Interim report for the evaluation of the Emergency Laparotomy Collaborative project

Dr Katerina Gousia, Research Associate in Health Economics
Annette King, Academic Team Lead in Kent for the NIHR Research Design Service South East
Dr David Lowery, Research Fellow and NIHR RDS SE Research Adviser
Ugochi Nwulu, Research Associate and NIHR RDS SE Research Adviser
Professor Simon Coulton, Professor of Health Services Research
Professor Stephen Peckham, Director of CHSS and Professor of Health Policy

Centre for Health Services Studies
University of Kent
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Introduction

This is the interim evaluation report on the Health Foundation funded Emergency Laparotomy Collaborative (ELC) project, which is being rolled-out to 28 trusts in the South of England over a 2-year period (2015-2017). The programme aims to improve patient outcomes after emergency abdominal surgery by scaling up the use of a 5-item care pathway in acute hospitals, using Quality Improvement (QI) methodology. The pathway used in the ELC project was derived from the Emergency Laparotomy Pathway Quality Improvement Care-Bundle (ELPQuIC). The ELC aims to embed the pathway in hospitals spanning the geographical area covered by three Academic Health Science Networks (AHSN) (Kent Surrey Sussex, West of England and Wessex) and improve the mortality outcomes for emergency laparotomy across this area. The ELC project was funded by round one of the Health Foundation’s Scaling Up Improvement funding programme. It is one of 13 projects that have been piloted and shown to improve care at a small scale and the funding allows them to be tested to see if they can improve care at scale. The long term goal of the funding is for the work to be sustained beyond the life of the projects and for the projects to have the potential to be adopted across the UK health service.

The interim evaluation report covers the first year of the ELC project and focuses on the interim process data which were generated in the first year, covering the efforts of the project and AHSN teams, and the first round of data collection in the case study sites. We also give an overview of the plans for the outcome evaluation and cost analysis.

Emergency Laparotomy

Emergency laparotomy (EL) is a high-risk surgical procedure. 30-day mortality for this group of patients is reported at 14.9% and rising to 24.4% for patients over the age of 80 years (Saunders et al. 2012). Patients that survive this operation often suffer post-operative complications and have associated long stays in hospital. Significant variations in standards of care have also been reported. An evidence based care pathway (ELPQuIC) was developed at Royal Surrey County Hospital (RSCH) in Guildford. It was introduced at RSCH and 3 other English hospitals as part of a quality improvement collaborative pilot (Huddart et al. 2015). The ELPQuIC pathway was the basis for developing the ELC pathway and the quality improvement work programme for this project. The amended pathway used for the ELC project contains five elements:

- Early assessment and resuscitation
- Antibiotics administered to patients who show signs of sepsis
- Prompt diagnosis and early surgery
- Goal-directed fluid therapy in theatres and continued to ICU
- Post-operative Intensive care for all

The data element of the project
The ELC uses the online audit facility, the National Emergency Laparotomy Audit (NELA), to chart the progress of the implementation of the project across all participating trusts and to enable trust teams to monitor their own progress via their own internal space on the database. NELA is an online database which collates routinely collected clinical data from all providers of emergency laparotomy, and transforms them into reports for monitoring quality of care and comparing data from all providers of emergency laparotomy (http://www.nela.org.uk/). It has been adapted and extended to accommodate the ELC bundle items and enables monitoring data on the five dimensions of the bundle. Reports on uploaded data can be drawn down by trusts themselves; an overview is available to all the trusts. The data bundle also allows comparisons between trusts – although that facility is available to the project team only. Individual trusts can compare themselves against the national average. A dashboard has been developed by the project to enable functionality of the NELA database and make the creation of reports easier.

Quality Improvement methods
The implementation of the ELC bundles is facilitated by quality improvement techniques delivered to the participating hospital teams over the two-year project period. A range of activities are offered over the course of the project to facilitate the process of adoption of the care pathway in trusts, enable collaboration across teams and regions on improvement, enhance diffusion of innovation, and ensure sustainability of the improvement over time. These activities will be time limited to the duration of the project. They are:

- A set of education and network events, alternating between events for all participating teams and separate events for trusts in the AHSN areas. These events encompass educational and coaching elements for the local trust teams. They incorporate training of how to use the NELA database (if not already used), how to draw down relevant reports and how use them to track improvement, identify areas of good practice and for improvement. In addition, training on how to employ improvement methods, such as PDSA, is provided. Lectures and discussion on soft project skills such as leadership and engagement are also part of the network events.
- There is a website for the project which has number of resources attached. Webinars have been held on specific topics.
- Bespoke support is provided in the form of access to the expertise in the project team, with team members visiting trusts when requested, holding phone conversations, and answering email queries.
- Letters explaining the project to chief executives, newsletters to the ELC participants have also been utilised to support engagement with the project within the trust hierarchies and among wider stakeholders.
- The project team has spoken at conferences to promote the project to the wider QI and professional community; it has also invited high level speakers to present at ELC events.

Purpose of the evaluation

The evaluation element has been funded to run alongside the implementation project, but remains independent from it. The overall aim of the evaluation is to determine whether and to what extent the approach for improvement used by the ELC programme delivers sustainable improvement in outcomes of emergency laparotomy, and what can be learned from the quality improvement methods employed by this project. This is not a standalone evaluation, in terms of the Health Foundation’s Scaling Up Improvement funding programme. The evaluation of the ELC project will contribute to the learning as part of the overall programme as the other scale up projects are in a number of diverse geographical areas, patient populations and clinical settings.

The objectives of the evaluation are as follows:

- To assess the benefit and relevance of the ELC bundle to improved patient care and outcomes;
- To determine the feasibility of collaborative approaches (e.g. peer influence, clinical networks) to supporting the diffusion of the ELC pathway;
- To assess the adoptability of the ELC pathway by surgical teams, directorates etc. in individual NHS trusts;
- To determine the degree of adoption of ELC by surgical teams in the roll-out hospitals;
- And to explore the impact on staff (eg work practices), patients and their carers.

The evaluation objectives (and research questions) can be found in the appendices of this report (Appendix A)
In line with the requirements of the Health Foundation, the report presents the progress of the evaluation and highlights emerging findings. By necessity, findings reported here are interim and the focus will be on the data currently available for analysis, mainly in regards to the process evaluation. Updates on the milestones for the summative and the health economics evaluations also are referred to where appropriate.

**Background**

**Existing evidence of scaling up**

“Scaling-up” in the healthcare literature refers to activities of spreading, diffusing and disseminating initiatives and innovations. All of these terms mainly refer to the spread of an intervention from one clinical area (hospital, ward, GP practice) to a larger area (hospitals, networks, regions, nationally). Scale-up is often used interchangeably with these terms (especially with ‘spread’) and there is a lack of accepted, universal definitions (Norton et al. 2012).

Scaling up has mainly been used to describe activities needed to spread healthcare programmes (often population health interventions) and innovations in health systems in developing countries. The World Health Organisation (WHO) defines scaling-up as:

“...deliberate efforts to increase the impact of successfully tested health interventions so as to benefit more people and to foster policy and program development on a lasting basis” (World Health Organization 2010).

Examples in the literature that specifically use the phrases “scale-up” and quality improvement (QI) can again be found in health services in developing countries (Hermida et al. 2005) but a change of emphasis is often found in studies in developed countries. Here, scale-up of quality improvement is a little more nuanced in that it seeks to enable wider implementation of QI innovation which will lead to less variation in care and a narrowing of the “quality chasm” as defined by the Institute of Medicine (IOM 2001). How to spread good quality evidence-based innovations is an ongoing problem for health systems and the “spread and sustainability” of successful QI initiatives is something the Health Foundation is keen to promote through its Scaling Up Improvement funding grant (Health Foundation 2016).

Many QI pilots have little to moderate impact when applied more broadly and the wider and more complex the change (such as having multiple components and / or through multiple organisations),
the least likely that spread will happen (Perla et al. 2015). Bevan (2015) found that when more resources are invested in pilot programmes run by enthusiastic teams in single hospitals, issues of spread and scale can often become afterthoughts. Successful small scale implementations often attribute that success to the implementation mechanisms when it may be due to having access to exceptional resources - such as a project team, technical assistance, training and support for staff. Challenges to any planned scale up/spread occur when these resources are no longer available as by their definition they are project-specific and therefore time-limited. This lack of resources coupled with features of the innovation, target adopters, environment/context, and scale up/spread strategy can lead to unsuccessful scaling up of a previously successful pilot implementation. Norton et al define scaling-up as the spread of a tested or successful pilot to increase the impact of the innovation (Norton et al. 2012) and others have looked at how social innovations are successfully scaled up and related those methods to healthcare –

“Unless a program can be replicated and sustained on a large scale, it will not be transformational… We can no longer evaluate programs simply based on how well they’ve performed in a given locality. Instead, we need to factor in their potential to achieve scale” (Davis 2014; as quoted by Bevan 2015).

**Models of scale or spread**

A number of studies and reports outline ways in which innovations/programmes should be scaled-up or spread. Many of them build on or have adapted the influential work of Everett Rogers, with his diffusion of innovation theory (Rogers 2003), and Greenhalgh and colleagues who have studied how innovation is spread in healthcare contexts (Greenhalgh et al. 2004).

The evidence scan in the appendices (Appendix B) will touch upon the elements that are influential to scaling up of innovation as outlined in the WHO’s conceptual framework - the innovation, the user organization, the environment, the resource team and the scaling up strategy itself.

**Evaluation approach used**

The evaluation is using a mixed methods approach combining quantitative routine data, documentary evidence and a comparative case study approach. ELC is categorised as a complex intervention due to the number of hospitals involved in the collaboration and the number of components required to implement the ELC pathway (Craig et al. 2008). Mixed methods evaluations are suitable for types of
service delivery/organisational interventions that may not yield the conclusive results of evaluating treatments based solely on measuring patient outcomes (Lilford et al. 2010). The use of mixed methods allows for data triangulation where increased confidence can be placed on the findings as different types of observations and levels of evidence can be used for corroboration (Brown et al. 2008a; Brown et al. 2008b). Even though one of the key priorities of the ELC is a reduction in mortality rates, understanding the processes by which the hospitals are able to implement the pathway and reach their outcomes is also important. Additionally, it is important to understand how the ELC as a quality improvement collaborative (QIC) works in engaging and supporting hospital teams as they implement the pathway.

The process evaluation uses a multiple-case design with qualitative analysis of documents, meeting observations notes and interviews transcripts. The main objective is to understand and compare the processes by which selected cases implement the ELC pathway and to elicit views on the role the ELC plays as a QIC. The initial qualitative analysis is thematic using an inductive approach to draw out salient themes for scaling up, which can be further explored and refined through the progress of data analysis and then mapped onto the broader analytical framework of the Normalisation Process Theory and tested out. (Boyatzis 1998; Fereday & Muir-Cochrane 2006).

Normalisation Process Theory (NPT) focusses on the processes through which innovation and change are made workable and becomes integrated into everyday practice within organisations (May et al. 2007). NPT provides a framework for assessing the “normalisation” of practice (sense-making, cognitive participation, collective action and reflexive monitoring) and for exploring on how legitimate space is created for the work of the intervention to become a routine part of the organisational landscape (Willis et al. 2012). NPT is finding recognition as a suitable theory informed framework for analysing implementation processes, as well as for guiding them (McEvoy et al. 2014).

Methods

Outcome evaluation

In order to explore the potential effect of the amended ELPQuIC bundle we will conduct two quantitative analyses. Outcome data will be retrieved from the NELA database. Primary analysis will focus on in-hospital mortality, but we will also explore the effect of the intervention on: Intensive Treatment Unit usage, emergency re-admissions to theatre and longer term mortality status (up to
180 day). Further analysis of the NELA dataset will explore the influence of age group and fidelity to intervention.

While this approach will provide information on the potential impact of the care bundle within participating hospitals, it would be beneficial to explore for any potential contemporaneous confounding factors by comparing intervention patients in participant hospitals with similar patients across the wider NHS. We are currently exploring the possibility of obtaining a matched control group from outside the ELC project area. Hospital Episode Statistics may not provide suitable data; consequently, we are exploring the possibility of obtaining matched data from NELA.

Further detail can be found in the attached draft Statistical Analysis Plan (Appendix C).

**Progress**

Data will be retrieved from the NELA dataset and collated by the central ELC delivery team, and provided to the evaluation team. It is anticipated that data will be provided in March 2017 to cover the period September 2014 - August 2016 (24 months). There is currently a delay of approximately 3-6 months from individual patient level event to retrieval of data by the central delivery team. The central team anticipates that this may reduce. This might allow for a broader period of time (~36 months) to be included in the analysis.

**Health Economics**

We will conduct a hospital level descriptive analysis using the NHS Reference Cost data. This analysis will involve graphical investigation of the overall average costs, average costs per life saved across all hospitals, by hospital and by hospital groups (based on the degree of compliance with the bundle and the degree of reduction in mortality). We will also present descriptive statistics (mean, median, standard deviation) of these costs.

A patient level analysis will also be conducted with the use of the NELA dataset. A multi-level regression model will be used to estimate the costs of length of stay as a function of different predictors including patient characteristics such as sex, age and co-morbidity, number of surgeries per admissions and intervention compliance indicators. Random effects will be included to allow for hospital effects while alternative specifications accounting for different hospital characteristics will be considered. A difference-in-difference regression specification will also be considered to allow for a
more causal investigation of the effect of the intervention if there is sufficient variation in the time and degree of adoption of the intervention across hospitals.

**Progress**

We have collected the 2014-2015 NHS Reference Costs which are publicly available. The 2015-2016 NHS Reference Costs will become available in November 2016. Data from the NELA database will be retrieved in March 2017 and 2014-2015 and 2015-2016 data will be taken as the pre-intervention and post-intervention periods respectively. This data will be used in line with the cost analysis plan (Appendix D) with the aim of understanding the distribution of costs of emergency laparotomy across hospital groups and over time.

**Process evaluation**

Using a case study approach, 10 case studies study sites were selected, initially based on size and type of hospital, CQC ratings, and baseline pre-implementation questionnaire responses amongst other factors. The sites were selected so that we could ensure that there would be a representative selection of sites across the three geographical AHSN areas (see Table 1).

For all trusts in the implementation process, the following documentation are being collected by the research team for analysis: cross-collaborative and local events meeting agendas, team membership, any data reports and presentation slides. We are using the documentation to map the process across the implementation programme. We are also collecting documentary evidence throughout the project and asking for routine provision of any meeting notes or copies of policies from AHSNs and hospitals. Documents are being indexed by site and type and where possible in electronic forms to allow easier searching and extracting of relevant data. Documents are being coded using the same coding framework as for the interviews.

In the case study sites, observations and interviews with key informants are being conducted at two time points (beginning and end) of the implementation process. The interviews are based on a topic guide developed to elicit the views of key informants about the plans for the implementation, how the process is working, the value of the improvement activities in accessing this, organisational issues encountered as part of the implementation process. The topic guide varies slightly in its emphasis according to the role in the organisation and relationship to the improvement project, taking into
account the roles in the process and the particular perspective individuals can contribute (Appendix E).

Table 1. Characteristics of the case study sites

<table>
<thead>
<tr>
<th>Sites</th>
<th>No of beds</th>
<th>Teaching hospital</th>
<th>Foundation trust status</th>
<th>CQC rating</th>
<th>ELC in split sites</th>
<th>EPOCH* participant</th>
</tr>
</thead>
<tbody>
<tr>
<td>AHSN 1</td>
<td>Trust A</td>
<td>272</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
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<td></td>
<td>Trust B</td>
<td>945</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td></td>
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<td>974</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>AHSN 2</td>
<td>Trust D</td>
<td>605</td>
<td>Yes</td>
<td>No rating</td>
<td>No</td>
<td>No</td>
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<tr>
<td></td>
<td>Trust E</td>
<td>1176</td>
<td>Yes</td>
<td>No</td>
<td>Requires improvement</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Trust F</td>
<td>1046</td>
<td>No</td>
<td>No</td>
<td>Requires improvement</td>
<td>No</td>
</tr>
<tr>
<td>AHSN 3</td>
<td>Trust G</td>
<td>1041</td>
<td>Yes</td>
<td>Requires improvement</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Trust H</td>
<td>541</td>
<td>No</td>
<td>Requires improvement</td>
<td>Inadequate</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Trust I</td>
<td>901</td>
<td>Yes</td>
<td>Requires improvement</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Trust J</td>
<td>1,368</td>
<td>Yes</td>
<td>Outstanding</td>
<td>No</td>
<td>Yes</td>
</tr>
</tbody>
</table>

*EPOCH - Enhanced Peri-Operative Care for High-risk patients (EPOCH) trial.

The information listed here was obtained through the sign up questionnaire sent to all trusts as part of the project set-up. Subsequent discussions with the trusts have highlighted that some of the trusts did have EPOCH involvement. We will amend the accuracy of the table once we have verified the information for all trusts.

Process evaluation progress

Permissions

Permissions for the evaluation project were obtained as follows:

University Ethics permissions were applied for in November 2015 and granted in December 2015. On advice of the University Governance office, the project sought Health Research Authority (HRA) approval via the Integrated Research Application System in January 2016. The project was assessed during the period January/February 2016, which included additional small adjustments, and approval came through in March 2016 (Appendix F).
Parallel to this the application for research passports for three of the evaluation staff were applied for at a local trust. This was granted end of March 2016.

The HRA letter stipulated a trust response time to accept or reject the application of 25 days. In one case, approval came through automatically. For the other trusts, a process for email contacting, forwarding paperwork and repeated follow-up had to be adopted in order to receive permissions. The average time between sending an initial email asking to clarify the permission process in the trust and the actual granting of permission was around 6 weeks.

One trust eventually declined to participate in the study despite direct approaches to the clinical leads and their R&D department and a further site needed to be opened up.

It is unfortunate that the evaluation fell into the transition period of the first full implementation period for the new integrated HRA system. From our experience many of the trusts are still operating under the old system, in which checks are carried out by the trusts themselves. In conversations with Research and Development (R&D) departments in the participating trusts, it became clear that some R&D staff were uncertain about the appropriate procedures and were on a learning curve. Contacting and keeping a dialogue with R&D offices turned into a time consuming effort. We intend to feed back this information at the end of the project to the HRA as a reminder that the system may need additional support to clarify the relative responsibilities regarding checks and paperwork for the different projects between HRA and R&D in trusts.

