim telephone interviews with around 2 key informants at each hospital, at the mid-point between annual visits (around six months after each visit), to gain insight into progress and challenges during the periods between observation visits. 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 field notes from observations and informal chats with hospital staff, patients and relatives, 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. A small sample of patients who are in hospital over the weekend of the observational visit (or their relatives if appropriate) in participating hospitals, will be approached with an invitation to participate in an interview. Interviews will be conducted by telephone within one month of the patient's stay in hospital, if possible. 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. 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 and from focus groups. 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.

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

We will 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. A preliminary model will be informed by prior estimates of key parameters elicited from experts and by data from the literature. As the study progresses, the model will be updated with information from the HES and OPCS national datasets and from the case note review.

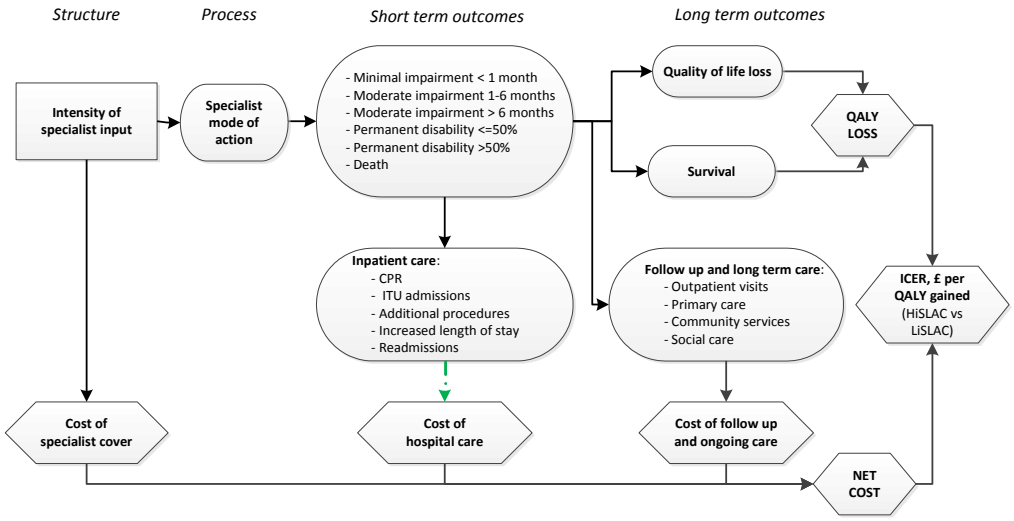
Conceptualisation of model structure

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 Oversight & Governance Committee) following a process of consultation with subject experts at the stakeholders' workshop.

First we will develop a programme theory in the form of an influence diagram (a causal model) to show how HiSLAC may – or may not – achieve its desired objectives, and what those objectives might be. We will do this through expert groups involving different stakeholders – specialists, trainee doctors, nurses and our patient and public representatives. Second, we will use this to construct a diagram 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.

Fig Error! Reference source not found.**6** 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).

Fig 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].

Consultation with stakeholders will allow us to test and strengthen the influence diagram. For example, deeper exploration of the methods by means of which higher-intensity specialist input may reduce errors, and of the type of errors most and least sensitive to specialist input, will be explored by experts who are aware of the relevant literature. This theory development will be made available to the ethnographers because it may inform them 'where to look' during their observations of weekend practice.

Preliminary parameter estimates

When the structure of the model has been finalised, it will be implemented and populated with prior parameter estimates obtained from experts who will make their judgments in the light of the world literature which will be assembled and presented to them by the project team. This will provide preliminary results, which will then be updated when data becomes available throughout 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 in a hospital context, but not domain experts in the particular subject of consultant weekend working as recommended by Khalil [Khalil 2010].

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, in the preliminary phase, 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 Oversight & Governance Committee who will advise the funder and research team as appropriate.

Repopulating the model with empirical data

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.

Throughout Phase 2 the preliminary model will be repopulated with empirical data from Workstreams A and B. The data inputs for the model are summarised in Table 2. 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 2. 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	Length of stay	+	+
	Unplanned ICU admissions	+	+

contingent on effectiveness	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 [Lilford 2014]. 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. 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 Oversight & Governance 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.

OUTCOMES, DELIVERABLES AND DISSEMINATION

Outcomes and Deliverables

Given the project duration of five years, we have considered how to make available to Trusts the interim findings from the project to assist their plans for developing seven-day services, and in particular the move towards higher intensity specialist led care at weekends. In Fig 2 we have shown the inter-relationship between the work packages, phases, interim products, and final outcomes. Interim products include literature (systematic reviews and library of policy documents), historical trends in weekend admission outcomes, a national map of HiSLAC penetration, a preliminary health economics model and programme theory, preliminary insights from the ethnographic observations, and contributions to the NICE service delivery best practice guidance on acute Medical Emergencies.