**Data collection tools**

For the outcome evaluation the project will utilise the routinely collected NELA data as well as ONS data.

For the Health Economics cost applications, the agreement is now to use NHS reference cost data and NELA data.

For the process evaluation a number of data collection tools were developed.

- An agreed approach has been adopted to annotating, indexing and analysing the collected meeting documents (agendas, minutes, papers) which have been made available to the evaluation team. Documents associated with trust events have also been collated where possible.
- An interview topic guide for the process evaluation was developed for individual interviews and group discussions (Appendix E).
- An activity data recording sheet was developed for use in the central team to collect data on the activities related to the informal exchanges on the project (Appendix G). Their use has been somewhat inconsistent, as not all participants asked to fill this in have been able to do so yet. The agreement at the last evaluation advisory meeting was that a further attempt will be made to have this completed. Where used, it has provided a useful insight into the informal exchanges on the project. In addition, one AHSN has provided a breakdown on the activities of the AHSN staff and time spent via routinely collected data on work allocation.

- A star or spider diagram has been completed by some of the project team members at the end of the initial interview. This shows graphically the most important contacts of individual team members and allowed some insight into the roles and linkages of individuals in the team.

- Meeting observations are recorded via extensive note taking at meetings, which then are subsequently typed up.

Data collection

Progress on process evaluation data collection

<table>
<thead>
<tr>
<th></th>
<th>Sites</th>
<th>Interviews</th>
<th>Planned</th>
</tr>
</thead>
<tbody>
<tr>
<td>Central team interviews*</td>
<td>-</td>
<td>7</td>
<td>1</td>
</tr>
<tr>
<td>AHSN teams' interviews *</td>
<td>2 (WoE, Wessex); KSS counted as central team as staff are overlapping</td>
<td>5</td>
<td>-</td>
</tr>
<tr>
<td>Trust interviews*</td>
<td>10</td>
<td>20 (in six sites)</td>
<td>in 4 more sites (ca. 16)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Observations</th>
<th>Planned</th>
</tr>
</thead>
<tbody>
<tr>
<td>ELC collaborative network events</td>
<td>8</td>
<td>9</td>
</tr>
<tr>
<td>Observations in trusts*</td>
<td>10</td>
<td>5</td>
</tr>
<tr>
<td>Other meetings, ELC steering group meeting, attendance at other events</td>
<td>9</td>
<td>As required</td>
</tr>
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</table>

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<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Literature</td>
<td>Review attached</td>
<td></td>
</tr>
<tr>
<td>Data transcribing, coding, analysis</td>
<td>Ongoing and as appropriate for all primary data collected, plus for the documentary analysis</td>
<td></td>
</tr>
<tr>
<td>Ethics, HRA</td>
<td>Y</td>
<td></td>
</tr>
</tbody>
</table>

15
The project team has collected data through interviews from the central project team and AHSN teams in full. One additional interview (not originally planned) has been added for reasons for completeness. Relevant documentation from meetings are collected at the meeting; the project team has also made its meeting folder available to supplement any other meeting information.

Progress has been made in data collection (interviews, observations, meeting agendas for observed meetings and presentations and graphs) in six case study sites today. Permissions for the others have been obtained and interviews are being arranged and continue to be conducted. There has been a delay due to bereavement and ill health. The time is now being made up through internal arrangements within the evaluation organisation, which will provide more time for one the evaluators to spend on the project to complete the first round of interviews in the case study sites.

Arranging interviews in the trusts has been quite time consuming, with a delay between first approach, reminders and setting up dates of up to two months. Help has been received from the AHSNs when an initial contact with a named contact person has not worked. The project has also used the ELC network meetings to make relevant first contacts. Once contacts are established, we have generally found trust staff to be very willing to conduct interviews with us. The preferred method of interviewing is via telephone. When scheduling interview dates, the time lap between agreement to be interviewed and the date of the interview has generally been around two to three weeks. However, delays have been experienced due to annual leave, the doctors’ strike and other scheduling conflicts. The clinical workload often requires identifying a reasonable length of time where the interview can be conducted without interruption. Where necessary we have suggested out of hour appointments in order to increase flexibility.

Site visits for observation have to be arranged well in advance, but in all cases have been successfully conducted. Meeting observations provide the opportunity to introduce the evaluation in the ELC once
more and make personal contact with team members, who may not attend the network meetings regularly.

Observing project steering group meetings continues on a regular basis; where required more than one evaluation team member has been present. The evaluation team started to attend steering group meeting before the formal commencement of the evaluation, there has been a presence at most steering group meeting since March 2015 (the evaluation formally commenced in September 2015). This has been a useful early contact with the project and demonstrates the commitment of the evaluation team to the project.

Interim findings: Process evaluation

Findings from the set up phase

Set-up of the ELC relates to the activities and processes that occurred within defined time periods or phases and by each level of the ELC. The central project team started to organise and plan the project within a “funding phase” where the principal investigator (PI) approached potential stakeholders (the Kent Surrey Sussex AHSN being one) to discuss a possible joint funding application. A “strong core team” of a PI, project manager (PM), clinical and QI experts was therefore built up as part of the application process. The PI already had the experience of implementing an emergency laparotomy pathway (ELPQuIC) in 4 hospitals and so was in an ideal position to plan a rollout with more of a focus on QI and collaborative working. The ELPQuIC bundle elements had been chosen through the previous pilot work and a dedicated database had been created for it. At the time of the funding application, the team saw that NELA audit database was in use by hospitals and they saw this as an opportunity to use some elements not addressed by NELA (like sepsis or antibiotic cover) but adjusted the number of elements to keep the additional data collection requirements at a minimum. The ELC bundle was refined and finalised in the pre-launch period. Regular steering group meetings discussed bundle items for inclusion, the outline of the Quality Improvement work and the collaborative network meetings. With increasingly pressing time scales, a number of decisions were taken outside the meetings (not observed by the evaluation team) and the planning of the launch seemed to become more focussed among a smaller number of people in the central team (interviews with project team members and notes from the meetings).
The funding application to the Health Foundation brought together co-applicants with expertise in QI, emergency laparotomy and evaluation. It was recognised that using a collaborative approach to the QI implementation would require a network of hospitals with regional coordinators who had QI expertise in other clinical areas - such as the AHSNs. One of the requirements was that a model of distributed leadership was to be employed to avoid over reliance on any one individual or group. The value of this was borne out by two members of the core team leaving but the work continued with minimal disruptions as personnel changes were made. Additionally, a governance steering group was formed that monitored progress and kept communication going from the central team to the recruited AHSN team members.

The post-funding pre-launch phase was essentially an engagement phase where approaches were made to the chief executives of the other two AHSNs. Subsequently, hospitals within each region were approached and clinical leads identified. The launch event in September 2015 marked the beginning of the implementation phase. This was the point when the project details (the bundle, evidence-base, QI training) and requirements (use of QI to make changes, NELA data returns, attendance at collaborative and local events) were fully outlined to the hospital teams and other stakeholders. The work of mapping processes and collecting data started at this stage with some hospitals already ahead in terms of data collection processes, organisational support and staff resources.

Having a “local model” with clinical leads and project managers within the AHSNs meant that where possible there would be regional representation of the project and a “continuation of the dialogue at a local level” [Respondent, Central team]. Engagement of hospitals was started by the central team but at the clinical lead of one of the AHSNs also made visits to the hospitals to further engage clinicians. It was stated a few times by members of the central team that this project will enable the AHSNs to mobilise in this QI area in future once networks are established. Engagement was seen to be positive due to the perceived importance of the work - previously poor outcomes and “… the strong evidence base” [Respondent, Central team] and that implementing a pathway to address this variation in care was not new to clinicians.

At the hospitals, clinicians were engaged in various ways and had different motivations - some had already carried out work in this area (were NELA leads, for example) and were keen to take part or saw it as an extension of NELA. Some did not actively choose to participate; they were asked to front it as a medical director was particularly keen. One of the case study sites, disappointed by not being able to take part in EPOCH, had started their own QI project using NELA data and were keen to progress the QI work form within the ELC. Other clinicians saw their participation with the ELC as a
way of making the changes, in response to their NELA data, that they had been unable to make (i.e. system or process changes).

Emerging themes

The following section highlights some of the topic areas and concepts which are emerging as salient in terms in the scaling up effort. They are presented below in preliminary form and will need to be further expanded on and modified as the data collection for the first round is completed. As we collect more data in the next phase of data collection, we expect that the analysis will use a general thematic approach with the NPT analytical framework to guide us.

Collaborations

A key component of the ELC is the use of QI to implement change in the context of a collaborative in order to improve QI capacity and provide peer support. The collaborative works at many levels and this can be seen by the way the central, AHSN, local hospital teams communicate with each other.

Role of the meetings and local events: The meetings have generally been reported as being useful. There were some initial concerns as to their relevance but generally people felt that it was good to be taken away from their workplaces to concentrate on QI and the ELC in general.

“...want to keep on going with meetings. For myself, they reenergise me... a way for me recharging batteries”. [Respondent, Trust B - AHSN 1]

It was mentioned that being in the meetings allowed people to be open and compare themselves to other hospitals through the use of the presentations. They used the meetings as an opportunity to reassure themselves that they were not falling behind.

“I like us to compare ourselves to others ... to see that our mortality figures are not too different from others if they are risk adjusted. “ [Respondent, Trust A - AHSN 1]

Generally, the meetings were seen as opportunities for shared learning. Some hospitals were already more used to doing this than others as they were part of an AHSN where hospitals had stronger links. More specifically, one participant questioned the balance of external experts and sessions that felt like lectures rather than shared learning sessions as “When you ask to show a bit of your work, you

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1 For an explanation on how interview respondents in the project team, the AHSNs and the trusts have been labelled in this report, please see Appendix H
are asked to share, you are being recognised, valued. The debate that generates new ideas and is really important.” [Respondent, Trust A - AHSN 1]

Some lessons learnt:

- Invites need to be sent out more than 8 weeks in advance to cover clinics.
- The breakout sessions were not initially planned but the central team listened to the local teams who felt that they were needed to help with relationship building.

Central team interactions: Initially, members of the central team handled the communications - Twitter, newsletters and through a website, but the project host AHSN started to manage some of those processes with their communication and PR capacity.

The central team, AHSNs and other stakeholders attend a monthly steering group meeting and these were perceived to be sufficient for setting up the project and monitoring progress. However, as operationalising the ELC needed different requirements from the regional teams during this early implementation phase, the project team agreed that a project managers’ meeting would be needed. Some of the interview participants commented that this was an important step in maintaining communication flows and helping with trouble shooting. All who mentioned the “PM teleconferences” were happy with them and thought it benefited their work. For some respondents, having this additional forum was a way of further devolving responsibilities from the central team to the local AHSN and rebalance a communication gap whereby trust teams would contact members of the central project team directly with queries and requests, and the regional AHSNs would not necessarily know what was happening. It took some time for this “devolved responsibility” to trickle through and achieve a degree of rebalance between highly centrally driven aspects of the project and regional involvement.

After the launch event, the central team tended to cascade information to and through the AHSNs to access the hospitals. The communication flow from the central team directly to hospitals was mainly about events, progress of the collaborative project and forthcoming data deadlines. One respondent felt that they were in the loop and that “everybody is included” another said that centres initially thought that the information cascade was “a deluge” but that has now balanced off [Respondent, AHSN 2]. Key ELC hospital team members who did not attend events did not tend to sign up for ELC news and they relied on (and where happy with) information being cascaded through the clinical leads in their hospitals.
In January 2016, the central team scheduled webinars for the 3 regions to monitor the progress being made and how hospitals could be supported:

“As a programme we are recognising this as a challenge [keeping the momentum going, collaborating among each other]; so we are setting the WebEx...to solve problems...” [Respondent, Central team]

**AHSN to hospital interactions:** AHSNs were seen to be the natural coordinators for the regional networks as they “run QI events for years, it is easy to see...the expertise of what works in making these events successful” [Respondent, Central team]. As regional collaborations are being strengthened the role of the AHSN is seen as pivotal. In some instances, the central team still has an input but it is often the local team that delivers the help, information or advice. It was mentioned a few times though that where a clinician needed advice or help, they would often prefer to liaise directly with clinicians on the central team instead of their local AHSN team. The information cascade was seen as stopping at the ELC clinical leads however, and AHSNs were also keen to connect with the local teams and colleagues to further promote the work. There was some frustration with accessing clinicians in their hospital environments and with not being able to attend MDT meetings for further engagement. In the main though, thoughts from the central team were that the collaborative could lead to improved local decision making.

AHSNs were seen as having an intermediary role in linking hospitals up and putting hospitals in touch with each other if one hospital had a solution or if they had a similar problem:

“We suggest “this hospital has put this process into place”, so we are sharing these ideas. This has been the way of working here in the last five/six years. We already have these mechanisms in place.” [Respondent, Central team].

**Hospital to hospital interactions:** There were few hospital-to-hospital interactions between ELC meetings and events. Participants tended to make contact with neighbouring hospitals they already had established relationships with or where there were established regional networks for related clinical projects. The use of webinars was praised as a way of getting around the reluctance to network:

“...have taken part in one group telephone conversation. Useful for exchanging ideas and see how other hospitals work.” [Respondent, Trust A - AHSN 1]
**Within hospital interactions and communications:** For some respondents, communications are mainly internal. They have not been to any of the ELC events and some respondents were not aware of them. Some of the ELC trust teams are part of the ELC through their job roles in the hospital - audit team or a QI team member for instance. Hospitals either have specific ELC team meetings (weekly or monthly) or include the ELC in established meeting rotas (ICU, anaesthetist, MDTs, governance or QI meetings).

“Meet every Friday morning initially, went down to monthly and along the way have lost a little bit of surgical input. But can still communicate with the surgeons to let them know of progress.” [Respondent, Trust D - AHSN 2]

Trust H in AHSN 3 started with a small ELC team that met regularly but eventually opened out to include more staff members once they were identified as being instrumental to the EL pathway (ICU staff, surgeons and theatre staff, anaesthetists, medical assessment unit staff, sepsis nurses etc.). To keep in touch with this expanding number of team members, the clinical lead in this trust uses WhatsApp to keep in touch as they felt that clinical staff were less likely to pick up emails but they would have their phones on them. NELA data collection is encouraged in some sites by an engaged participant who sends daily emails to colleagues who have admitted a “NELA patient”. One interviewee in the trust felt that “active harassment” of colleagues had led to 99% data completion.

Other sites have displayed posters in theatre areas to keep staff appraised of progress - both in NELA data completion and in mortality rates. And one site theatre staff communication specifically:

“We have staff from level three, they may not be aware of NELA, we make sure that they know. But if deficits arise, it is because they don’t know (they do electives); most of the anaesthetic assistants do know what NELA is and work in this way. We are getting the word out.” [Respondent, Trust B - AHSN 1]

**Project structure**

The ELC initially had a purposeful hub-and spoke design with the information cascading to the hospitals through the AHSNs. As the project evolved and the local teams started to form collaborations, it was the intention for the model to change and for the AHSNs to become the lead for the regions. Concerns were reported of miscommunications that occurred in the earlier days of the project [launch and early set-up], when the AHSNs would not be aware of what was happening regionally if hospitals communicated directly with the more prominent central team and that they would in turn could not be responsive in these situations. This no longer is much of an issue as local links are now
being formed and strengthened, and the information flow is enhanced through additional project manager meetings.

The three AHSNs also have different arrangements in terms of staffing and the way in which the resources are diverted to them; common to all is that they have a clinical lead, who is clinically active in a trust in the region and project managers from the AHSNs.

**Leadership**

The project has used a combination of more centralised and distributed leadership approaches in the project. One of the challenges for the project team has been to develop an appropriate balance between the need to deliver the project within the agreed milestones and the need to develop the collaborative approaches for the project. Four areas for leadership have been identified:

- Leadership on the ELC bundle, the approach to the evidence
- Leadership on QI
- Project management leadership
- Data/and data management leadership

The first two of these emerged out of the expertise from the core group of applicants to the Health Foundation award. They encompass clinical expertise in emergency laparotomy and quality improvement methodology.

**Clinical leadership and leadership on QI**: Decision on the bundle were ultimately made on the basis of clinical expertise and experience. As one of the central team members highlighted this as the basis of the project:

‘[the] ELC bundle was made simple due to the data requirement of the NELA audit and didn’t want to overburden hospitals with more data gathering and wanted to use existing NELA data collection. Decided on some elements that weren’t addressed by NELA (like sepsis = antibiotic cover) but adjusted the number of elements to keep the additional data collection requirements at a minimum.’ [Respondent, Central team]

The development of the bundle was completed in early summer 2015. This then allowed the work of the development of the data dashboard, which came online a number of months later.

The QI component of the ELC is also strongly expertise led. The clinicians in the team have extensive experience and expertise of QI development in health care and are able to draw on a number of QI projects, including those in emergency laparotomy. The development of the quality improvement
syllabus was a more emergent process, with content of the process building on experience in the network events and reflection between events.

**Project management**: the approach to project management has been more fluid and continues to evolve. In planning the first events, and the delivery of milestones, there has been a tendency to keep the decision making and management with the central team among a smaller group of people.

From an AHSN perspective, aspects of the early phase of the project had been a difficult context to adapt to, and some team members in the AHSN were uncertain what their roles were at that point. While the expectation was that

“...to be leading and supporting the hospitals in the AHSN area and assumed that the clinical leads and project managers would have direct contact with the trusts with support from the central team. [Respondent, AHSN 1]

the experience was different. Trusts would often make direct contact with the central team, with the project team members in the AHSNs in some cases not knowing what their specific roles were. This created uncertainty also about the required support expected from the AHSN team members and the role of the AHSN in the ELC delivery.

“ I felt that I had the role of forwarding emails that come from the central team and not much more” [Respondent, AHSN 1]

In the early stages of the project, the leadership of the ELC has had some heavily centralised aspects, maybe more than some of the wider ELC project team members anticipated. Everyday decision were taken by a smaller number of members of the group in order to progress the milestones of the project. A number of drivers underpinned this development:

- The need to deliver on a tight timetable for a large project with a large number of deliverables within the first eight months of the project required a streamlining of decision making;
- The existing expertise in introducing the bundle and delivering QI were firmly linked to clinical expertise and were the focus of the initial project activities;
- The development of the team from a tightly defined applicant group to a multi-layered team structure involving quite different organisations may have led to confusion and uncertainty about roles and processes;
- There was a lack of time available for developing the team and shared structures given the project confines;
- Some early changes to the team staff created additional uncertainty and change at crucial points in the team formation.
However, as the trusts are beginning to implement the project, there are indications that more devolved and distributed approaches are emerging in the leadership of the project.

**Data management:** The work on the data collation for ELC and the associated infrastructure for this in the form of the online data dashboard and the development of comparative data presentation facilities is currently evolving. It draws on analytical and data management expertise, plus the collation and use of the data. Created by the central team, with additional input from one AHSN, the fine tuning and delivery of the data is emerging as a more shared responsibility. AHSNs have become more involved in encouraging the trusts to provide timely returns on the data and also receive necessary updates on progress of their trusts. It is also the area of work where the ELC trusts have proactively and visibly contributed to the overall data production, as a baseline for feeding back to the overall project. That process appears to enhance a more developed leadership approach, with trusts taking responsibility for the production and presentation of their data in network meetings, as well as internally.

**Outlook on the leadership of the trust:** As the participating trusts are still setting up and continue to implement aspects of the ELC in their organisations, energy is focussed on making it work. In some cases this has meant the project seems to lie within a tightly knit group of clinicians within the organisation. However, particularly in some of the larger organisations, teams have widened their approach and are involving a larger range of groups in the implementation, including staff with expertise in patient safety work, from other QI initiatives, and with colleagues from the wider hospital systems. It will be interesting to follow how and if the different organisations will adapt the leadership of the ELC and adapt as the project evolves locally.

**Communication**

Over the course of the first year a number of communication strategies have been developed to keep the teams informed of the progress of the project but also encourage engagement beyond the network meetings.

Much of the formal communication channels such as the website, the newsletter, social media, are used as a means of keeping trust teams informed about aspects of the project, and also to engage a wider audience outside the project (the wider trust communities, professional networks, etc.). The project team has invested quite heavily in these communication channels and they are seen as keeping the information flow going between network meetings and they provide internal communication to
engage with the trust ELC teams. In addition, a number of webinars have been organised to clarify questions that teams may have and highlight aspects of this.

The purpose is to deepen the opportunities for ELC trust teams to clarify questions about the implementation, address any problems and build up resource tools for monitoring progress and document outcome through data. In addition, more traditional channels like visits, phone calls, mail exchanges are used to answer and address specific questions and problems that trusts experience. There have also been visits to the trusts by central team staff to support teams which were perceived to be struggling or who wish to discuss issues. This constitutes a variety of pathways for exchange with trust teams. From the feedback in meetings, it seems that the meeting and phone calls are still the most effective in working through individual queries from the trust teams. They are particularly time consuming for central team members.

Project communication: An additional set of project manager skype meetings, plus more frequent steering group meetings have been instituted to manage the flow of communication and the flow of interaction among the project team more effectively.

An early lesson for scaling up is the considerable effort (in terms of time and resource) required to sustain communication on a scale of a project like this. It also highlights that there is still a great deal of bespoke support required by some of the organisations to work through individual problems. Again, with the project maturing, it is likely that the pattern of communication will evolve to accommodate the changing needs of the trusts and engender greater independence and autonomy.

Learning

One the emerging aspects in delineating scaling up in this project is the way the potential for learning is realised by the trusts, how they use what they learned about quality improvement methods, implementation, about strategies for engagement with internal stakeholders about the project. Reflective learning of both hard/technical skills, but also soft skills may be a major driver in sustaining the project and in maintaining the scaling up effort beyond the end of the project.

The curriculum put together by the project team and delivered over the course of the two years will have covered a number of topic areas in relation to QI techniques, the use and interpretation of the NELA data through the dashboard for monitoring and reporting purposes, skills on persuasion and pitching, and leadership concepts, engagement approaches etc.. In addition, the networking opportunities and the other media channels offer the opportunity for the trust teams to exchange and adopt good ideas and bring them into their own organisational settings.
The way the different trust teams respond to the opportunity for learning is emerging quite slowly in trusts and is tied up with the experiential learning that occurs through the setting up and implementing of the ELC bundle in the trusts. At this interim stage a number of developments are emerging.

**The use of “technical” skills in the project:** Trusts so far have made considerable progress in using the run charts, data comparisons and applying them in their team work, but also for dissemination. In one of the trusts, a co-lead of the project described the data dashboard as a main distinguishing feature of the ELC in comparison to other QI initiatives, but also something which distinguishes the ELC initiative from the introduction of NELA “we are now using the charts and the data much more systematically and can trace our progress” [Respondent, Trust C - AHSN 1]. Knowledge of the data dashboard and how it can be used is noticeably improving and the dashboard graphs have been used in all of the trust ELC meetings that were observed so far. Outcome data extracted from the dashboard were also used in larger meetings where the project was presented to a wider audience. The ELC teams have plans to use their performance data at wider meetings in the future.

**Quality improvement skills:** PDSA cycles and trying out and reviewing the set-up of the bundle in the trusts had also been used; in most of the case study sites, the ELC MDT meetings are an important forum where the ELC agenda can be taken forward operationally and where informal reviews about progress can occur; the meetings are also used for developing new ideas on how to take them forward. For example, one of the trusts is using monthly charts pinned up in the operating theatre suites to highlight outcomes on various dimensions of the bundle as a way of creating ‘talking points’ among staff about the ELC and its progress.

It needs to be noted that some of the lead clinicians in the trusts did not see themselves as active QI practitioners or as consciously using the QI methods

“I don’t think I am doing anything else than I did before. The younger generation of doctors is much better trained in this and they are better set up in using these tools. I am familiar with some, but I can’t say am actively using them” [Respondent, Trust D - AHSN 2]

**“Soft” skills:** devolved leadership, persuasion, engagement were all present in the trust observations and meetings, but interviewees did not highlight these as ‘new’ skills which were acquired through the project. Most of the case study sites so far visited had experience of using soft skills through previous initiatives, like the implementation of NELA audit tool, and in some cases the EPOCH and ELPQUIC initiatives. But the ELC trust teams so far were not using them as strategic tools for pushing the ELC project within their organisations. In Trust G, AHSN 3, the initially reluctant engagement of
the surgical teams had been overcome some time earlier, through a number of presentations of NELA mortality data to the surgical colleagues by the clinical lead for NELA, who is also continuing in the ELC role. It will be interesting to see in the further case studies and also in the progression of the ELC projects in the trusts, to what extent soft skills such as furthering engagement and ‘winning’ over both clinical colleagues but also in overcoming persistent barriers encountered with the bundle, will engender more deliberate and reflective approaches to the implementation of the bundle.

One area where none of the trust teams have as yet made use of the opportunities of the ELC is to network across organisations and make more of informal collaborative learning through networking outside the meetings. All interviewees have valued the meeting not only for the ELC, but also specifically for the networking opportunities it offered. “It is good to hear about the experience of the others …” is a common response when asked about the events. However, the current network activity is limited to internal exchanges, with no systematic attempt to take advantage of the networks outside the meetings. Over time, as trusts teams get to know each other better, this may evolve further.

**Stakeholders**

At this point in the project time table, the trusts are still engaged in implementing the bundles and focussed on developing the improvement in all the elements in the bundle. However, as data is accumulating and the trends in improvement are becoming visible, the project is becoming known among the wider stakeholder group in the trusts.

Improved stakeholder interest can be a motivating experience. In one of the trusts, the availability of data has been recognised as an opportunity for further use. In Trust G, AHSN 3, the clinical lead was asked for data to support the Trust in a case before the coroner’s court. While none of the ELC data was used directly, the interest in the data indicates that trusts are interested in the outcome of the ELC initiative and may wish to use this data for other purposes.

This can have both beneficial as well as challenging outcomes: in Trust C in AHSN 1, ELC outcome data have been translated into saved bed days and acknowledge as supporting financial savings in the trust. This constitutes a significant success for the ELC team in the Trust. Conversely though, in Trust A, AHSN 1, the outcome data have led to a challenge by senior trust staff about the timescale of the progress; the ELC work may have increased expectations about the rate of improvement and its sustainability.

One of the upcoming challenges for the trust teams will be on how to manage the expectations of a project like this beyond the confines of the QI work. Maybe not surprisingly, with increased data
availability, the focus on outcomes makes the ELC an interesting area for discussing broader issues in trust performance. This is of course positive and can result in the heightening of the profile of the initiative and lead to greater support, as well as recognition. There is also has the potential for cutting across the ‘spirit’ of QI if expectations in the wider internal trust stakeholder community are not managed appropriately and over inflated expectations about the pace and degree of improvement develop. In turn, this may undermine the efforts of the ELC Trust teams. Expectation management may well be something that the trust teams will have to address further over the next period. This may require further guidance and input from the central team and the AHSNs.

Role of the evidence-base

Whilst the original reasoning for the use of the bundles is clear cut and was piloted successfully, issues have arisen with ELC hospitals having low compliance with some of the components of the bundle.

For the central team, the ELC bundle is a protocol-driven implementation that has been shown to work and has a strong evidence-base. The question is really why would it not be used, with some acceptance that there is a change in how people are now appraising the evidence:

“The project takes a fairly didactic approach to the fluid directed therapy. The evidence base may have slightly shifted in that from the ELPQuIC project. The evidence is still in favour, but people are challenging more than [they did] 5 years ago” [Respondent, Central team]

However, some clinicians in the trusts participating in ELC are not wholly convinced and have raised this at meetings and in interviews:

“...goal directed therapy – most of us believe it is completely unconvincing. Some of the evidence cited is showing the opposite and wholly unconvincing.” [Respondent, Trust B -AHSN 1]

Others pointed to the fact that their mortality rates had already decreased substantially without complying fully with the ELC bundle. They had previously reviewed their care processes before joining the ELC and were not convinced about adopting Goal Directed Fluid Therapy (GDFT) as part of their EL pathway:

“...we struggle with GDFT, not clinically accepted overall.... it’s used on very sick patients even though the clinicians say they don’t use it... the trust has the equipment and we organised training at the start of ELC but it’s still not being used by all doctors. The doctors using it, used it before they started ELC and weren’t necessarily convinced by ELC “ [Respondent, Trust D -AHSN 2]

Whilst the evidence-base and being convinced of the legitimacy of the bundle elements is of obvious importance, low compliance was also reported as being due to local contexts and organisational
concerns. Admitting every EL patient to ICU was the next bundle component were these particular
care. Admitting every EL patient to ICU was the next bundle component were these particular
concerns were raised:

“ICU admission: there is no evidence for benefit of all of this. Admitting a patient with a low
risk of mortality of 2% means not admitting somebody with trauma with a 5-10% mortality. You
can imagine if the medics are coming and say, oh we have a patient with pneumonia we
think it is slightly arbitrary. And although where we can see that a patient might benefit to
come to ICU, we will try and admit them, I think taking on everybody is bit of a difficult sell.”
[Respondent, Trust B -AHSN 1]

“The problem has always been on availability of beds. High dependency beds. We have only
five beds; Level one can get usually, but if the beds are full, then we have a problem we because
then they need to move out. ICU beds are also limited.” [Respondent, Trust A - AHSN 1]

While ELC trust teams remain overwhelmingly enthusiastic about the ELC and the bundle, they are
also compromising on some aspects of implementation either because it is difficult to implement an
element in the trust for pragmatic reasons, for example because the service is organised mitigates
against full compliance. On occasion ELC team members come across opposition because clinical
colleagues are not convinced of the evidence underpinning the element of the bundle, something ELC
trust project members may well share in. The teams have developed different ways of dealing with
this, by making alternative arrangements or by modifying the expectation of complying with the
bundle.

Varying rates of progress

Hospitals engaged with the ELC project at different rates:

- QI experience - personal experience of QI projects, QI projects within their departments and
within their organisations. Most of the team members in Trust I in AHSN 3 have personal
experience of QI as part of their previous and current job roles and work in an organisational
culture which encourages QI. One of their clinical leads has started a QI academy for junior
doctors. Trust D in AHSN 2 paid for staff to have access to the online patient safety and QI
course run by the Institute for Healthcare Improvement. Their QI team also run monthly QI
training courses.

- Engagement with their data -the hospitals further ahead with the NELA data collection process
were also further ahead with engaging with their data and lining it up with other areas of work
(sepsis, deteriorating patient etc.) and were planning other pieces of work (on care of the
elderly, frailty scores).

- Hospitals varied in terms of stakeholder engagement - the size of their teams varied and the
team members who attended ELC events and meetings varied.
Data

The use of data is a large component of the ELC project and as would have been expected it plays a large role in the day to day activities of the central team members and the hospital ELC teams’ activities.

**Data collection processes:** As has been mentioned, the central team incorporated the use of an established NELA audit database into the ELC project. NELA was in its second year of existence when the funding application was being written. As part of the set up process, the central team negotiated access to the NELA data and required the hospital teams to complete and send in their NELA data on a quarterly basis.

Collection of data was organised through the central team, predominantly by the data analyst and project manager. Links have been made with personnel in the hospitals who either coordinate the data collection or who are data collectors. The majority of these members of the ELC trust teams do not attend the ELC events. Approaching the quarterly data deadlines, a reminder is sent out to the hospitals and then teams are chased up by the central team project manager or by the AHSN project managers. Only 18 of 28 centres returned their data at the first quarter but by the second all had completed and this was sustained at the third quarter.

The data dashboard has been coordinated by the central team also. A great deal of time was spent getting information sharing agreements signed by the executive levels of the hospital so that hospitals can see each other’s data. This contrasts with the open way in which the hospitals share their data and progress at the ELC meetings.

By the start of the ELC project, hospitals were in their second year of collecting and sending data to NELA. It is a centrally-funded national audit that is on the list of national audits for inclusion in Trusts’ Quality Accounts so hospitals should already have systems in place for regular data collection and submission. What we found in the first few months of the ELC was that a number of hospitals were still trying to get their data collection processes to run smoothly. Hospitals which were ahead in terms of their data collection have engaged a number of people on their clinical teams to be involved in the process such as trainees, a senior consultant to coordinate and/or an audit team staff member to facilitate the data collection. These hospitals had already brought in the equipment to collect data as part of their care pathway such as having a laptop in theatre [*ELC meeting attendee from Trust G-AHSN 3*] or having a form on their electronic health records [*Respondent, Trust H-AHSN 3*]. The
hospitals that were struggling were smaller, relied on one person and were collecting all of their data retrospectively.

**Learning to interpret the data:** Each of the cross-collaborative events provided training which enabled attendees to share their data and to learn how to interpret the data through using run charts. The breakout sessions in each meeting allowed for hospital teams to present to each other and to ask for further help with areas they may have been struggling with. The central teams were on hand in each breakout session to help with this and in the last cross-collaborative event in Spring 2016 the AHSN teams had more prominent roles in helping to coordinate the running of the breakout sessions. What has emerged from these sessions is that hospital teams have become more familiar with their data and are aware of its limitations for operational use. Some of the interpretations of the data limitations were discussed openly in the breakout sessions such as the data not being complete that month or that quarter, low activity in their hospital for that time period or issues with recording deaths. Never the less, the hospitals cold see the value of working with the data, despite limitations, to chart their progress. They have been able to see how their compliance with certain measures compares with other hospitals - such as presence of consultant surgeons or anaesthetists or the use of GDFT.

**Engagement with the data:** The better organised (or resourced) hospitals, in terms of NELA data collection, are further ahead in how they are able to engage with the data. They demonstrate thorough knowledge of their own data and have ownership of it. Work has also been done to develop strategies to explain outliers and take remedial action if the data shows that progress is slowing. The interviews so far indicate that clinical leads in these trusts embrace the opportunity to engage with the data within and outside of their organisations. Data is variously used to communicate the progress being made with the project implementation and with improved patient outcomes in Trust newsletters, posters in theatres and on a poster at an international conference [Trust H in AHSN 3]. Data and involvement in the project has helped with negotiating extra staff and resources [Trust I in AHSN 3] and having the data has been useful for reporting outcomes outside of the trust [Trust G in AHSN 3]. Engaging with the data has allowed trust teams to look further ahead to see where else in the EL pathway they can improve. Some trusts are now looking at their clinical decision making and are looking to see if all their EL patients should be operated on. Trust D in AHSN 2 want to incorporate the use of frailty scores in their pathway and have a Care of the Elderly research fellow to look at morbidity in older patients. Trust I in AHSN 3 is also looking at risk scores and mentioned that they had developed their own trust ELC data dashboard.
Linking with other work

A number of the trusts have already engaged with wider systems and initiatives in their organisations, including working with patient safety, internal quality improvement divisions and other clinical initiatives, which were deemed to be of relevance. These are regarded by the teams as opportunities not only to develop additional support for the project, but also start to develop the longer term supporting structures for ELC in the trusts. This theme is something that will be pursued further over the second year to see how common place this practice of linking becomes.

Sustainability

The ELC project is time limited. The experience of other projects of this type has been that when the project ends, there is the danger that the progress made through quality improvement is diminishing as core staff move on, as organisational goals change, pressure of other priorities tend to take over, and the learning dissipates. Time and resources may become more limited. Sustaining the progress made and developing means of supporting the work beyond the end of the project is emerging as an additional goal for the project.

The project team is beginning to focus on the challenge of preserving the ELC work beyond the end of the project. The project has produced a number of resources which may help in this process. These include the dataset, accessible through the dashboard; the various project materials that were developed as the part of the project, the website, the ELC syllabus and resources linked to it; documentation, webinars, social media. These are concrete resources that can be used by the ELC trust teams and of course others. The project team has begun to discuss on how these resources could be curated and maintained proactively after the end of the project. Recent discussions (June/July 2016) have focussed on developing ideas around this.

There are also some more intangible legacies that have been developed as part of the ELC work, which also need to be preserved including:

- ELC teams in trusts experienced in QI and collaborative working;
- Networks of ELC teams in AHSN and across the geography;
- Learning, knowledge and competencies acquired during the projects by individuals and teams;
- The practices of data recording and monitoring established in the trusts.