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.

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 its evolution from 2014-18.

- **An Influence Diagram** to inform a 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 prospectively 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].
- Across the HiSLAC collaborative of acute Trusts we will provide year-on-year data of HiSLAC status during implementation of 7-day services.

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. Across the two epochs we will also look for a further difference over time as low provision hospitals close the gap with the implementation of 7-day services in compliance with NHS England's policy initiative. 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.

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.

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.

Systematic Reviews: Two inter-linked reviews of the weekend-weekday mortality difference to characterise possible causes, confirm effect size, evaluate the impact of case mix, and possible modifiers.

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

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, NHS Improving Quality, and groups focussed on promoting professional leadership (Faculty of Medical Leadership & Management). In addition, the National Institute for Health and Clinical Excellence has commissioned the National Clinical Guideline Centre to produce best practice guidance on service delivery for acute medical emergencies. This two-year programme is running concurrently with the HiSLAC project, and offers an important opportunity to share evolving information and incorporate research findings in national guidance.

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]. 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. If high-intensity specialist led acute care is associated with improvements in quality of care and patient outcomes, this will act as an important stimulus to all health systems internationally as well as in the UK.

Beneficial outputs include new knowledge, evidence to support the NICE clinical guideline group on service delivery for acute medical emergencies, and 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. The study will also be directly useful to policy makers who need to understand current implementation of recommended practice and barriers to further roll out, and will also yield a health economics 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 Oversight & Governance Committee, and will contribute as one of seven 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.

PPIs will have their own working group when developing the programme theory for the causal effect (mechanisms of action) of specialists in improving the outcome of patients admitted to hospital at weekends. Up to 5 patient and public focus groups will be undertaken to develop this programme theory. Participants will be provided with an information sheet and given the opportunity to ask questions. If they agree to participate informed consent will be obtained using a consent form.

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.

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 **(Fig 9).** 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)

We will analyse 11 years of data (seven years retrospective, four years prospective) from about 150 hospitals, examining Length of Hospital Stay (LOHS), 7-day readmission rates, and hospital and 30 day mortality. 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 the measure of weekend specialist intensity ('SLAC') developed in phase 1 will be collected prospectively for 2014-2018. 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)

Case records from two epochs will be reviewed. Epoch 1 will include admissions between 2011-2013, and Epoch 2 between 2016-2017. Both epochs will be analysed together in parallel (anticipated duration of reviews approximately 12 months) to examine the association between the intensity of specialist engagement and the process and outcomes of care, in 20 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 3. 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. 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 at the beginning of phase 2 will be updated [Hemming et al 2012].

Table 3: 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	0.033	0.029	0.76	0.66	0.26	0.23
	0.8	0.18	0.15	3.48	3.03	0.31	0.27
	0.6	0.23	0.20	4.59	3.99	0.34	0.30
Comparison between weekend and weekday admissions within one group of 10 hospitals	1	0.024	0.020	0.56	0.49	0.20	0.17
	0.8	0.13	0.11	2.73	2.36	0.25	0.21
	0.6	0.18	0.16	3.81	3.30	0.29	0.25
Comparison of weekend vs weekday difference between two groups of 10 hospitals	1	0.033	0.029	0.79	0.69	0.28	0.24
	0.8	0.19	0.16	3.85	3.33	0.35	0.30
	0.6	0.26	0.23	5.39	4.66	0.41	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. Meetings will take place every two-four months either through teleconferencing or meeting in person. The committee will report to the Oversight & Governance Committee and the HSDR Board.

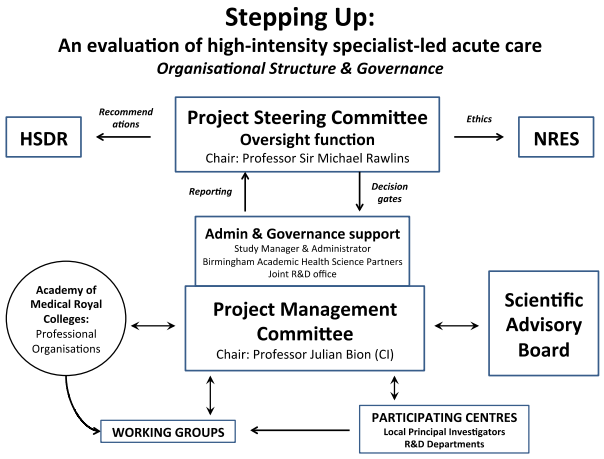
The project will be governed by the **independent Oversight & Governance (steering) Committee** chaired by Professor Sir Michael Rawlins. The Oversight & Governance Committee will monitor project progression and will make recommendations to the HSDR Board. The Oversight & Governance Committee will receive regular 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



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 utilise 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.

Intellectual Property

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

Research Timetable

This project will be a 60-month, two-phase parallel theme project (Gantt chart, **Fig 5)**.

Phase 1 (Developmental, months 1-12): During this time we will establish the workshops, develop the definitions and metrics, and disseminate the survey. The independent Oversight & Governance Committee will monitor progress.

Phase 2 (Prospective natural experimental study, Months 12-60): This consists of 42 months for data acquisition, and a six 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 hospitals (Workstream B) as well as create the health economics model. This will involve site visits,

ethnographic observations, data acquisition from local and national databases, and two epochs of case record reviews. Information from the mapping of current HiSLAC penetration linked to 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.

The final six months will be used for data analysis and preparation of final reports and publications. The project will conclude January 2019.

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FIGURES

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

Mo	Phase	Clinical Themes	Cross-cutting Themes	Deliverables: Outputs, Analyses
3 6 9 12	**Phase 1: *Developmental***	**HiSLAC Measurement:** • Workshop on measurement; pilot, refine **Survey of all English NHS acute Trusts:** • HiSLAC penetration; models, current & past 3 yr **HES/ONS data acquisition** • Set up, preparation, 'dry run' **Systematic Review of weekend mortality** • Elicit focus group opinion to inform reviews into mechanisms and costs of weekend effect	**Health economics** • Start development of causal model **Ethnography** • Researcher training in clinical pathways • Institutional approval for ethnography	• National collaboration – local project leads with Trust senior management buy-in • HiSLAC measurement methods (HiSLAC, LoSLAC) • HiSLAC map across English NHS • HES database, search terms & fields • Online collaborative workspace • Focus group opinion elicitation to frame systematic reviews.
15 18 21 24 27 30 33 36 39 42 45 48 51 54 57	**Phase 2: *Natural experiment prospective study***	**Workstream A: System-wide analysis of unplanned non-op admissions to all English NHS acute Trusts.** • **HES/ONS data:** 6-yr retrospective and 4-yr prospective analysis (2007-2018) • Comparison with other national datasets (UK, USA, Aus) **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** (e.g.: PAS; ICNARC-CMP) to supplement national (HES/ONS) data • **Case record reviews of 50 weekend vs 50 weekday admissions to each Trust:** 2 epochs, 4000 case records iii. Implicit review of quality of care iv. Evaluate explicit (criterion-referenced) analysis of best practice adherence **Link with concurrent national quality initiatives:** • NICE-Service Delivery Standards for acutely ill patients • NHS Improving Quality projects	**Health Economics** • Develop model structure & QA • Populate with Bayesian priors • Model verification & validation • Repopulate model with empirical data — Effectiveness parameters — Cost-drivers • Feedback to subject experts ('synthetic posterior') **Ethnography** (annual visits years 2-4) • Observe delivery of weekend care • Identify contextual & social factors • Interview staff, patients & relatives • Explore diagnostic pathway precision **Track 7-day services implementation**: • Annual surveys via Local Project Leads • Triangulation with NHS-IQ: NHS(E) standards for 7-day services • Compile library of public and policy documents on 7-day services	**Workstream A:** NHS-level case mix-adjusted mortality, length of stay, 7-day readmission rate by: • HiSLAC status • Weekend vs weekday • Change over time — *Difference-in-difference* **Workstream B:** As workstream A, plus… • Local (PAS) data analyses: CPR rates, unplanned ICU admissions; absenteeism; satisfaction rates • Quality of weekend vs weekday care – two epoch comparison exploring change over time **Ethnography** • Characterise fidelity of HiSLAC over time • Determine mechanisms, barriers, facilitators **Health Economics** • Final model estimates of cost-effectiveness and budget impact
60		**Analytical phase: Triangulation** of systems level and local level quantitative metrics with ethnographic findings and health economics.		