The ELC trust teams themselves have not explored sustainability directly, given that some are still preoccupied with driving the implementation forward. However, when asked in the interviews about
this, some respondents from the more experienced ELC teams, where there is experience of participating in a number of projects in relation to emergency laparotomy, point to the realistic chance that work may well continue through other projects or through the NELA initiative itself. It will be interesting to see to what extent less experienced trusts will be able to continue with the work without this history of activity to fall back on.

Over the course of the next period in the project, the trust ELC teams will need to develop the plans for the continuity of their work; this may be an area of work where the AHSNs may play a specific role in engendering a debate around this, but they also may be able to develop geographical based solution in partnership with the trusts in their respective areas.

**Discussion**

The emerging themes discussed in the process evaluation are interim. Hence, the following comments are preliminary reflections of these findings.

One of the central challenges emerging for the scaling up work in the ELC is that the project is having to strike a balance between delivering the numerous elements for the project (introducing the bundle to multiple trusts, developing the data platform and managing data delivery, developing the QI syllabus etc.) in a timely manner, while also developing a collaboration over a number of organisations, maintaining attention to regional diversity, and working with differences among the collaborating organisations. This constitutes a significance challenge for the ELC project team, including the ASHN team members, on a continuous basis. It highlights the need to adapt strategies of working in order to be able to respond to the changes in the project. As a consequence, the tasks of the project have been more challenging, more time consuming and more resource intensive than were and could have been anticipated. From informal discussion we know that the members of the project team and the collaborating organisations have expended considerably additional time (including personal time) and resource into the project and continue to do so. It is to the credit of the overall team and their commitment to the collaborative that the project has progressed at pace and the various elements of the projects continue to be developed, by moving between more centralised and collaborative ways of working. This can be seen in parts of the set-up phase for the project, when the delivery of the launch, the planning of the QI syllabus required more centralised planning. It was also noticeable in the development of the NELA database dashboard and the set-up of the regular data collection processes from the trusts. Centralising some of the project work has not been without tension or confusion, as the various team members of the collaborative have become uncertain about their roles
within the project. In response, contact has been increased through additional meetings, for example the project manager phone conferences which constitute additional contact points for exchange and team work.

As the project matures, there are also elements where the project is beginning to draw on the broader collaborative to deliver the aims of the project and is moving to more localised decision making. Lanham et al. highlight the importance of self-organisation which determines the success of scaling up in their organisations and where improvement is guided by available resources and organisational set-ups (2013). In the AHSN network meetings, increased time is given to exchanges of experience among the trusts ELC teams, their successes, difficulties, barriers and set-backs, and to future plans. Working with the trust teams, collaborative reflection and exchange with trust ELC teams likely to occupy an increasingly significant part of the collaborative work in the project (Nembhard 2012). Facilitating local learning and exchange is also an area where the AHSN may play an increasingly important role, because of their regional knowledge about the trusts and the existing relationships (Lanham et al. 2013; Glasgow et al. 2012; Ayers et al. 2005).

The process of implementation adopted by the ELC echoes experiences of QI work more generally, which have highlighted the patterns of vertical co-leadership approaches (integrating top down and bottom up approaches) (Stewart et al. 2015; Morrow et al. 2012). In the case of the ELC project, the complexity is further amplified by an emerging horizontal diffusion of leadership between the clinical, QI and project management roles (across the project team) and changes of leadership emphasis over the duration of the project (the temporal dimension).

A lesson for the broader agenda of scaling up of QI initiatives is that the overarching project team needs to have flexibility and robustness in its structure and relationships in order to utilise different approaches for different tasks of the scaling up effort (Simmons et al. 2007). For scaling up initiatives which involve working across organisational boundaries, it will also involve developing project teams across a number of organisations, in a context where there may be limited time for team formation. Hence, developing ways for accelerating team building is central. It will involve development and agreement on functions and roles, plus the building of good team relationships. The ELC responded to these challenges by adapting its working at different stages of the project set-up and implementation, and by adjusting communications and structures within the project team. For future projects, there is a case for building in additional space and time for team building and reflection on approaches to make this process easier.
Communication at all levels is recognised as centrally important to the progress of QI projects (Health Foundation 2015). In the ELC, developing communication has been a demanding and time consuming activity. Balancing the demands of various aspects of communication linked to spread the QI elements of the project, making resources available to all the teams, developing strategies for supporting individual teams, as well as providing a public profile for the ELC has been a significant task throughout the project so far and remains a resource intensive element of the project. The work of scaling up seems to require an equivalent scaling up of communication work, in order to ensure that participating teams and wider stakeholders are kept informed, and that the project receives appropriate external attention. The ELC has made extensive use of online facilities and social media. The website and range of media employed are impressive and the project resources allocated to this task have been used to capacity. The hosting AHSN involved its own professional communication team to take on some of the work. Nevertheless the specialist nature of the project requires continued input by the project team members. The broader lesson is that a project like this may require a distinct and integrated work package for communication in order to maximise the communication channels and also to conserve the time team members have for other core activities.

To date, the ELC trust teams have the utilised mainly more tangible outputs of the project, by using the formal (the ‘taught’ aspects of the project) and informal learning opportunities through the networking with other trusts at the ELC meetings. The ELC trust teams have been enabled in their ‘sense making’ of the project in their trusts through the availability of the dashboard, the data graphs, the QI syllabus taught at the meetings, and on-line resources. They have also been able to draw on the informal support made available by the project team (phone calls, visits etc.). They are utilising ‘good ideas’ used by other trusts to enhance the implementation of their projects and increase engagement. In addition, in some of the case study sites the experience of the networking in the events seems to have focussed attention on opportunities for further collaboration within the trust. Linkages ‘within’ hospitals around shared areas of interest are emerging as “mini” collaborations, which are taken further by some groups. They are not taking place ‘between’ hospitals as yet. This is an area where there is be an opportunity for the project team and the AHSNs to do some further enabling work.

Less tangible outputs such as the strategic use of soft skills in progressing the ELC work (networking, relationship building, persuading) are currently less visible in the trust team discussions. In many cases, team members already network, are building relationships as part of the ELC work, but these actions are not necessarily strategically applied or deliberately built into the plans of the ELC trust teams. This is maybe not surprising because soft skills are less accessible for immediate use and have
to be built up over time. Some of the trusts have employed strategic engagement work with their stakeholders by using the data dissemination and advocacy to highlight problems and achievements, and by expanding on their engagement work outside the service areas involved in the teams (World Health Organization 2010).

The work of the ELC project is beginning to highlight a tension between the project delivery/project management focus of scaling up and the QI work. Project management works best in the context of tightly defined tasks and activities delivered within agreed time scales to agreed specifications. “Scaling up” fits into this ‘mould’ of project management, because it too requires a tight focus and mechanisms for monitoring in order to produce definite outcomes (Perla et al. 2013; Milat et al. 2016). On the other hand, Quality Improvement work is an iterative and fluid process, centred on relationship building, sense making and negotiation, and is non-linear in character (Kaplan et al. 2010). Hence, working on QI at scale does not lend itself easily to project management principles, because different elements of the system progress at different paces, are informed by different motivations and are constrained or enabled by diverse organisational contexts.

Within the experience of the ELC this is playing out at various levels of the project: the emerging patterns of centralised elements of the work linking with more collaborative approaches, the importance of the communication channels that have been developed in order to keep engagement and information flow going, and focus on the concrete examples of collaborative learning in the trust work on ELC.

As an organisational process, a wider question is beginning to emerge from the experiences of the ELC: How can output focussed project management with tight timelines, milestones and clearly defined outcome productively coexist with developmental and complex quality improvement work at scale in the longer term? This is a question to the overall scaling up initiative and whether other projects have had similar experiences. We hope to address this further in our work over the next year. We will also be interested to hear whether similar findings are emerging in the other scaling up projects.

**Interim conclusions and next steps**

At this interim stage, various themes for the evaluation have been developed. This includes preparatory work to enable the summative evaluation at the end of the project, work on the health cost analysis, as well as work in developing an understanding of the processes involved in the project set up and implementation. The work done on the outcome and health economics evaluation so far has centred on developing analysis plans.
First data have been analysed for the process evaluation, in particular the set-up of the projects in the central team, AHSN and trusts. The process evaluation findings to date indicate that developing and implementing a bundle such as the ELC is highly complex and challenging. Implementing the bundle across a number of organisations required the team to develop a mixed approach to the collaborative work. This involves combining more centralised approaches in delivering the learning elements, the data system and the QI syllabus with more distributed collaborative elements of working, as the project is developing in the participating trusts.

The project also highlights that there may be particular areas which need to be more fully resourced in scaling up work of this magnitude, including time to develop as a team at various stages, and space to reflect on the changing project requirements. Communication is emerging as a distinct work package for the project, enhancing the channels for effective dissemination of the project elements, enabling exchange among a large number of participating organisations, and engaging with a broad stakeholder group. For the trusts, emerging benefits of participating in the ELC project are that they have access to the tangible output to the project in the form of the NELA dashboard, which helps them with data processing, learning of how to interpret and make sense of their outcomes; as well as the learning and exchanges through the meetings. They also benefit from the ideas of other trusts through networking opportunities at the meetings.

The next steps for the health economics and outcome evaluation will be to collate the data and start analysis. Depending on agreeing the format of the outcome evaluation, data analysis will commence in spring 2017. Subject to agreement on the best way forward, this will be further expanded on beyond the end of the project.

For the process evaluation, the first round of case study work will be completed, for which additional time has been allocated. The second round of data collection will start from November 2016, including both interviews with team members of the project team (from the central team and the AHSNs), and in the trusts. We are also looking to develop the thematic analysis further by mapping the findings to the Normalisation Process Theory framework and testing out the themes as to their generalizability for scaling up health initiatives. We are looking forward to drawing on the experiences of the other evaluations of the Health Foundation programme at the meeting in the autumn. We believe that an early exchange on emerging themes and findings across the various project evaluations will be helpful in distilling the lessons of scaling up initiatives.
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Appendices

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Appendix A: Protocol
Evaluation of the Emergency Laparotomy Collaborative (ELC) Quality Improvement project: Improving outcomes after emergency laparotomy.

Principal Investigator: Professor Stephen Peckham
Centre for Health Services Studies, University of Kent.
George Allen Wing
Canterbury
CT2 7NF
Tel: 01227 827645
Email: s.peckham@kent.ac.uk
Research team: Professor Simon Coulton, Annette King, Dr David Lowery, Ugochi Nwulu, Dr Katerina Gousia.

Rationale and background information
This project evaluates the Quality Improvement project - Emergency Laparotomy Collaborative (ELC) funded by the Health Foundation. The improvement programme aims to improve patient outcomes after emergency abdominal surgery by scaling up the use of a new care pathway (the ELPQuIC pathway) in acute hospitals, using Quality Improvement methodology. ELC aims to work with hospitals and surgery services to embed the amended ELPQuIC pathway (developed and piloted in four hospitals) into at least 20 additional hospitals spanning the geographical area covered by three Academic Health Science Networks (AHSN) (Kent Surrey Sussex, West of England and Wessex). The improvement programme will run over two years, starting in September 2015. An evaluation will be conducted alongside to study the outcome and process of the ELC project.

Emergency Laparotomy
Emergency laparotomy is a high-risk surgical procedure. 30 day mortality for this group of patients is reported at 14.9% and rising to 24.4% for patients over the age of 80 years. Patients that survive this operation often suffer post-operative complications and have associated long stays in hospital. Significant variations in standards of care have also been reported. An evidence based care pathway (ELPQuIC) was developed at Royal Surrey County Hospital (RSCH) in Guildford. It was introduced at RSCH and 3 other English hospitals as part of a quality improvement collaborative pilot. The amended pathway used for the ELC project contains five elements:
• Early assessment and resuscitation
• Antibiotics administered to patients who show signs of sepsis
• Prompt diagnosis and early surgery
• Goal-directed fluid therapy in theatres and continued to ICU
• Post-operative Intensive care for all

Results from the pilot have shown improvements in key standards of care. Crude 30-day mortality for all patients has been reduced by 25%. Risk adjusted hospital mortality rates have been reduced by 42%. The scaling-up quality improvement programme aims to deliver a reduction in mortality similar to that achieved at the original sites. The adoption process will be facilitated by quality improvement techniques. The evaluation will assess how to and to what extent the programme can deliver this, examine whether key outcomes have changed, explore retrospective audit data to identify predictors of length of stay for older people including identifying the reasons for prolonged hospital stay or delayed discharge and assess whether there has been any changes in practice.

Improvement methods
Improvement in Emergency Laparotomy care will be measured by whether the pathway is followed in its entirety and consistently through data available through a new online audit facility, the National Emergency Laparotomy Audit (NELA). NELA is an online database which collates routinely collected clinical data from all providers of emergency laparotomy, and transforms them into reports for monitoring quality of care and comparing data from all providers of emergency laparotomy (http://www.nela.org.uk/). As NELA records compliance with the five relevant dimensions of the pathway, reports can be drawn down on the use of the amended ELPQuIC pathway and used to monitor progress on implementation.

In addition, the improvement framework proposes a range of activities offered over the course of the project to facilitate the process of adoption of the care pathway in trusts, enable collaboration across teams and regions on improvement, enhance diffusion of innovation, and ensure sustainability of the improvement over time. These activities will be time limited to the duration of the project. They are:

- A set of education and network events, alternating between events for all participating teams and AHSN local teams. This is organised by the core improvement team. These events will encompass educational and coaching elements for the local teams. They will incorporate training of how to use the NELA database (if not already used), how to draw down relevant reports and how use them to track improvement,
identify areas of good practice and need for improvement. In addition, training in on how to employ improvement methods, such as PDSA, will be provided. Activities envisaged at this level will also incorporate broader work on current evidence in laparotomy.

- Work at AHSN level will involve further events, designed to bring the various partners together to share experience, provide mutual support and build networks across the participating organisations. Each area has a specially appointed clinical lead/local improvement champion, who will also act as liaison between clinical services and implementation teams across trusts, AHSN and represent clinical leadership regionally. They will be supported by regional members of the core improvement team.

- Work within the participating organisations and services. The focus will be to support embedding the amended ELPQuIC pathway into the multi-disciplinary teams and practice, ensure continuous and proactive support of the initiative within the trust hierarchy, alert and highlight the work to internal stakeholders and enable dissemination. An internal improvement champion will work with the core team and the regional support to lead on the improvement. They can draw on core team support where required.

Evaluation aims and objectives

The evaluation element has been funded alongside the implementation project, but remains independent from it. The overall aim of the evaluation is to determine whether and to what extent the approach for improvement used by the EL programme delivers sustainable improvement in outcomes of EL, and what can be learned from the quality improvement methods employed by this project.

The objectives of the evaluation are as follows:

- To assess the benefit and relevance of the amended Emergency Laparotomy Quality Improvement Care (ELPQuIC) pathway to improved patient care and outcomes
- To determine the feasibility of collaborative approaches (e.g. peer influence, clinical networks) to supporting the diffusion of the ELPQuIC innovation
- To assess the adoptability of ELPQuIC by surgical teams, directorates etc. in individual Trusts.
- To determine the degree of adoption of ELPQuIC by surgical teams in the roll-out hospitals
- Explore the impact on staff (e.g. work practices), patients and their carers

Table 1 identifies the key research questions and how these meet these stated objectives.
### Table 1: Research questions.

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<thead>
<tr>
<th>Research questions</th>
<th>Sub-questions for data collection</th>
<th>Data collection method</th>
<th>Evaluation objective</th>
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<tbody>
<tr>
<td>Is the adopted collaborative implementation approach effective in embedding new</td>
<td>1. Does the set-up and structure of the improvement programme achieve effective scaling up?</td>
<td>Initial survey: (Q: 2, 7)</td>
<td>To determine the feasibility of collaborative approaches (e.g. peer influence, clinical networks) to supporting the diffusion of the ELPQuIC innovation</td>
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<td>clinical pathways in practice?</td>
<td>2. How does set-up and structure of the improvement programme work in scaling up?</td>
<td>Routine data: (Q:2, 3, 7)</td>
<td>To assess the adoptability of ELPQuIC by surgical teams, directorates etc. in individual Trusts</td>
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<td>3. What are the salient elements in the design and delivery of the programme in scaling up?</td>
<td>Case studies:</td>
<td>To determine the degree of adoption of ELPQuIC by surgical teams in the roll-out hospitals</td>
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<td>4. What are processes that enable scaling up and what hinders scaling up?</td>
<td>Interviews/ discussions with stakeholders at Trust, AHSN and central team level; Documents; Observations ; (Q1, 4,5,6,7, 8, 9)</td>
<td>To determine if there is a difference in fidelity to ELPQuIC care bundle after implementation in comparison to prior?</td>
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<td>5. What adjustments and changes in the set-up and delivery of programme are made during the</td>
<td>NELA data</td>
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<td>Improvement programme and what are the reasons for this?</td>
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<td></td>
<td>6. What can we learn from the set-up and structure that enable set-up?</td>
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<td>7. What is the role of the various stakeholders of the improvement programme in ensuring</td>
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<td>effective scaling up (i.e. steering group, the local implementation teams, the hospital organisation and hierarchy...)?</td>
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| To what extent does the delivery of ELPQuIC lead to improved patient care in individual hospitals adopting the ELPQuIC pathway? | 8. To what extent is the approach sustainable in the long-term?  
9. How adoptable is the approach for more wide scale adoption of ELPQuIC if found to be effective? | 1. How is the ELPQuIC bundle delivered in different hospitals  
2. Does it deliver on the agreed metrics and the key outcomes measures in individual sites and for the whole programme?  
3. How do the various sites introduce, implement and monitor ELPQuIC?  
4. What are the time scales and the degree of progress in metrics and outcome measure achievements over the course of the projects?  
5. What are the processes in implementing and reviewing the metrics and key outcome measures which help or hinder the delivery of ELPQuIC?  
6. What are the perceptions of key stakeholders about implementation and outcomes of the pathway?  
7. To what extent do changes in practice and patient outcomes meet key targets | Initial survey:  
Routine data: (Q 1  
Case study sites: (Q 3, 4, 5, 6)  
Documents;  
Interviews. discussions with stakeholders at Trust, AHSN and central team level;  
Observations  
NELA data | To assess the benefit and relevance of the ELPQuIC pathway to improved patient care and outcomes  
Explore the impact on staff (eg work practices), patients and their carers  
To assess for changes in adjusted mortality rates, rates of readmission to theatre and length of stay |
| Does adoption of the ELPQuIC pathway lead to reduced length of stay for older people? | 1. **For older people, does the ELPQuIC reduce length of stay in hospital?**  
2. **What are the factors that contribute to reduced length of stay or prolonged or delayed hospital stay of older people?**  
3. **What is the role of the addition to peri-operative care (including initial assessment and MTD input) to ELPQuIC impact on length of stay?**  
4. **What are the outcomes for patients by stratified age groups (<80 and ≥80)?** | Initial survey:  
Routine data: (Q2)  
Case study sites:  
Documents:  
Interviews, discussions with stakeholders at Trust, AHSN level; (Q2)  
NELA data (Q 1, 3) | To assess the benefit and relevance of the ELPQuIC pathway to improved patient care and outcomes  
Explore the impact on staff (eg work practices), patients and their carers |
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<tr>
<td>What are the costs of providing emergency laparotomy care and the specific costs of providing the ELPQuIC pathway?</td>
<td>1. <strong>What are the costs associated with LP care and those of the ELPQuIC pathway</strong></td>
<td>Economic analysis: Identify the unit costs for activity</td>
<td>To assess the benefit and relevance of the ELPQuIC pathway to improved patient care and outcomes</td>
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Study approach

The evaluation will employ a mixed methods approach encompassing process and summative evaluation (Petticrew et al 2013). It will use a combination of quantitative routine data, documentary evidence and a comparative case study approach (Craig et al 2008). The aim will be to assess whether the participating hospitals improve outcomes and to understand the processes that lead to particular outcomes. Process and summative evaluation are important in order to reduce bias and also to understand why particular outcomes are identified (Pronovost and Jha 2014).