Fig 2: HiSLAC project work packages, timelines, products, reports and outcomes

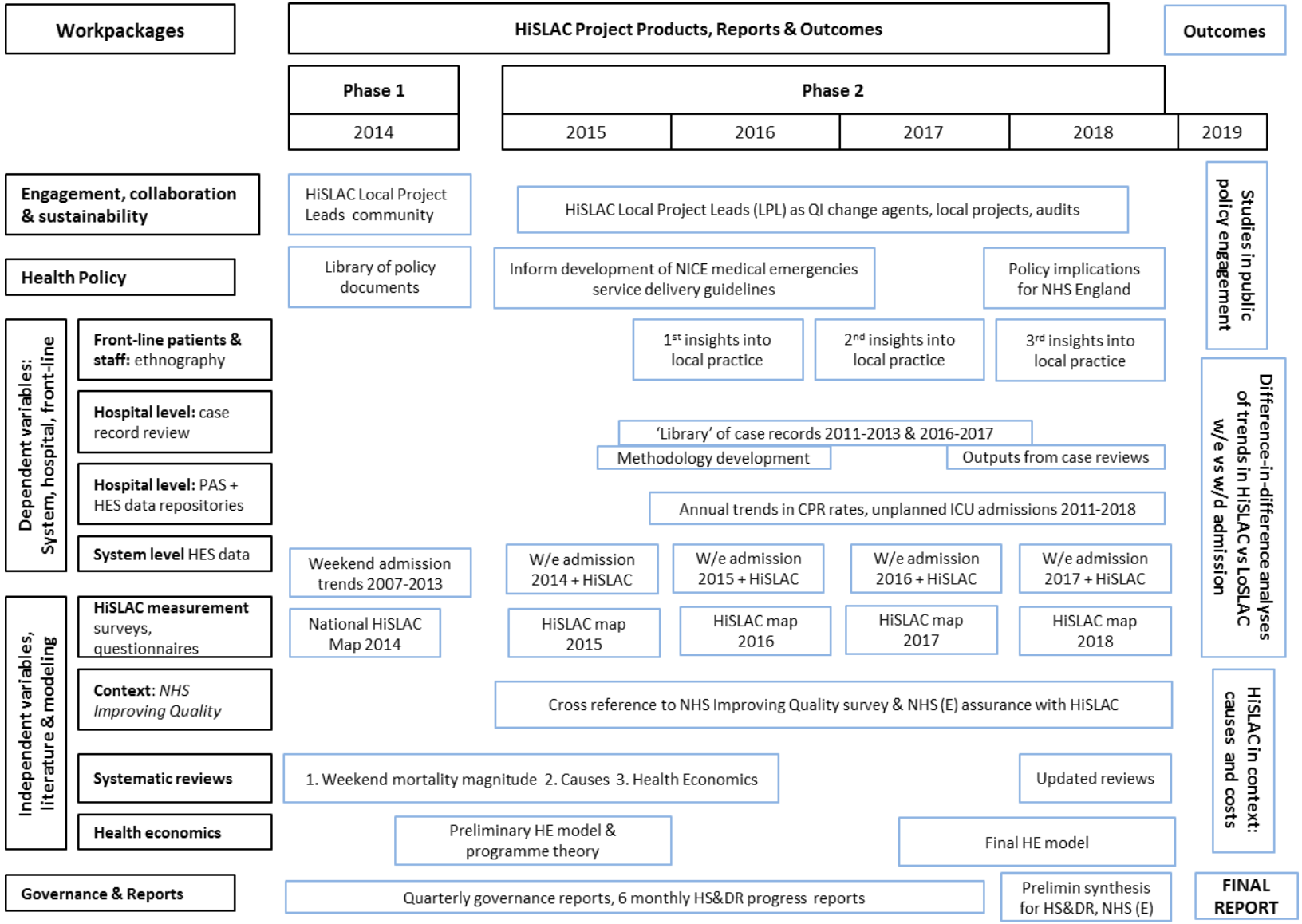


Fig 3: Location of HiSLAC intervention, and current standards for consultant staffing

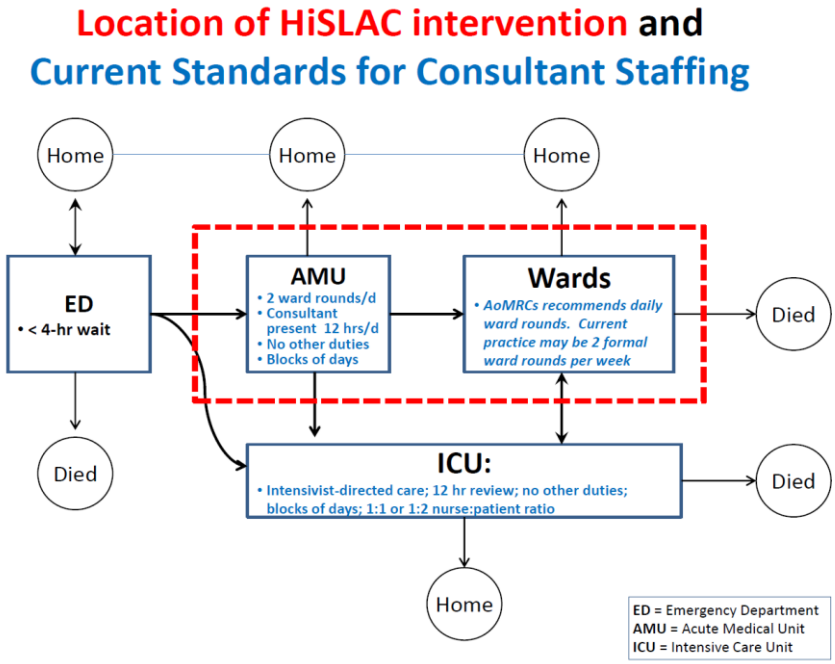


Fig 4: Emergency Admission Patient Pathways

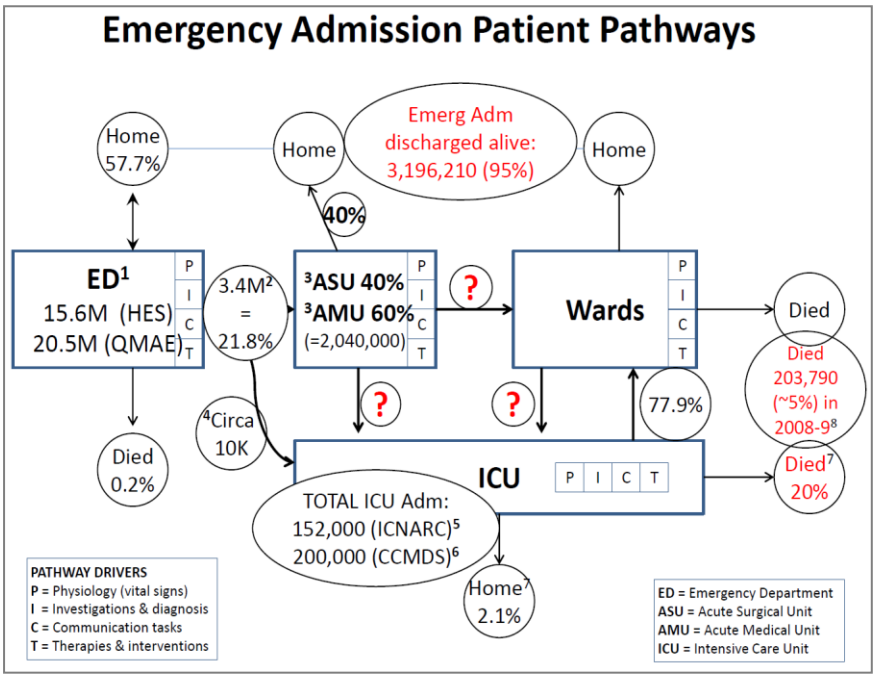


Fig 5: Gantt chart

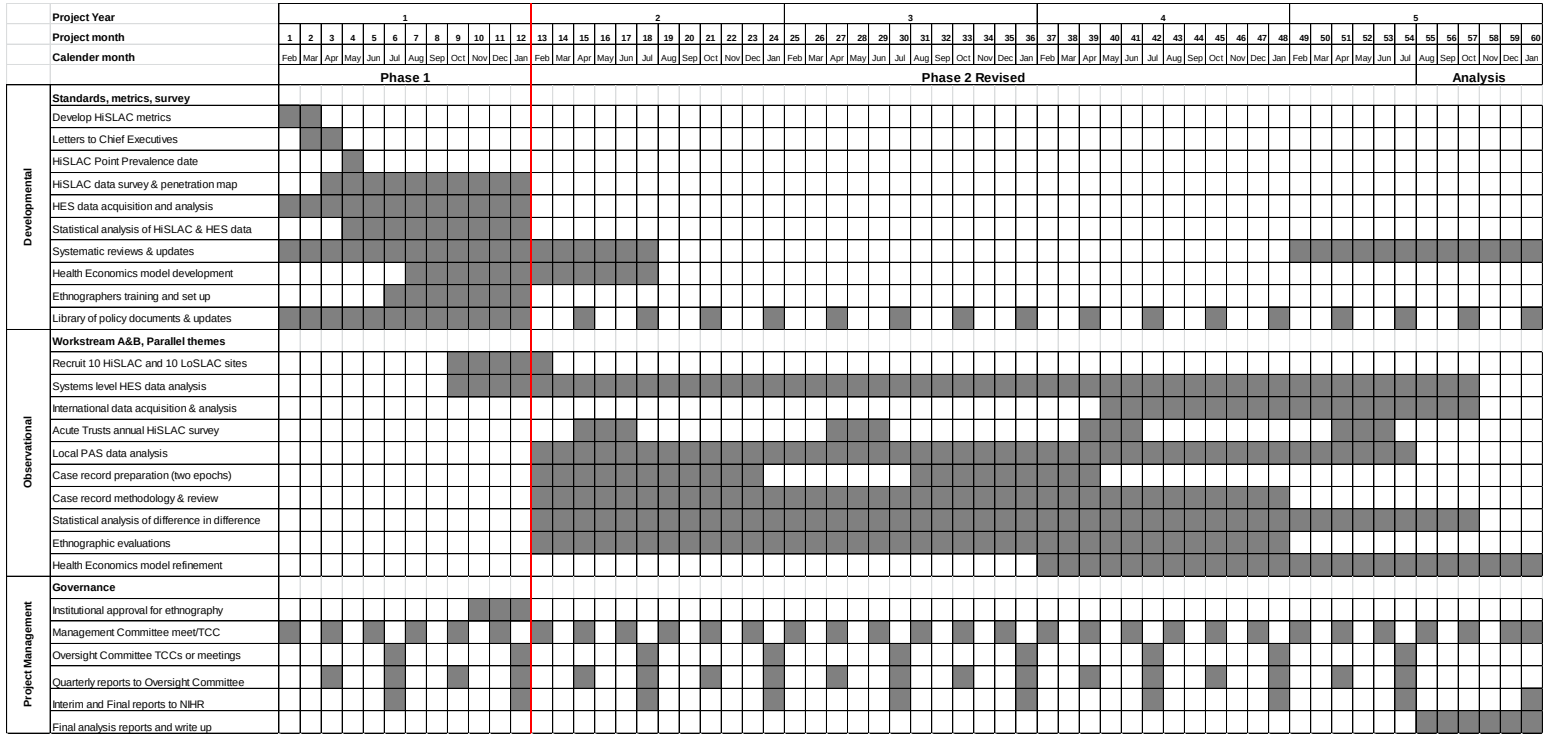