The evaluation will analyse routinely collected data from the National Emergency Laparotomy Audit (NELA), plus secondary health care data to analyse outcomes. NELA will provide baseline data for the study and data from non-participating hospitals for comparison.

The evaluation will collect qualitative data on the implementation of the amended ELPQuIC pathway, and examine the views and perceptions of key staff members to understand the organisational processes of knowledge diffusion and innovation implementation. It will focus on four dimensions of the scaling up programme: in particular the set-up and structure of the programme (the organisational and programme components), the delivery of ELPQuIC through metrics and outcome measures (management and performance components), the interrelationship and impact between the programme and the wider problem of length of hospital stay for older people (older people), and costs involved in delivering ELPQuIC (financial component).

Summative evaluation

The summative evaluation will use data collected through the NELA national audit system to:

- Examine whether there have been changes in outcomes assessing mortality, ITU usage and re-admissions
- explore the potential effect of the intervention stratified by age group; <=80 years and 80 or more years
- Assess changes in practice and patient impacts against key metrics (See section 4.2)

In order to quantify the potential effect of the amended ELPQuIC bundle we will conduct two quantitative analyses. Outcomes will be collected as part of the routine NELA national audit data collection, and will include: in-hospital mortality, 30, 90 and 180 day mortality, ITU usage and emergency re-admissions to theatre.
As the intervention has the potential to have a differential impact on older patients a secondary analysis will explore the influence of age group; <=80 years and 80 or more years, as an interaction term on the analysis. Analysis will also explore the relationship between fidelity and any observed outcome over the post-implementation period. Care bundle elements assessed for fidelity will include: Assessment of sepsis with timely antibiotics, knife to skin within 6 hours of decision to operate, use of goal directed fluid therapy, consultant surgeon and anaesthetist presence and intensive care for all patients.

While this approach will provide information on the potential impact of the care bundle within participating hospitals a need arises to explore for any potential contemporaneous confounding factors by comparing intervention patients in participant hospitals with similar patients across the wider NHS. A matched control group will be derived from Hospital Episode Statistics matched on size of hospital and key demographic indicators.

Process evaluation approach
The process evaluation will draw on the principles of Normalisation Process Theory (NPT) to focus on the processes through which ELC, as an organisational process, is made workable and becomes integrated into everyday practice (May et al 2007, May et al 2009). This approach focuses on the actors and their behaviour, the objects (the means by which knowledge and practice are enacted) aimed at changing expertise and actions, and contexts. NPT provides a framework for assessing the “normalisation” of practice (sense-making, cognitive participation, collective action and reflexive monitoring) and a framework for analysis focusing on how legitimate space is created for the work of the intervention to become a routine part of the landscape (Willis et al 2012). A recent review of NPT supports the value of the approach “... as a conceptual framework to analyze implementation processes and inform recommendations to guide implementation work.” (McEvoy et al 2014: 9:2).

Through the comparative case studies approach, the process evaluation will track and compare the development of the improvement process, collecting data at two points (initial and final) stages. In line with the Normalisation Process Theory, it will investigate how and to what extent the improvement activities contribute to the embedding process, if at all and at what point teams will become independent operators in sustaining improvement achievements, or even pushing improvement further. It will explore the claims underlying the activities (Weiss 1998) and look for evidence as to whether or not these programme theories can be seen in practice. Delineating the
successful components in the programme will provide a significant learning opportunity for other contexts, as will activities that are less successful.

Methodology

Data collection

The project will use the following:

*Pre-implementation questionnaire*

A pre-implementation questionnaire will be sent out to all hospital trusts which agreed to participate. The questionnaire will cover basic information about the hospital and its laparotomy service, including number of beds in the hospital and level of activity in laparotomy, its status as a teaching hospital and any specialism in ortho-geriatric care (for identifying potential candidates for the length of stay sub study). The questionnaire will also collect basic information of experience with quality improvement initiatives and research, and about using of the NELA database.

*Routine data*

The National Emergency Laparotomy Audit (NELA) is part of the National Clinical Audit and Patient Outcomes Programme and is overseen by the Healthcare Quality Improvement Partnership. All patients aged 18 and over undergoing emergency laparotomy in England or Wales are enrolled automatically. A structured audit tool is used to collect data locally at hospitals (Appendix??); this is usually completed retrospectively by a research nurse or audit officer and stored remotely by the Central NELA team. Data is locked when all fields are completed and becomes available for extraction. Firewalls ensure that data can only be extracted by hospitals from which the data originated.

For the purposes of the planned evaluation, data will be retrieved from the routinely collected National Emergency Laparotomy Audit (NELA) patient audit dataset for all participating hospitals. The ELC implementation team will collate data from participating hospitals in pseudo-anonymised format for analysis by the evaluation team. Data will be provided at the patient level and will be recoded by the evaluation team where necessary to provide more meaningful analysis. Additionally, HQIP have been granted permission to retrieve additional data from ONS and link to the NELA dataset at the patient level. This data includes longer-term mortality rates and will be retrieved under the process described above.
All trusts participating in the implementation programme will be asked to provide additional basic information about the team composition, documentation central to the implementation process.

**Case studies**

Ten case studies study sites will be selected, based on assessment of early and late adopters of Quality Improvement (QI). Recruitment of all hospitals into the programme will be made in September 2015 however we anticipate that it is likely for some hospitals to implement the new pathway immediately (early adopters) others may take more time (late adopters). Early adopters may already have experience with QI and/or some of the improvement audit tools and projects, such as the NELA database. Conversely, late adopters may have little experience so far and require more intensive support and education/mentoring, particularly in the beginning of the process. The case studies will be selected using the pre-implementation questionnaire and discussions with the core implementation team and AHSN representatives, who will know participating trusts.

Care will be taken to achieve good spread across the three geographical AHSN areas, the type of hospital (teaching/ non-teaching) and size of service and number of beds. The aim is to develop a balanced portfolio of case study sites.

There is the opportunity to conduct work in up to two additional case studies sites, if it becomes clear that the implementation process in a trust, not originally included as a case study, warrants further investigation. For example, monitoring data may identify a hospital that has significantly different metrics (significantly “better” or “worse”) or more soft intelligence suggests that a particular hospital or surgical team has identified characteristics relating to implementation that is worthy of further investigation. These ‘outliers’ can then be pulled into the overall process evaluation.

**Plan of work**

For all trusts in the implementation process, the following documentation will be collected by the research team:

**Process analysis**

Implementation protocols, meeting schedules, team membership, meeting agendas and minutes, data reports, plus central communication exchanges with the trust hierarchy (report to trust boards,
internal and external presentations etc.) will be accessed via the project managers and/relevant implementation champions in the trusts. The documentation will be used to map the process across the implementation programme. We will collect documentary evidence throughout the project asking for routine provision of any meeting notes or copies of policies from AHSNs and hospitals. Documents will be indexed by site and type. Where possible electronic forms of documents will be collected to allow easier searching and extracting of relevant data. Documents will be coded using the same coding framework as used for interviews.

In the case study sites, observations and interviews with key informants will be conducted at two time points (beginning and end) of the implementation process. A topic guide will be developed that elicits the views of key informants about the plans for the implementation, how the process is working, the value of the improvement activities in accessing this, organisational issues encountered as part of the implementation process. The topic guide will vary slightly in its emphasis according to the role in the organisation and relationship to the improvement project, taking into account the roles in the process and the particular perspective individuals can contribute.

Key informants will include:

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<th>Individuals/functions</th>
<th>Central team (1)</th>
<th>AHSN (3)</th>
<th>Trust service teams (10)</th>
<th>Trust leadership (10)</th>
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</thead>
<tbody>
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<td></td>
<td>Programme CI and Co-I; the project manager; another</td>
<td>Project managers; Clinical leads; plus 1</td>
<td>Champion; local project managers; team members (surgeons, anaesthetists, nurse)</td>
<td>Medical Director; Improvement Lead; Data manager</td>
</tr>
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<td>Key informants Numbers up to</td>
<td>4</td>
<td>9</td>
<td>50</td>
<td>30</td>
</tr>
<tr>
<td>Plus two additional trusts as required</td>
<td>n/a</td>
<td>n/a</td>
<td>10</td>
<td>6</td>
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<tr>
<td>Total number of data collection points</td>
<td>8</td>
<td>27</td>
<td>120</td>
<td>n/a</td>
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</tbody>
</table>
The views of the central implementation team will be captured using semi-structured interviews with key personnel in the core team, AHSN level, and in trusts. We will interview up to four members of the central improvement team twice over the duration of the project. In addition the evaluation team will participate in core team meetings as a matter of course. There will also be observation at the educational events planned a number of local AHSN events will be attended.

At AHSN level, key individuals will be interviewed at two time points in the programme (beginning and towards the end). Up to three individual will be invited to participate, a total of six interviews in each AHSN area.

At trust level, for each service team up to five team members will be included in the data collection, plus up to three trust representatives.

A number of modes for eliciting the views of informants will be employed. On the basis of a common topic guide, a combination of telephone, face-to-face interviews and group discussions will be conducted. While core team members will be interviewed separately, informants from AHSN and service teams, will be invited to participate via group interviews, if possible as part of MDT or project meetings. This has the advantage of capturing various perspectives through a group process. Data collection in this phase will need to operate flexibly, so as not to burden the teams unduly with additional pressures on their time.

In addition, a limited number of observations will be conducted. Evaluation team members will be attending core project team meetings on a regular basis. They will attend a selection of events organised by the implementation team centrally and at AHSN levels. Evaluation team members will also observe a number of local implementation MDT meetings. Notes taken at these meetings will be provide an observation based context to the interviews. Between 4 and 8 meeting observations are planned.

*Health Economics component*

Where possible, in the sub-sample of hospitals we will also provide a description of the costs of providing emergency laparotomy care. Variations between hospitals will be studied and we identify methods and approaches utilised for reducing costs. The specific costs of providing the ELPQuIC pathway will be identified. There are few studies of the costs of laparotomy. Shapter et al (2012)
undertook a study of a single provider giving an estimate of £13,000 but as Murray et al (2012) demonstrate there are huge variations in care for patients giving rise to cost variations which are unrelated to patient outcomes. We will explore the potential of costing utilising different approaches such as unit cost and also time-driven activity based costing (French et al 2013, Öker and Özyapici 2013). The aim in this project will be to provide adequate costing details to support decision-making by provider organisations and commissioners and where possible provide cost and outcome data.

**Data analysis**

**Outcome study:**

In order to quantify the potential effect of the amended ELPQuIC pathway we will conduct two quantitative analyses. The first will explore data within participating centres using a difference in differences approach. We will evaluate differences observed in outcomes for a historical control, 12 months prior to implementation, versus an intervention group over the 12-months post implementation. Outcomes will be collected as part of the routine data collection, identified in sections 3 and 4 above and will include; in-hospital mortality, 30, 90 and 180 day mortality, ITU usage and emergency re-admission to theatre. The analysis will be weighted to address relative demographic differences in the two populations and robust standard errors, derived using the Huber-White Sandwich estimation approach and 95% confidence intervals will be presented for each of the outcomes in order to address potential within and between hospital influences. Data will be derived from existing audit data (NELA) available over the evaluation period from each of the participating sites.

A detailed statistical analysis plan will be written and agreed by the Evaluation Steering Group prior to the conclusion of the implementation phase. The Statistical analysis package SPSS (IBM Corp. Released 2013. IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp) will be used for all analysis.

**Process evaluation of case study and documentary material:**

The qualitative data collected will part-transcribed and otherwise summarised, focussing on major themes. The analysis will use a framework approach (Ritchie and Spencer 1994). Comparative case-study analysis seeks to identify and explain patterns across and within organisations and case-study sites and is especially suited to complex interventions. The analysis strategy will be to observe, describe and explain the interaction between implementation process delivered by the core team.
and uptake in local hospitals by surgical teams; to identify and explain patterns of implementation in each case study site; to examine the relative influence of the AHSNs and central project team on implementation; to compare and contrast different service models; identify interim outcomes in terms of changes in outcomes and process metrics and impact on patients. The analysis will be structured around the research aims identified above, using Ritchie and Spencer's ‘Framework’ for applied research (Spencer et al 2013). As described above interviews and focus groups will be transcribed and explored to uncover main themes. Transcripts will be analysed, drawing on a thematic framework that covers the key research questions for the study and issues that arise during the research. The framework will be kept under review and revised as necessary. Documents will be coded to identify key themes and decisions made. The NVIVO software package will be utilised to facilitate this process. Data collected at the will be analysed to identify major themes and compared in-case and cross-case. Data collected in the first stage (early part of the improvement project), will be analysed to identify and describe emergent organisational process structures/interactions, which inform the strategies for implementing the care pathway into everyday routines. In the second part of the data collection, the development of the organisational process structures/interactions will be analysed comparatively and developments tracked. Through this, success factors in the implementation process can identified and lessons learned about the normalisation process underpinning the implementation (May et al 2007, May et al 2009).

Data Management and Statistical Analysis
All data held on the project will be held in accordance with the data management requirements of the University of Kent. Qualitative data will be held securely and only the research team will have access. Data will be coded according to an agreed coding frame. Data coding will be conducted by two researchers of the research team; consistency in coding will be compared by double coding a sample of the data. Divergence will be identified and discussed and if necessary a third team member will be involved to resolve any remaining issues.

Data for the summative evaluation analysis will be retrieved from the routinely collected National Emergency Laparotomy Audit (NELA) patient data set for all participating hospitals. The ELPQuiC implementation team will collate data from participating hospitals for analysis by the evaluation team. The implementation team will collate extracted NELA data for all fields in the dataset and send an unmodified dataset (save for a code added to identify the participating site) to the evaluation team. The evaluation team will re-code - where necessary - any variables as per a pre-
agreed and locked statistical analysis plan. The evaluation team will retain the data on a password protected folder, with access permitted to only members of the evaluation team.

Our final analysis and synthesis of the data will focus on developing recommendations for policy and practice as well as contributing to an understanding of the process of local implementation highlighting inter-relationships between context, the role of local and regional organisations and the actions of local and regional practitioners/professionals as process adopters and implementation facilitators. Continuous feedback will help validate our analyses and act as a further opportunity to gather participant critiques of and reflection on the data collected. Thus our analyses will be informed by a range of stakeholder perceptions.

Quality Assurance
The protocol should describe the quality control and quality assurance system for the conduct of the study, including GCP, follow up by clinical monitors, DSMB, data management etc.

Steering group
A steering group for the evaluation has been established. It consists of the lead of the evaluation team, three representatives from the Implementation team, and up to three members of the evaluation team. The remit of the evaluation is to monitor the evaluation process, ensure a good fit between the evaluation and implementation, and as a link between the two components of the study. They will also be a forum to resolve any fundamental issues and problem encountered during the evaluation.

Expected Outcomes of the Study
The study will be used to support the implementation work for the ELPQuIC pathway. It will also provide a report on approaches to successful implementation for more general use as well as identifying strategies for supporting implementation in practice. We will provide regular updates to the research team and Health Foundation as well as a final report.

Dissemination of Results and Publication Policy
Dissemination and engagement with the implementation team and the Health Foundation (as funder) are key elements of the project. There will be continued engagement with local stakeholders and the implementation team throughout the project providing feedback on the process aspects of implementation. We will be involved in a final workshop for users and practitioners from the case studies and decision/policy-makers/practitioners from the wider NHS and community. Other research outputs will include a final report, articles in peer reviewed academic journals such as *Implementation Science* and articles in practitioner journals such as the *Health Service Journal*. We will present at relevant professional/academic conferences and meetings. Summary reports from all phases and the final report will be submitted to the funding body.

### Duration of the Project

The initial stage of work commenced in June 2015 focusing on formulation with the process and outcome phases commencing in September 2015. The project ends 30th June 2017.

### Project Management

The evaluation project will be undertaken by a research team based at the Centre for Health Services Studies, University of Kent. The team will be led by Professor Stephen Peckham and Professor Simon Coulton. Qualitative aspects of the evaluation will be undertaken by Annette King and Ugochi Nwulu and quantitative analysis by Dr David Lowery. The economics element of the study will be undertaken by Dr Katerina Gousia.

### Ethics

NHS ethics approval is not required for this project but we will be applying for NHS research governance. Ethics approval for the study will be applied for from the School of Social Policy, Sociology and Social Research at the University of Kent.

### Financing and Insurance

Research funded by the Health Foundation.

For the evaluation research component the University of Kent will be the sponsor and insurer.
References:


Ritchie, J., & Spencer, L. (1994). Qualitative data analysis for applied pol-icy research. In Brynam & Burgess (Eds.), Analyzing qualitative data (pp. 173-194)


Appendix B: Evidence Scan
Evidence scan of the scale-up of quality improvement initiatives
Key points:

- A number of terms are used interchangeably with ‘scale-up’ - spread, diffusion and dissemination.
- Methods that have been described for scaling up of innovations are broadly based on those for “spread of innovations”.
- Spread and sustainability models have components that concentrate on the innovation, the settings, context and the spread strategy.
- Factors that positively influence the spread of innovation are also likely to contribute to sustained implementation.

Questions that the evidence scan will answer:

- How is “scaling-up” defined?
- What are successful characteristics of scaling-up programmes?
- What are the barriers to successfully scaling-up interventions/innovations/programmes?
- What contributes to sustainability and spread for long-term implementation of interventions/innovations/programmes?
- What kind of QI interventions/innovations/programmes have been scaled-up?

Methods used:

The evidence scan was comprised of a non-systematic literature review using two bibliographic databases – Medline and Google Scholar. This database search was accompanied by searches of the reference lists in the reports and journal articles retrieved. Whilst the evidence was sourced and compiled systematically the scan itself is not systematic and was not used to summarise every study about the scale-up of quality improvement interventions. Instead the overarching aim was to identify and summarise the themes in the literature about the scaling up of QI interventions and the factors that may affect their success.
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Key terms

“Scaling-up” in the healthcare literature refers to activities of spreading, diffusing and disseminating initiatives and innovations. All of these terms mainly refer to the spread of an intervention from one clinical area (hospital, ward, GP practice) to a larger area (hospitals, networks, regions, nationally). Scale-up is often used interchangeably with these terms (especially with ‘spread’) and there is a lack of accepted, universal definitions (1). There are, however, some key distinctions that are outlined in the definitions below.

Adoption: the process through which an entity (organisation, sector, setting) comes into knowledge of, forms attitudes about, decides to take on or reject, and implement an innovation (2)

Diffusion: passive spread of innovation through a healthcare system (3), it refers to the process of an innovation spreading, being adopted, or being communicated.

Dissemination: active and planned efforts to persuade target groups to adopt an intervention (3)

Implementation: active and planned (systematic) efforts to achieve uptake of an innovation within an organisation (3)

Spread: the consistent and reliable spread of dissemination of best practice across a whole system that involves the implementation of proven interventions in each applicable health setting (4,5)

Scale-up: efforts to disseminate and implement a successful intervention across a system or systems. This can be done horizontally – where innovations are replicated in different locations or are expanded to serve a larger population. Vertical scaling up occurs when innovations are institutionalized through policy or legal action. Diversification, which is also referred to as functional scaling up, consists of testing and adding new interventions to existing innovations (6).

Scale-out: a distinction made when an intervention is rolled out to other locations at the same scale, e.g. from one team to another within an organisation (7)

Large scale change: multiple, system-wide interventions that aim to improve efficiency, quality and patient outcomes in a health care system (8)

Sustainability: when new ways of thinking and practice within an organization becomes a routine part of care delivery and continues to deliver improved outcomes (9)
Introduction

Scaling up in health care literature has mainly been used to describe activities needed to spread healthcare programmes (often population health interventions) and innovations in health systems in developing countries. The World Health Organisation (WHO) defines scaling-up as:

“...deliberate efforts to increase the impact of successfully tested health interventions so as to benefit more people and to foster policy and program development on a lasting basis” (6).

Examples in the literature that specifically use the phrases “scale-up” and quality improvement (QI) can again be found in health services in developing countries (10) but a change of emphasis is often found in studies in developed countries. Here, scale-up of quality improvement is a little more nuanced in that it seeks to enable wider implementation of QI innovation which will lead to less variation in care and a narrowing of the “quality chasm” as defined by the Institute of Medicine (11). How to spread good quality evidence-based innovations is an ongoing problem for health systems and the “spread and sustainability” of successful QI initiatives is something the Health Foundation is keen to promote through its Scaling Up Improvement funding grant (12).

Many QI pilots have little to moderate impact when applied more broadly and the wider and more complex the change (such as having multiple components and / or through multiple organisations), the least likely that spread will happen (13). It has been stated that more effort or resources are invested in pilot programmes run by enthusiastic teams in single hospitals and that issues of spread and scale can become afterthoughts (14). Successful small scale implementations often attribute that success to the implementation mechanisms when it may be due to having access to exceptional resources - such as a project team, technical assistance, training and support for staff. Challenges to any planned scale up/spread occur when these resources are no longer available as by their definition they are project-specific and therefore time-limited. This lack of resources coupled with features of the innovation, target adopters, environment/context, and scale up/spread strategy can lead to unsuccessful scaling up of a previously successful pilot implementation. Norton et al define scaling-up as the spread of a tested or successful pilot to increase the impact of the innovation (1) and
others have looked at how social innovations are successfully scaled up and related those methods to healthcare –

“Unless a program can be replicated and sustained on a large scale, it will not be transformational…. We can no longer evaluate programs simply based on how well they’ve performed in a given locality. Instead, we need to factor in their potential to achieve scale” (14,15).

Models of scale or spread

A number of studies and reports outline ways in which innovations/programmes should be scaled-up or spread. Many of them build on or have adapted the influential work of Everett Rogers, with his diffusion of innovation theory (16), and Greenhalgh and colleagues who have studied how innovation is diffused in healthcare contexts (3).

This evidence scan will touch upon the elements that are influential to scaling up of innovation as outlined in the WHO’s conceptual framework (see Figure 1) - the innovation, the user organization, the environment, the resource team and the scaling up strategy itself.

![Figure 1: The ExpandNet/WHO framework for developing a scaling up strategy](image-url)
Factors that influence spread / scaling up of innovations

The innovation
To increase the likelihood of spread and adoption at scale, stakeholders must consider how the benefits, relevance and feasibility of an innovation will appeal to adoption sites. Absence of any of these features will affect the scale up as potential adopters may modify the innovation or look for alternatives.

For successful take up, the innovation must be evidence-based and evaluated and supported by empirical data, published in reports or in peer-reviewed journals (17–19). The evidence must relate to the effectiveness of the innovation, how it works in different settings and how it is of benefit in relation to current practice (20). Potential adopters must perceive the innovation (or parts of it) as being useful and having a relative advantage over current practices and incurring little or low risk if adopted (2). The innovation must be simple as complex interventions may get lost at scale (21). There may also be tensions around the complexity of the innovation to be scaled up. Innovations are more likely to be adopted at scale if they are simpler but paradoxically with regards to the context of healthcare settings the problem being addressed may need a more complex innovation (2,22).

The process of scaling up may be affected if potential adopters are sceptical of the usefulness of the innovation, or the methods needed to implement it and if there are unresolved tensions about elements of the innovation and/ or implementation (2,9,23).

The user organization
The target adopter must have in place adequate resources (staffing, skills, time, space, equipment and funds) before they adopt an innovation to give it the best possible chance of being implemented with the impact and success of the original pilot (24,25). The use of skills and capacity audits within each adoption site or setting will help to determine the feasibility of scaling-up there as well as which frontline staff members are already in place and if more need to be recruited (2). In addition, for organisations to adapt to the planned changes and get the expertise of the pilot site, processes such as staff retraining, mentoring, coaching and leadership development should be in place (26).
Strong leadership (as well as the capacity to develop leadership in the organisation) is a facilitator of innovation adoption at scale (27). Whilst leadership from supportive senior management and clinicians is important when committing the organisation to adopt QI innovation (28) it must also be participative in order for it to be effective (29). Other studies have identified that the leadership (and influence) should be multi-directional and not just top-down (30). Distributed leadership means that influencers / local champions are therefore present at more levels of an innovation site (not just at the top) and for the purposes of the scaling up, they’ll ideally be placed across innovations settings as well (31). Whilst it is important to have senior management (and they will give local champions authority and legitimacy), all staff would be aware of and be engaged in the changes need for adopting the innovation (19,32).

Conversely, studies have identified some limitations in using local champions, especially if there is an over reliance on one person within an organisation or on one organisation within the scaling up process as it could lead to organisational fatigue (2). Other organisational barriers identified are a lack of financial and human resources from the outset as well as insufficient resources to last the length of the scaling up process - especially if an organization does not have qualified or committed personnel.

**The environment / culture**

Each organisation will have an organisational culture or context that should be recognised as being influential to any scale up plans. It is essential that stakeholders identify potential cultural strengths and weaknesses when planning large-scale change (27). For instance, adoption of an innovation is more likely in an organisation that has a culture of adoption of innovative practices and strategies.

Scale-up and spread initiatives are often designed to be implanted and reproduced with total fidelity. Failures of these initiatives can be due to not considering the variation in local contexts among different health care organisations. Lanham argues that allowing organisations to “self-organize” leads to better adoption of innovation in complex systems across diverse organisations and settings (33). Self-organisation is described as a process whereby local planning and interactions give rise to patterns of organising that can’t be
predicted and are hard to influence. These local interactions are shaped by how people determine the most effective way(s) to complete tasks given their locally available resources and contexts (33). Understanding how local contexts can shape intervention implementation and allowing for it can be challenging (34) but it can facilitate successful scale up and spread (33).

Other identified barriers in the literature are that the economic drivers behind the adoption of innovation are not as clear cut in the healthcare sector as in other industries. QI and efficiency in processes have been adopted far quicker in other industries (e.g. manufacturing) as the cost of providing care and the economical decision making in complex healthcare systems with diverse payment arrangements obfuscates the economic advantages of adopting an innovation over current practice (35).

Other perceived barriers are around the cultural traits in the medical profession that inhibit large scale QI, such as it being a conservative professional body when it comes to change in processes as well as the perceived loss of hard-won autonomy of medical practice by adopting behaviours needed for change (35). Meier and colleagues further outline these factors of resilience to change when looking at the slowness in adopting electronic health records (36).

The spread and scale up strategy

*Preparation phase*

Commonly, studies have reported on the utility of preparation phases:

- For the innovation - that it takes at least one year to develop and test a pilot before it is ready for wide scale dissemination (37);
- For the identified adoption sites - to audit their preparedness to adopt the innovation (2);
- For the scale up strategy - to develop systems to monitor progress and the impact of the scale up. Monitoring progress requires a reliable data process and infrastructure to collect data and to link the data to the changes and the results (27). And ideally the systems should focus on measuring effectiveness, reach, fidelity, acceptability and costs (26).
**Scale up team and timeframes**

Whilst a traditional project management team is an important resource for local change efforts, a large-scale initiative will need a team with a more diverse and flexible skill set (24). In addition, timescales need to be realistic in order to set up partnerships and to develop new skills in the innovation sites.

**Spread and scale up methods**

In small-scale implementations, “push” factors greatly influence the success of innovations. An example would be having an on-site team that encourages staff to adopt innovative practices. By contrast, large-scale implementations tend to use “pull” factors, such as external pressures, regulatory or normative expectations, incentives and rewards (38). Successful adoption in sites requires a more balanced approach to motivators as change is often experienced by front line staff as an imposition rather than them wanting to change (14). Frontline staff, who often are the ones changing their work processes or behaviour to incorporate QI implementations, often feel they have little ownership to these changes being imposed on them (39). Staff in localities outside the pilot site, may also feel this lack of ownership with the innovation. One way of engaging staff more is to have a distributed leadership plan or local innovation champions who are part of or connected with the scale up team.

**Collaborative or learning networks**

Studies have described the use of networks as a mechanism for large-scale sustainable improvement. The networks connect stakeholders with a common interest in QI and are known as being a valuable tool to increase workforce QI capability. As well as raising awareness of better practice and of the evidence-base, networks work to develop QI knowledge that hopefully will lead to behaviour change (40). Collaborative networks are mainly based on the multi-organizational collaborative improvement model (Breakthrough Series) developed by the Institute of Healthcare Improvement (41,42). Social connections made through participating in the collaborative networks allows for further engagement though social support which is available when difficulties are encountered (43) and through collaborative relationships sustained outside of the initial implementation phase (44).
Sustainability

Some of the factors for effective spread of QI adoption of innovation are also important factors that influence the sustainability of the implementation (14).

Internal factors, within organisations, that are important to successful sustainability of QI work are:

1. Senior leadership involvement as part of the implementation as this can lead to organizational changes, strategies and support that encourages sustainability (41). Organizational leadership can also lead to continued promotion of the work and resource allocation that allows for the work to continue (45,46);
2. Changes to organizational culture as part of the QI work can increase the perceived value and importance of the work;
3. Efforts made to embed changes in organizational systems can lead to a transfer of QI capacity in motivated individuals to organizational processes that then become routine (47);
4. Involvement of multidisciplinary teams as this enhances the rate and breadth of change as communication across a range of disciplines in organizations is enhanced (44).

External factors, outside of the participating organisations, that can lead to sustainability are:

1. The changes and influence of the wider healthcare environment – i.e. the impact of other hospitals and organisations such as professional and regulatory bodies;
2. Alignment of the QI implementation objectives to national policy directives and priorities;
3. Intentional spread strategies through the QI collaboratives and social networks (45)

Some barriers to sustainability as identified in the literature:

1. Differing motivations that adoption sites, organisations and people may have in participating (48);
2. If the topic or topics are not seen as relevant, busy clinicians may not be incentivized to adopt or sustain changes regardless of the evidence-base (49);
3. Waning enthusiasm/commitment after the initial implementation period;
4. Reliance on a small number of champions to spread the changes and sustain the work in the long term;
5. Lack of dedicated time or resources that allows for continued consistent participation;
6. Lack of senior leadership in engaging and supporting the work;
7. And a hesitation to participate due to ‘fatigue’ or “this is just another initiative” (50)

Finally, the role of communication and engagement are also important factors in sustainability. Communication contributes to the successful spread and sustainability of the QI work if strategies are developed at an early stage, ideally in the pre-implementation phase. Effective communication strategies sustain interest in the QI work if opportunities are created for participants to communicate; if everyone’s contribution is celebrated throughout the phases of the implementation; and if communications are kept up-to-date, targeted and two-way (51).

**Conclusions**

This brief scan of the literature has identified several factors that can contribute to successful scale-up and spread efforts. Firstly, innovation adopters need a preparatory phase to assess their resources and any requirements needed to develop and implement the innovation. This pre-adoption time will also allow them to align any available incentives and expectations. Secondly, a communication strategy should be developed that allows adopters to develop awareness and assess the costs and benefits of the innovation as this will lead them to an understanding of the requirements needed to adopt. Third, potential adopters should be provided technical assistance, tools, and resources, including guidance for adaptation of the innovation and for management of their local context. Finally, if heterogeneity across settings is recognized and addressed then adoption will most likely be accepted and sustained at the adoption sites.
Examples of scaled up QI initiatives

Case study 1

The effect of a national quality improvement collaborative on prehospital care for acute myocardial infarction and stroke in England. (52)

In England, a two-year collaborative aimed to improve ambulance care heart attack or stroke patients. Quality improvement teams were set up in each of 12 ambulance services, supported by a national expert group that conducted workshops about improvement methods. Teams shared ideas at three national workshops and improvement leads had monthly teleconferences. Annotated control charts were used to provide feedback about progress. The focus was on improving the delivery of care bundles (aspirin, glyceryl trinitrate, pain assessment and analgesia for heart attacks and face-arm-speech test, blood pressure and blood glucose recording for stroke). Analysis of change over time found significant improvements in heart attack care bundles in nine out of 12 services and in stroke care bundles in nine out of 12 services. Overall care bundle performance increased in England from 43% to 79% for heart attacks and from 83% to 96% for stroke.

This QI collaborative aimed to provide an environment that supported quality improvement. This was achieved through engaging staff, particularly frontline staff at various levels of seniority, to share QI expertise and experience at both local and national levels, and by feeding back their improvement data. This engagement of frontline staff from the beginning of the project meant that they were able to take ownership of and lead the changes that took place. Engagement also engendered positive responses from colleagues towards the changes that local collaborative members implemented and the trusts reported that this encouraged their colleagues to adapt these methods to improve the delivery of care for other clinical conditions.

Case study 2

MRSA prevention in six hospitals (33,53,54)

Researchers in this case sought to reduce the incidence of health care-associated Methicillin resistant S. aureus (HA-MRSA) in six hospitals by promoting adherence to evidence-based infection prevention practices (e.g. hand hygiene, appropriate use of personal protective equipment, and active surveillance). This study was conducted over 3 years, from 2005 to 2008, and hospitals piloted the process in a number of nursing units. The initiative generated interest, so that other units sought to participate. The design employed activities that were intended to encourage interactions among local stakeholders and exchanges of information both within and between participating hospitals. This study was one of the first multi-institutional, geographically dispersed efforts to show positive results for HA-MRSA.
prevention. All six participating hospitals achieved significant decreases in MRSA infection rates (the aggregate absolute decline across all hospitals was 44%).

Lindberg et al. used a change process called Positive Deviance (PD), which is grounded in their understanding of health care delivery systems as complex systems. The PD approach to behaviour and social change is based on the assumption that in most social systems, individuals or groups develop practices and patterns of interaction that enable them to achieve better outcomes than their peers who have the same resources. They employ self-organization plans in a different, more effective way that is suited to their local context. These better practices are used as the platform for more widespread behaviour change.

PD was associated with positively influencing self-organization at multiple scales within nursing units, within hospitals, and across health systems and it showed the nonlinear nature of behaviour in complex systems. Small changes in the pilot units lead to larger changes across the hospitals which in turn lead to the diffusion of PD to numerous other health care organizations.
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35. Easton J. An Opinion Piece: Why quality improvement at scale is hard in healthcare and what deep action we might take to address the issue. [Internet]. London; Available from: https://www.ucl.ac.uk/pcph/research-groups-themes/isl-pub/further-reading/Why_Quality_Improvement_in_healthcare_is_hard_v3_JWE.pdf


Appendix C: Outcomes Evaluation – statistical analysis plan
Statistical Analysis Plan for Summative Evaluation of Outcomes at the Conclusion of the Emergency Laparotomy Pathway Quality Improvement Care (ELPQuiC) bundle delivered by the Emergency Laparotomy Collaborative (ELC).