Fig 6: Illustration of possible structure for health economic model

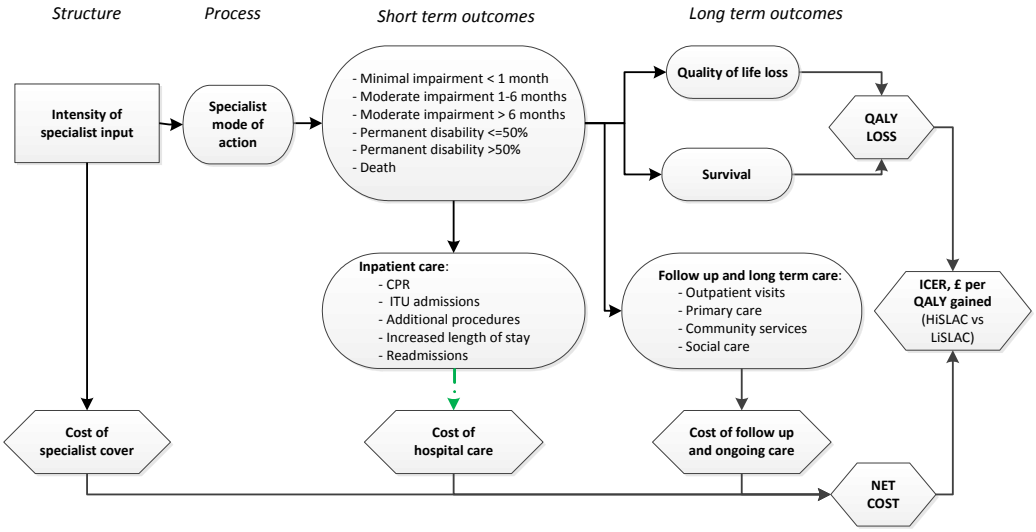


Fig 7: Schematic of possible distribution of Acute Hospital Trusts by Intensity of Specialist-Led Acute Care