Version: 1
Date: 29/07/2016

David Lowery, Simon Coulton
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### Analysis Plan Development

- First draft prepared by David Lowery 16th May 2016  
- Modified by Simon Coulton 21st July 2016  
- Version 1 presented to Advisory group – 29th July
1. Introduction

This statistical analysis plan has been developed based on information from the study protocol (version 1) combined with detail agreed through discussion with the Evaluation Advisory committee (29th July 2016) and further meetings. The plan is focused on evaluating the implementation of the Emergency Laparotomy Pathway Quality Improvement Care (ELPQuIC) intervention for patient outcomes after emergency laparotomy surgery.

Implementation of the ELPQuIC intervention commenced in November 2015. Data will be retrieved for summative evaluation in March 2017 with data analysis to begin in March 2017. It is intended that the intervention would become standard practice within the participating sites and consequently use of the intervention would continue beyond the conclusion of this evaluation.

The statistical packages STATA (version 13) will be used for all analyses.

2. Aims and objectives

Research Aim

To determine whether and to what extent the approach for improvement used by the EL programme delivers sustainable improvement in patient outcomes.

Objectives

1. To assess the effect of the Emergency Laparotomy Quality Improvement Care (ELPQuIC) pathway on patient outcomes
2. To explore the relationship between fidelity to the ELPQuIC bundle and observed patient outcomes
3. To explore whether age is important for outcomes after emergency laparotomy surgery (ELS)
4. To determine whether adoption of the ELPQuIC pathway leads to reduced length of stay for people older than 80 years?
5. To identify factors that predict length of stay for older people undergoing ELS?
6. What is the role of the addition to peri-operative care (including initial assessment and MTD input) to ELPQuIC impact on length of stay?

3. Design

In order to explore the potential effect of the amended ELPQuIC bundle we will conduct two quantitative analyses. Outcomes will be retrieved from the National Emergency Laparotomy national audit (NELA). This will include: in-hospital mortality, ITU usage and emergency re-admissions to theatre. In addition, longer term mortality status (30, 90 and 180 day) will be retrieved from the Office for National Statistics dataset (ONS). The Health Quality Improvement Partnership will provide ONS data linked at the participant level to individuals on the NELA dataset.
As the intervention has the potential to have a differential impact on older patients, a secondary analysis will explore the influence of age group; <80 years and 80 or more years, as an interaction term on the analysis. Analysis will also explore the relationship between fidelity and any observed outcome over the post-implementation period. Care bundle elements assessed for fidelity will include: Assessment of sepsis with timely antibiotics, knife to skin within 6 hours of decision to operate, use of goal directed fluid therapy, consultant surgeon and anaesthetist presence in surgery and discharge to intensive care for all patients following surgery.

While this approach will provide information on the potential impact of the care bundle within participating hospitals a need arises to explore for any potential contemporaneous confounding factors by comparing intervention patients in participant hospitals with similar patients across the wider NHS. A matched control group will be derived from Hospital Episode Statistics matched on size of hospital and key demographic indicators.

4. Outcomes

The primary outcome will be patient level risk adjusted mortality.

Secondary outcomes include length of stay, number of days spent in Intensive Care Unit or High Dependency Admission, need for further surgery in addition to first emergency laparotomy, post-operative P-PoSSUM mortality risk.

Age and sex will be entered as interaction terms

5. Intervention

Current Care Pathways

The ELPQuic intervention

The ELPQuic intervention uses a ‘care bundle’ approach to incorporate evidence-based clinical guidelines into the care pathway for emergency laparotomy procedures. The elements of the care bundle for the purposes of this implementation study include: involvement of surgical and anaesthetic consultants; the use of intra-operative goal directed fluid therapy; timely administration of antibiotics and post-operative intensive care.

Implementation

The ELQUiPC intervention was piloted in four National Health Service hospitals. Implementation of the intervention is to be rolled out to NHS hospitals across the geographical area covered the three Academic Health Science Networks (AHSN) (Kent, Surrey, Sussex, West of England and Wessex) as part of an Emergency Laparotomy Collaborative (ELC).

Participating centres

- Royal Sussex County Hospital (Brighton and Sussex University Hospitals NHS Trust)
- Princess Royal Hospital (Brighton and Sussex University Hospitals NHS Trust)
- Conquest Hospital (East Sussex Healthcare NHS Trust)
- Eastbourne Hospital (East Sussex Healthcare NHS Trust)
- East Surrey Hospital (Surrey and Sussex Healthcare NHS Trust)
- Caterham and Dene Hospital (Surrey and Sussex Healthcare NHS Trust)
- Oxted Health Centre (Surrey and Sussex Healthcare NHS Trust)
- Crawley and Horsham Hospitals (Surrey and Sussex Healthcare NHS Trust)
- St Richard’s Hospital (Western Sussex Hospital NHS Foundation Trust)
- Southlands Hospital (Western Sussex Hospital NHS Foundation Trust)
- Worthing Hospital (Western Sussex Hospital NHS Foundation Trust)
- Darent Valley Hospital (Dartford and Gravesham NHS Trust)
- Queen Mary’s Hospital (Dartford and Gravesham NHS Trust)
- Medway Maritime Hospital (Medway NHS Foundation Trust)
- Maidstone and Tunbridge Wells NHS Trust
- William Harvey Hospital (East Kent Hospitals University NHS Foundation Trust)
- Queen Elizabeth the Queen Mother Hospital (East Kent Hospitals University NHS Foundation Trust)
- Ashford Hospital (Ashford and St Peter’s Hospital NHS Foundation Trust)
- St Peter’s Hospital (Ashford and St Peter’s Hospital NHS Foundation Trust)
- Frimley Park and Wrexham Park Hospital (Frimley Health NHS Foundation Trust)
- Royal Surrey County Hospital NHS Foundation Trust
- Dorset County Hospital NHS Foundation Trust
- Hampshire Hospitals NHS Foundation Trust
- Isle of Wight NHS Trust
- Poole Hospital NHS Foundation Trust
- The Queen Alexandra Hospital (Portsmouth Hospitals NHS Trust)
- The Royal Bournemouth and Christchurch Hospitals NHS Foundation Trust
- University Hospital Southampton NHS Foundation Trust
- Cheltenham General (Gloucestershire Hospitals NHS Foundation Trust)
- Gloucestershire Royal Hospitals (Gloucestershire Hospitals NHS Foundation Trust)
- Great Western Hospital (Great Western Hospitals NHS Foundation Trust)
- Frenchay Hospital (North Bristol NHS Trust)
- Cossham and Southmead Hospital Bristol (North Bristol NHS Trust)
- Royal United Hospital Bath NHS Trust
- University Hospital Bristol NHS Foundation Trust

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6. Data Collection

The National Emergency Laparotomy Audit (NELA) is part of the National Clinical Audit and Patient Outcomes Programme and is overseen by the Healthcare Quality Improvement Partnership. All patients aged 18 and over undergoing emergency laparotomy in England or Wales are enrolled automatically. A structured audit tool is used to collect data locally at hospitals; this is usually completed retrospectively by a research nurse or audit officer and stored remotely by the Central NELA team. Data is locked when all fields are completed and becomes available for extraction. Firewalls ensure that data can only be extracted by hospitals from which the data originated.

For the purposes of the planned evaluation, data will be retrieved from the routinely collected National Emergency Laparotomy Audit (NELA) patient audit dataset for all participating hospitals. The Emergency Laparotomy Collaborative implementation team will collate data from participating hospitals in pseudo-anonymised format for analysis by the evaluation team. Data will be provided at the patient level and will be re-coded by the evaluation team to ensure robust analysis and where necessary to provide more meaningful results. Data to be retrieved are listed in Table 1 below.

Additionally, the Health Quality Improvement Partnership (HQIP) have been granted permission to retrieve additional data from ONS and link to the NELA dataset at the patient level. This data includes longer-term mortality rates and will be retrieved under the process described above.
Table 1 Data to be extracted from NELA database

<table>
<thead>
<tr>
<th>Variable</th>
<th>Field name</th>
<th>Description</th>
<th>Excel location</th>
<th>Proforma question</th>
<th>NELA Original Value</th>
<th>Recoded Value</th>
<th>Data Type</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Demographics/Baseline Characteristics</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age on arrival</td>
<td>S01AgeOnArrival</td>
<td>Age on admission¹</td>
<td>J</td>
<td>1.4.a</td>
<td>Free</td>
<td>Unchanged</td>
<td>Scale</td>
</tr>
<tr>
<td>Sex</td>
<td>S01Sex</td>
<td>Sex of patient</td>
<td>K</td>
<td>1.5</td>
<td>1=Male 2=Female</td>
<td>Unchanged</td>
<td>Categorical (Binary)</td>
</tr>
<tr>
<td>Pre-op Mortality risk</td>
<td>S03PreOpPPOSSUMPredictedMortality</td>
<td>Pre operative mortality risk score</td>
<td>BZ</td>
<td>3.23</td>
<td>Free</td>
<td>Unchanged</td>
<td>Scale</td>
</tr>
<tr>
<td>Pre-op Morbidity risk</td>
<td>S03PreOpPPOSSUMPredictedMorbidity</td>
<td>Pre operative morbidity risk score</td>
<td>CA</td>
<td>3.24</td>
<td>Free</td>
<td>Unchanged</td>
<td>Scale</td>
</tr>
<tr>
<td><strong>ELQUIPC Intervention</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Assessment of sepsis with timely antibiotics</td>
<td>S02Abx_Datetime</td>
<td>Antibiotics first administered</td>
<td>AR</td>
<td>2.10</td>
<td>Free</td>
<td>If date in AR and AV does not = 1: recode to 1, administered. If AR empty or AV =1: recode to 0, not administered</td>
<td>Categorical (Binary)</td>
</tr>
<tr>
<td></td>
<td>S02Abx_NotAdministered</td>
<td>Antibiotics not administered</td>
<td>AV</td>
<td>2.10.c</td>
<td>1=ticked</td>
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<td></td>
</tr>
</tbody>
</table>

¹ Date of Birth not provided as it is a potential identifier
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<tr>
<th>Measure</th>
<th>Code</th>
<th>Description</th>
<th>Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date and time of decision to operate</td>
<td>S02Date_DecopDatetime S04EntryInToOperatingTheatreDatetime</td>
<td>Date and time of decision to operate Date and time of operation</td>
<td>X CC</td>
</tr>
<tr>
<td>Date and time of operation</td>
<td></td>
<td></td>
<td>2.2 Free</td>
</tr>
<tr>
<td>Date and time of operation</td>
<td></td>
<td></td>
<td>4.1 Free</td>
</tr>
<tr>
<td>1, difference between X&amp;CC &lt;6 hours</td>
<td></td>
<td></td>
<td>Categorical (Binary)</td>
</tr>
<tr>
<td>0, difference between X&amp;CC &gt;=6 hours</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Use of goal directed fluid therapy</td>
<td>S04Fluid_Therapy</td>
<td>Use of goal directed fluid therapy</td>
<td>CM 4.4</td>
</tr>
<tr>
<td>0= Not provided</td>
<td></td>
<td></td>
<td>0, Not provided</td>
</tr>
<tr>
<td>1= Cardiac output monitor</td>
<td></td>
<td></td>
<td>1, Provided</td>
</tr>
<tr>
<td>2= Other</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0, Not provided</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 and 2 recoded to 1, Provided</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Categorical (Binary)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Consultant surgeon and anaesthetan presence</td>
<td>S04Surg_Grade S04Anael_Grade</td>
<td>Grade of senior surgeon Grade of senior anaesthetan</td>
<td>CG CJ 4.2</td>
</tr>
<tr>
<td>1=Consultant;</td>
<td></td>
<td></td>
<td>1=Consultant;</td>
</tr>
<tr>
<td>2=Post-CCT fellow</td>
<td></td>
<td></td>
<td>2=Post-CCT fellow</td>
</tr>
<tr>
<td>3=SAS grade</td>
<td></td>
<td></td>
<td>3=SAS grade</td>
</tr>
<tr>
<td>4=Research Fellow/Clinical Fellow</td>
<td></td>
<td></td>
<td>4=Research Fellow/Clinical Fellow</td>
</tr>
<tr>
<td>5=Speciality trainee/registrar</td>
<td></td>
<td></td>
<td>5=Speciality trainee/registrar</td>
</tr>
<tr>
<td>6=Core trainee/SHO</td>
<td></td>
<td></td>
<td>6=Core trainee/SHO</td>
</tr>
<tr>
<td>9=Other</td>
<td></td>
<td></td>
<td>9=Other</td>
</tr>
<tr>
<td>Where CG &amp; CJ = 1, recoded to 1, present; other wise recode to 0, not present</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Categorical (Binary)</td>
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</tr>
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*Statistical Analysis Plan ELC Summative Evaluation*

*29th July 2016 Version 1*
<table>
<thead>
<tr>
<th>Intensive Care for All Patients</th>
<th>S06Proc_Dest</th>
<th>Discharge destination for post-operative care for following surgery</th>
<th>GX</th>
<th>6.24</th>
<th>1=Ward 2=Level 2 HDU 3=Level 3 ICU 4=Died prior to discharge from theatre complex</th>
<th>1, 2 &amp; 4 recode to 0, not discharged to ICU; 3 recode to 1, discharged to ICU</th>
<th>Categorical (Binary)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other Procedures/Processes</td>
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</tr>
<tr>
<td>Elderly Care Input</td>
<td>S07Geriatric_Postop</td>
<td>Was the patient assessed by elderly care post op</td>
<td>HC</td>
<td>7.3</td>
<td>1=yes 0=no 9=unknown 8=N/A</td>
<td>Recode 9 and 8 to blank</td>
<td>Categorical (Binary)</td>
</tr>
<tr>
<td>Outcomes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Further Procedures</td>
<td>S07Comp_Theatre</td>
<td>Did the patient return to theatre within this admission</td>
<td>HD</td>
<td>7.4</td>
<td>1=yes 0=no 9=unknown</td>
<td>Recode to 0= no; 1= yes; and 9 to blank</td>
<td>Categorical (Binary)</td>
</tr>
<tr>
<td>Mortality</td>
<td>S07Status_Disch</td>
<td>Mortality status at discharge</td>
<td>HO</td>
<td>7.7</td>
<td>0=Dead 1=Alive 60=Still in hospital at 60 days</td>
<td>Recode 60 to 1, otherwise retain coding</td>
<td>Categorical (Binary)</td>
</tr>
<tr>
<td>Statistical Analysis Plan ELC Summative Evaluation</td>
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<tr>
<td>29&lt;sup&gt;th&lt;/sup&gt; July 2016 Version 1</td>
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</table>

<table>
<thead>
<tr>
<th>Length of stay</th>
<th>S01Adm_Datetime</th>
<th>S07Date_DischDate</th>
<th>Date of admission</th>
<th>Date of discharge</th>
<th>P</th>
<th>HP</th>
<th>Free</th>
<th>Difference between P and HP</th>
<th>Scale</th>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1.9</td>
<td></td>
<td></td>
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<td></td>
<td></td>
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<td></td>
<td></td>
<td>7.8</td>
<td></td>
<td>Free</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Length of stay</th>
<th>S07Level3_Stay</th>
<th>S07Level2_Stay</th>
<th>Post operative ITU</th>
<th>Post operative HDU</th>
<th>HA</th>
<th>HB</th>
<th>Free (days)</th>
<th>Free (days)</th>
<th>Scale</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>7.1</td>
<td>7.2</td>
<td>Free (days)</td>
<td>Free (days)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Number of Surgeries In admission</th>
<th>S03NumberOfOperativeProcedures</th>
<th>Number of operative procedures</th>
<th>BU</th>
<th>3.18</th>
<th>Free</th>
<th>Unchanged</th>
<th>Scale</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Post-op Mortality risk</th>
<th>S06PostOpPPOSSUMPredictedMortality</th>
<th>Post operative mortality risk score</th>
<th>GU</th>
<th>6.21</th>
<th>Free</th>
<th>Unchanged</th>
<th>Scale</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Post-op Morbidity risk</th>
<th>S06PostOpPPOSSUMPredictedMorbidity</th>
<th>Post operative morbidity risk score</th>
<th>GV</th>
<th>6.22</th>
<th>Free</th>
<th>Unchanged</th>
<th>Scale</th>
</tr>
</thead>
</table>
7. Baseline and follow-up measures

Baseline demographic data is limited to: age at admission (Continuous, years) and sex (categorical, male/female) and is available for all included patients.

Mortality and morbidity risk scores – (Continuous measure) are provided using the Physiological and Operative Severity Score for the enUmeration of Mortality (P-POSSUM) and Morbidity (POSSUM) formula (1,2). Both scores are based on 12 physiological and 6 operative parameters. Physiological factors include: age, cardiac signs, respiratory history, electrocardiogram, systolic blood pressure, pulse rate, serum Haemoglobin concentration, serum white cell count, serum urea concentration, serum sodium concentration, serum potassium concentration, and Glasgow Coma Score. Operative factors include: Operation severity, number of operative procedures in preceding 30 days, clinically estimated likely intraoperative blood loss, clinically estimated likely degree of peritoneal soiling, severity of malignancy and ‘urgency status’ at time of booking (National Confidential Enquiry into Patient Outcome and Death, NCEPOD). Data is transformed to values of 1, 2, 4 or 8 according to predetermined thresholds for each variable and then summed to provide composite physiological and operative scores. The two scores are entered into the following equation to provide POSSUM and P-POSSUM respectively:

POSSUM: -7.04 + (0.13 x physiological score) + (0.16 x operative severity score)
P-POSSUM: -9.065 + (0.1692 x physiological score) + (0.1550 x operative severity score)

POSSUM and P-POSSUM are provided as a percentage for both pre-operative and post-operative risk. Scores range from 0 (no risk) to 100 (maximum risk).

ELQPuIC Intervention – (Categorical measure) Eight variables from the NELA dataset will be used to produce binary categorical variables to indicate compliance with each individual component of the ELQuIC intervention (1., use of antibiotics; 2., surgery within 6 hours of decision to operate; 3., use of goal directed fluid therapy; 4., presence of consultant surgeons and anaesthetist; and 5., discharge to Intensive Care Unit). Values of 0 (not complied with) and 1 (complied with) will be attributed according to the rubric described in Table 1. In addition, a composite measure of compliance will be created to indicate 0 (compliance with 4 parts or less) and 1 (compliance with all 5 elements of the ELQPuIC intervention).