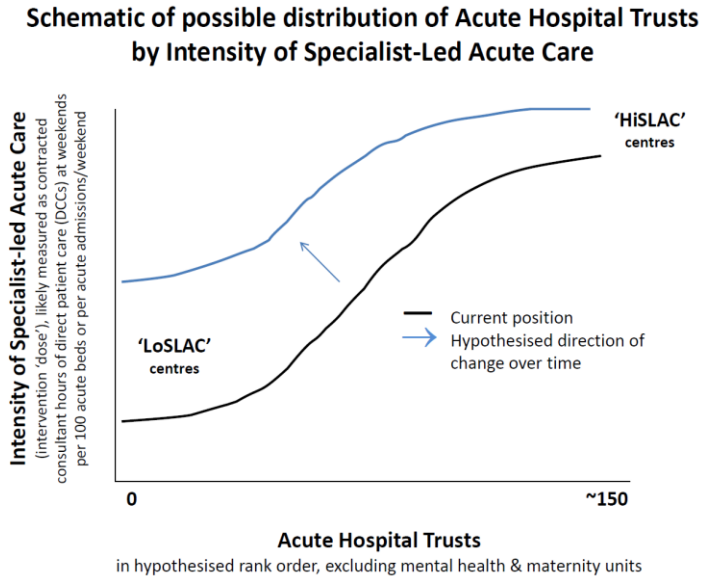


Fig 8: Project Management and Governance

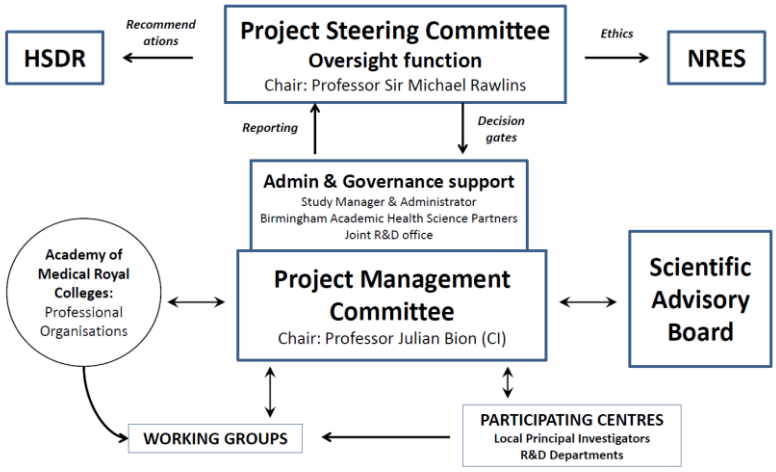
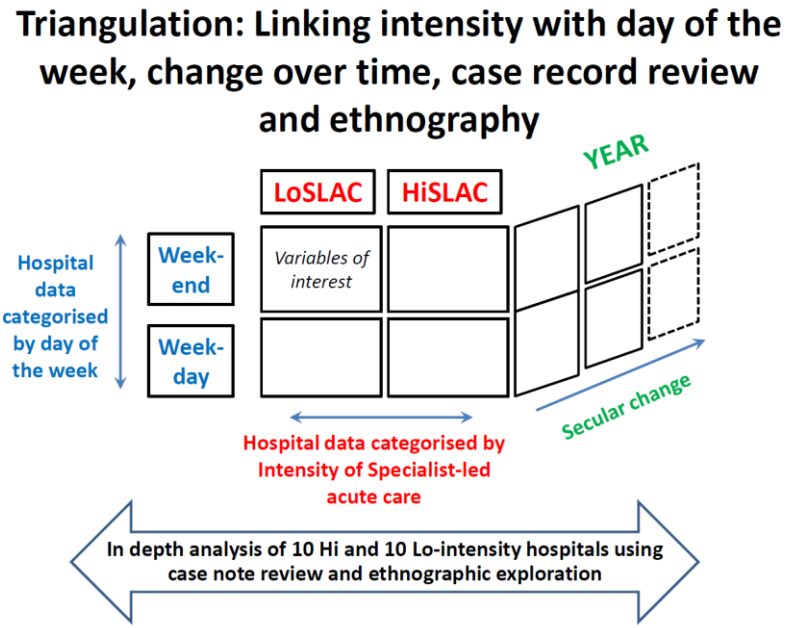


Fig 9: Triangulation and difference-in-difference analyses



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

General unselected hospital admissions

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 (e.g.: OR, RR)**	**p**	**Morbidity or other outcome**
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 (e.g.: 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 meta analysis. 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 non-routine 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 (e.g.: 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 (e.g.: 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 appendectomy 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. Point prevalence survey

Point Prevalence Survey Questions, all specialist staff in the Trust *Specialists = all CCT holders (consultants and associate specialists)*	Were you providing Direct Clinical Care to emergency admissions?	*If Yes…* ➔	Approximately how long did you spend providing direct care? *(Max 12 hours)*	Were you the specialist responsible for continuing care of these patients? (i.e.: 'named consultant')	Which of the following locations best describe where you spent most time delivering direct patient care? *(Max 2 choices for each period)*
1. **Last Sunday [date] were you physically present in the hospital** at any point between 08:00h-20:00hrs providing direct clinical care to patients who had been admitted for their current admission episode as an **emergency** to an in-patient bed including CDUs/Observation wards?	**YES / NO**	*If Yes…* ➔		**Yes** ☐ **Some** ☐ **No** ☐	☐ Acute Medical Unit ☐ Acute Surgical Unit ☐ Combined Med/Surg acute unit ☐ Adult medical wards ☐ Adult surgical wards ☐ Specialist wards or units ☐ High Dependency Unit ☐ Obstetrics or Gynaecology ☐ Intensive Care Unit ☐ Operating theatre ☐ Radiology ☐ Endoscopy ☐ Laboratories ☐ Paediatrics wards/unit ☐ ED Clinical Decision Unit ☐ Other
2. **Last Wednesday [date] were you physically present in the hospital** at any point between 08:00h-20:00hrs providing direct clinical care to patients who had been admitted for their current admission episode as an emergency to an inpatient bed including CDUs/observation wards?	**YES / NO**	*If Yes…* ➔		**Yes** ☐ **Some** ☐ **No** ☐	☐ Acute Medical Unit ☐ Acute Surgical Unit ☐ Combined Med/Surg acute unit ☐ Adult medical wards ☐ Adult surgical wards ☐ Specialist wards or units ☐ High Dependency Unit ☐ Obstetrics or Gynaecology ☐ Intensive Care Unit ☐ Operating theatre ☐ Radiology ☐ Endoscopy ☐ Laboratories ☐ Paediatrics wards/unit ☐ ED Clinical Decision Unit ☐ Other

3. Please identify your main speciality *(only 1 choice)* *Please answer this question even if you had no clinical duties on the two days identified above.*	☐ Acute Internal Medicine ☐ Allergy ☐ Anaesthetics ☐ Cardiology ☐ Cardio-thoracic Surgery ☐ Chemical pathology ☐ Clinical Genetics ☐ Clinical Neurophysiology ☐ Clinical Pharmacology and Therapeutics ☐ Dermatology ☐ Emergency Medicine	☐ Endocrinology and Diabetes ☐ Gastroenterology ☐ General Surgery ☐ Genito-urinary Medicine ☐ Geriatric Medicine ☐ General (Internal) Medicine ☐ Haematology ☐ Histopathology ☐ Immunology ☐ Infectious Diseases ☐ Intensive Care Medicine ☐ Medical Microbiology	☐ Oncology ☐ Ophthalmology ☐ Otolaryngology ☐ Oral and maxillo-facial Surgery ☐ Obstetrics & Gynaecology ☐ Neurology ☐ Neurosurgery ☐ Nuclear Medicine ☐ Paediatrics ☐ Palliative Medicine ☐ Pharmaceutical Medicine ☐ Plastic Surgery	☐ Radiology ☐ Rehabilitation Medicine ☐ Renal Medicine ☐ Respiratory Medicine ☐ Rheumatology ☐ Sport and Exercise Medicine ☐ Trauma and Orthopaedic Surgery ☐ Tropical Medicine ☐ Urology ☐ Other

Appendix 3. Directorate Level Questionnaire.

	Please note that 'Specialist' = consultants + associate specialists (CCT holder or article 14 CESR). It does not include Trust doctors without a CCT, or trainees. *DCC = direct clinical care*	Emergency Department + CDU	Acute Medical Unit	Intensive Care Units	Acute medical Wards receiving Acute Medical emergencies
On a weekday					
D040	**How many specialists are normally physically present in this clinical area providing direct clinical care on a weekday during the daytime (08:00-20:00hrs)? (Please include only those with contractual DCC-PAs for this area, not visiting specialists).**				
D140	**On average, how many hours would a specialist normally spend providing direct clinical care in this area, on a typical weekday during the daytime (08:00-20:00h)?**				
D070	**Do specialists provide direct clinical care on single days (e.g. 'physician of the day' model) or in blocks of 2 days, or 3 or more days? Answer 1, 2 or 3** **1) Single days** **2) Blocks of two days** **3) Blocks of three or more days**				
D120	**How often are patients in this clinical area reviewed by a specialist on weekdays? Answer 1, 2 or 3** **1) All patients are reviewed at least once each day by a specialist** **2) Selected patients are reviewed at least once each day by a specialist** **3) Patients are reviewed by a specialist less frequently than daily**				
On a Sunday					
D050	**How many specialists are normally present in this clinical area providing direct clinical care on a Sunday during the daytime (08:00-20:00hrs)? (Please include only those with contractual DCC-PAs for this area, not visiting specialists).**				
D150	**On average, how many hours would a specialist normally spend providing direct clinical care in this area, on a Sunday during the daytime (08:00-20:00h)?**				
D080	**Do specialists provide direct clinical care on Sundays only (e.g. 'physician of the day' model) or in blocks of 2 days, or 3 or more days incorporating Sunday? Answer 1, 2 or 3** **1) Single Sunday** **2) Blocks of two days (eg whole weekend)** **3) Blocks of three or more days incorporating Sunday**				
D110	**How often are patients in this clinical area reviewed by a specialist on Sundays? Answer 1, 2 or 3** **1) All patients are reviewed at least once each Sunday by a specialist** **2) Selected patients are reviewed at least once on Sunday by a specialist** **3) Patients are reviewed by a specialist less frequently than daily**				

D060	**What model of specialist care is provided in this clinical area on Sundays? Answer 1, 2 or 3** **1) Only specialists with weekday daytime sessions in this clinical area provide care on Sundays** **2) Specialists whose weekday daytime sessions are exclusively in a different clinical area provide care in this area on Sundays** **3) Care on Sunday is provided by specialists both with and without weekday sessions in this area**				
D090	**Please indicate the type of specialist weekend rota: Answer 1, 2 or 3** **1) On call** **2) Shift work (ie scheduled to be actually present in the clinical area providing direct clinical care for a period)** **3) Combination of both**				
D092	**What is the usual Sunday working frequency for specialists with contracted DCCs for this clinical area? [eg 1:4, 1:6 etc]**				
Weekday or Sunday					
D100	**Do you currently have consultant vacancies resulting in gaps in the specialist rota in this area? Yes/No**				
D130	**Please enter any additional general comments if you wish:**				