Further surgical interventions – (Categorical measure) indicates whether a patient returns to surgery (1) or not (0) during their current period of admission.

Mortality – (categorical measure) Mortality status is provided as a binary variable dead (0) or alive (1). In hospital mortality is recorded up to 60 days from admission.

Length of stay – (Continuous measure) recorded as number of days between date of admission and date of discharge.

Number of surgeries in admission – (Continuous measure) provided as a count.
8. Descriptive analysis

Data summary

Acute Hospitals in KSS AHSN (n=)

Hospitals excluded from Emergency Laparotomy Collaborative (n=)
- Do not provide Emergency Laparotomy Surgical services (n=)
- Declined to participate (n=)
- Did not respond (n=)

Introduced to the Quality Improvement Emergency Laparotomy Collaborative programme (n=)
Did not start the Quality Improvement Emergency Laparotomy Collaborative programme (n=)

Withdrawn from the Quality Improvement Emergency Laparotomy Collaborative programme (n=)

Hospitals included in the analysis (n=)
Patients included in the analysis (n=)
Additional summaries will be provided for:

### Hospital Characteristics

<table>
<thead>
<tr>
<th>Number of hospitals (n=)</th>
<th>Number of patients per hospital ($\bar{x} \pm \sigma$)</th>
</tr>
</thead>
</table>

### Patient Characteristics

<table>
<thead>
<tr>
<th>Knife to skin within 6 hours (n=)</th>
<th>Consultants in Surgery (n=)</th>
<th>Fluid Therapy (n=)</th>
<th>Anti-biotics (n=)</th>
<th>ICU (n=)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age ($\bar{x} \pm \sigma$)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sex (female/male)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-operative P-POSSUM ($\bar{x} \pm \sigma$)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-operative POSSUM ($\bar{x} \pm \sigma$)</td>
<td></td>
<td></td>
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</table>

### Patient Outcomes

<table>
<thead>
<tr>
<th>Risk Adjusted Mortality</th>
<th>30 days ($\bar{x} \pm \sigma$)</th>
<th>60 days ($\bar{x} \pm \sigma$)</th>
<th>90 days ($\bar{x} \pm \sigma$)</th>
<th>180 days ($\bar{x} \pm \sigma$)</th>
</tr>
</thead>
</table>

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**Processes and Procedures**

<table>
<thead>
<tr>
<th></th>
<th>Mean = ( \bar{x} ); Standard Deviation = ( \sigma );</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of surgeries</td>
<td></td>
</tr>
<tr>
<td>per hospital (( \bar{x} \pm \sigma ))</td>
<td></td>
</tr>
<tr>
<td>per patient (( \bar{x} \pm \sigma ))</td>
<td></td>
</tr>
<tr>
<td>Proportion of patients:</td>
<td></td>
</tr>
<tr>
<td>Operated on within 6 hours of decision to operate (%)</td>
<td></td>
</tr>
<tr>
<td>Surgical and anaesthetic consultants involved (%)</td>
<td></td>
</tr>
<tr>
<td>intra-operative goal directed fluid therapy used (%)</td>
<td></td>
</tr>
<tr>
<td>timely administration of antibiotics (%)</td>
<td></td>
</tr>
<tr>
<td>Discharged to intensive care after surgery (%)</td>
<td></td>
</tr>
<tr>
<td>Received full ELPQUiC Care Bundle (%)</td>
<td></td>
</tr>
</tbody>
</table>
Data Summaries

Characteristics of hospitals and patients will be provided using summary statistics. Numbers and proportions will be presented for binary and categorical variables while means and standard deviations or medians with lower and upper quartiles (IQR) will be presented for continuous variables.

Missingness will be examined for all main study variables. Where available, reasons for missingness will be summarised. Multiple imputation approaches will be employed to assess the nature of missing data using logistic regression approaches. The assumptions underlying the predictive models developed will be assessed using sensitivity analysis to explore the potential impact of missing data on the observed primary outcome.

9. Planned analysis

The primary clinical outcome for the analysis is risk adjusted mortality measured at 30 days. This outcome will be analysed using a difference of differences approach. Risk adjusted 30-day mortality will be compared for a 12-month period prior to the implementation and the 12 months post-implementation. As the study involves an element of clustering, with implementation nested within hospitals, the analysis will be adjusted for site using a mixed model approach. Differences will be presented as mean lives saved per 100 and associated 95% confidence intervals.

Secondary outcomes; risk adjusted mortality at 60, 90, 120 days and length of stay, will be analysed in a similar manner.

In order to explore potential age as a contributory factor to outcome, the primary analysis will be repeated with the inclusion of age group (<80; 80 or more years) as an interaction term.

Exploratory analysis will be employed to explore the relationship between fidelity to intervention and outcomes observed for the primary outcome. After exploration of variable redundancy an exploratory multi-level linear model will be including risk-adjusted 30-day mortality as the primary outcome and including dichotomised elements of the intervention and known covariates as the independent prognostic variables. The results of the model, after appropriate model checking, will be presented as coefficients and associated 95% confidence intervals.

A prognostic analysis will be employed to explore potential factors on admission that impact on the risk adjusted 30-day mortality rate. After exploration of variable redundancy an exploratory multi-level linear model will be developed, including risk-adjusted 30-day mortality as the primary outcome and potential prognostic covariates as the independent variables. The results of the model, after appropriate model checking, will be presented as coefficients and associated 95% confidence intervals.

10. References

Appendix D: Health Economics – cost analysis plan
Cost Analysis Plan for the Emergency Laparotomy Pathway Quality Improvement Care (ELPQuiC) bundle delivered by the Emergency Laparotomy Collaborative (ELC)

1. Introduction
This plan is focused on assessing the costs associated with the Emergency Laparotomy Pathway and investigating changes after the implementation of the ELPQuiC bundle. Implementation of the ELPQuiC intervention started in November 2015. Data will be obtained from publicly available sources including the NHS Reference Costs publications and the National Emergency Laparotomy national audit (NELA) and will be collected as they become available. Statistical analysis will be carried out starting from March 2017 but descriptive analysis of the available data will begin in between.

The statistical package STATA version 13 will be used for the analysis.

2. Aims and objectives
The aim of this analysis is to measure the costs associated with emergency laparotomy surgery and how these compare before and after the implementation of the bundle.

In particular we will address the following objectives:

- Estimate the average cost of emergency laparotomy before and after the implementation of the bundle and the average cost per life saved
- Estimate how this cost varies across different hospital subgroups depending on the degree of compliance with the bundle and mortality rates
- To determine what patient and/or hospital characteristics affect emergency laparotomy costs (NELA data)
- Assess the effect of the implementation of the bundle on the costs of length of stay, number of days spent in post-operative Intensive Care Unit and post-operative High Dependency Admission

3. Intervention
The ELPQuiC intervention uses a ‘care bundle’ aimed at improving the standard of care to patients by coordinating anaesthetic and surgical management, avoiding post-operative complications and use of care bundles to improve consistent delivery of evidence based care. It consists of 5 key stages of care: early assessment and resuscitation, use of antibiotics administered to patients who show signs of sepsis, prompt diagnosis and early surgery, goal-directed fluid therapy in theatres and in continued to ICU and post-operative intensive care.

The new pathway was developed at the Royal Surrey County Hospital in Guildford and introduced in Royal United Hospital Bath, South Devon NHS Trust Torbay and Royal Devon and Exeter Hospital and it has expanded in acute care NHS Trusts in England covering geographic areas in Kent, West of England and Wessex.
4. Data

NHS Reference Costs

The reference costs collection is the single national collection of service costs within the NHS (NHS 2015). Reference costs are the average unit cost to the NHS of providing defined services to NHS patients in England in a given financial year and are collected annually. Reference costs are produced under the arrangements put in place following the Health and Social Care Act (2012) which transferred responsibility for the National Tariff Payment System in England from the Department of Health to Monitor and NHS England. The quality of the cost data is supported by an ongoing collaborative process led by Monitor with support from the Department of Health and other Arm’s Length Bodies through the Costing Transformation Programme (CTP).

The reference costs provide the average costs for different units of activity and include all hospital expenditure in the year including overheads, depreciation and capital charges, net of private income, research income and training income. For the purposes of the evaluation and in order to conduct a by hospital analysis, data will be retrieved from the source data submitted by trusts. Data are collected for Finished Consultant Episodes (FCE) which is the time a patient spends in the care of one consultant. Where care is provided by two or more consultants in the episode, one consultant takes overriding responsibility and only one FCE is recorded. The unit of activity is the HRG for inpatient and day case and attendance for outpatient and accident and emergency. For surgery procedures the reference costs provide the average cost per day in ITU including all drugs, consumables and overheads. The average laparotomy costs, with and without resection, will be estimated as the weighted average cost of day case, inpatient costs and excess bed days weighted by the proportion of patients. Both cases with and without complications will be considered.

We will consider data for the year 2014-2015 as the pre-intervention period and data for the year 2015-2016 as the post-intervention period. The 2014-2015 data are already available while the 2015-2016 data are expected to be published in November 2016.

NELA Data

The NHS Reference Cost data do not include patient characteristics. In order to expand the analysis and study variation of costs by patient characteristics NELA data will also be used.

The National Emergency Laparotomy Audit (NELA) is part of the National Clinical Audit and Patient Outcomes Programme and is overseen by the Healthcare Quality Improvement Partnership. All patients aged 18 and over undergoing emergency laparotomy in England and Wales are automatically enrolled. A structured audit tools is used to collect data which is usually completed retrospectively locally at the hospital and stored remotely by the Central NELA team.

Data will be retrieved from the routinely collected NELA patient audit dataset for all participating hospitals. The ELC implementation team will collate data from participating hospitals in pseudo-anonymised format. Data will be provided at the patient level. The key outcome of interest collected from the NELA dataset is length of stay and number of days in post-operative ITU and post-operative HDU. National average unit cost data will be used to estimate the cost associated with length of stay at the patient level (PSSRU 2015). Other variables retrieved from the NELA dataset include:
- Age, sex, mortality and morbidity risk scores measured by POSSUM and P-POSSUM scores data
- An intervention variable to take into account compliance with the intervention will be constructed from the NELA data:
  o Eight categorical variables indicating compliance with each component of the ELPQuIC bundle will be constructed: use of antibiotics; surgery within 6 hours of decision to operate; use of goal directed fluid therapy; presence of consultant surgeons and anaesthetist; discharge to Intensive Care Unit
  o A composite measure of compliance will be constructed to indicate compliance with 4 parts or less and compliance with all 5 elements.

5. Analysis

Hospital level analysis

Hospital level analysis using the NHS Reference Cost data will involve:

- Investigation of the distribution of costs using graphical methods. Overall average cost and average cost per life saved across all hospitals and by hospital will be presented.
- Descriptive statistics and graphical display before and after the implementation of the bundle and by hospital group (differentiating by the degree of compliance to the bundle and the degree of reduction in mortality).

Patient level analysis

A patient level analysis studying the costs of the length of stay will be conducted using the NELA data.

Preliminary exploratory descriptive analysis will involve:

- Graphical presentation of the overall cost of length of stay; before and after the bundle implementation and by different patient characteristics (e.g. age)
- Descriptive statistics (mean, median, standard deviation) of costs overall and by different subgroups

The main statistical analysis will involve a regression model to study length of stay costs as a function of patient and hospital characteristics and the bundle implementation. We will develop a multi-level regression model at the patient level where costs of length of stay will be studied using the following predictors: age, co-morbidity and sex of the patient, number of surgeries per admissions and intervention compliance indicators (both for individual components and the composite indicator). Random effects will be included to allow for hospital effects. Alternative specifications accounting for different hospital characteristics (e.g. volume, teaching) will be considered. Standard errors will be clustered at the hospital level to account for potential patient clustering within hospitals. Various diagnostic tests for different assumptions of the model will be presented. Estimated coefficients and standard errors with respective P-values and confidence intervals will be presented showing the significance of each coefficient. Significance of the whole model will be measured with statistics such as R-squared and F statistic.
If variation in the time and degree of implementation across hospitals is sufficient we will also consider a difference-in-difference model (DID) to estimate the effect of the intervention in a more causal way. The DID methodology estimates the effect of the intervention by estimating the difference between hospitals implementing the intervention and hospitals without the intervention of the difference before and after the intervention. The identification assumption is that the trend in costs for both groups of hospitals during the pre-treatment era is similar conditional on the intervention and other characteristics. We will a DID model in a regression framework controlling for the available patient characteristics. The pre- and post-intervention periods will cover as far as one year around the intervention depending on the adoption of the bundle across hospitals.

References

_PSSRU (2015). Unit Costs of Health and Social Care, PSSRU._
Appendix E: Interview Topic Guide
**Interviewer to:**
- Note time/date and location of interview
- Welcome and thank participant for agreeing to taking part
- Briefly run through the study aims
- Remind that there are no right or wrong answers as each individual’s experiences are important
- Confidentiality and audio-recording: only the research team will hear the recording and personal details will be removed. Any quotes used will be anonymous.
- Plan to keep to 30 to 45 minutes but participant can ask for a break when needed
- Any further questions?

- Review participant information sheet & sign consent form
- Let the participant know that the recorder has been switched on now

<table>
<thead>
<tr>
<th>Question (for interviewee)</th>
<th>Rationale &amp; probes (for interviewer)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Could you tell me a little about yourself</td>
<td>Useful to have basic professional details</td>
</tr>
<tr>
<td>a. Job role</td>
<td></td>
</tr>
<tr>
<td>b. Years of experience</td>
<td></td>
</tr>
<tr>
<td>c. Years at this hospital</td>
<td></td>
</tr>
<tr>
<td>d. Motivation for assuming a role within the project</td>
<td></td>
</tr>
<tr>
<td>2. Tell me what you know about the ELC and implementation programme?</td>
<td>Processes required in each hospital to set up the implementation with details of adjustments / changes made during the set-up and delivery process.</td>
</tr>
<tr>
<td>3. Can you outline any of the processes involved in the setup of the programme in your hospital?</td>
<td>Why were changes made (if any)?</td>
</tr>
<tr>
<td>a. What were you already doing within your organisation?</td>
<td></td>
</tr>
<tr>
<td>b. What have you had to change or adapt?</td>
<td></td>
</tr>
<tr>
<td>4. What role have you played in setting up the programme?</td>
<td>Who are the key people – in the hospital, in the AHSN and possibly elsewhere…</td>
</tr>
<tr>
<td>5. Who are the key people who have helped to set up the programme?</td>
<td></td>
</tr>
<tr>
<td>a. What are their roles? (Leaders, negotiators, facilitators etc…)</td>
<td></td>
</tr>
<tr>
<td>6. Is there anyone that you think should be involved that is missing?</td>
<td></td>
</tr>
<tr>
<td>Question</td>
<td>Answer</td>
</tr>
<tr>
<td>------------------------------------------------------------------------</td>
<td>--------</td>
</tr>
<tr>
<td>7. What other quality improvement projects have you been involved in?</td>
<td></td>
</tr>
<tr>
<td>a. How does this project compare?</td>
<td></td>
</tr>
<tr>
<td>8. What are your thoughts on the support and training given to the</td>
<td></td>
</tr>
<tr>
<td>hospital within the collaboration?</td>
<td></td>
</tr>
<tr>
<td>a. What interactions, if any, have you had with the ELC central team?</td>
<td></td>
</tr>
<tr>
<td>b. What interactions, if any, have you had with the local AHSN team?</td>
<td></td>
</tr>
<tr>
<td>9. What interactions, if any, have you had with other hospital trusts</td>
<td></td>
</tr>
<tr>
<td>in the collaborative?</td>
<td></td>
</tr>
<tr>
<td>10. Has being within the collaborative had any impact in the way you've</td>
<td></td>
</tr>
<tr>
<td>implemented this project in your hospital?</td>
<td></td>
</tr>
<tr>
<td>11. What will success look like in your organisation?</td>
<td></td>
</tr>
<tr>
<td>12. Are you confident that your organisation will be able to monitor</td>
<td></td>
</tr>
<tr>
<td>the progress of the programme?</td>
<td></td>
</tr>
<tr>
<td>a. Have you received enough training and supported in order to do this?</td>
<td></td>
</tr>
<tr>
<td>b. Are there any organisational issues that have to be addressed for you to be able to monitor the progress?</td>
<td></td>
</tr>
</tbody>
</table>
Appendix F: HRA Approval
Dear Professor Peckham

**Letter of HRA Approval**

**Study title:** Evaluation of the Emergency Laparotomy Collaborative (ELC) Quality Improvement project: Improving outcomes after emergency laparotomy.

**IRAS project ID:** 193034  
**Protocol number:** ResGov 333  
**Sponsor** University of Kent

I am pleased to confirm that the above study has been given **HRA Approval**, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

**Scope**

HRA Approval provides an approval for research involving NHS patients or staff in England. Organisations listed in your application are not obliged to undertake this study; arrangements for organisations to confirm their capacity and capability to undertake the study, where formal confirmation is required, are detailed in **Appendix B Summary of HRA assessment (Participating NHS Organisations, Capacity and Capability and Agreement sections)**.

If your study involves participating organisations in other countries in the UK, please contact the relevant national coordinating functions for support and advice. Further information can be found at [http://www.hra.nhs.uk/resources/applying-for-reviews/nhs-hsc-rd-review/](http://www.hra.nhs.uk/resources/applying-for-reviews/nhs-hsc-rd-review/).

If there are participating non-NHS organisations, local agreement should be obtained in accordance with the procedures of the local participating non-NHS organisation.
Participating NHS Organisations in England

The HRA has determined that participating NHS organisations in England do not need to formally confirm their capacity and capability to undertake their role in this research, because local staff at sites will only be required to submit existing data to the National Emergency Laparotomy Audit (NELA) online database. The only additional activity that will take place at selected ‘case study’ sites will be staff interviews and meeting observations conducted by members of the research team. It is expected that these organisations will become participating NHS organisations 35 days after the date of issue of this letter (no later than 22/04/2016) if they have not already confirmed participation, unless justification can be provided to the sponsor and the HRA as to why the organisation cannot participate, or the organisation requests additional time to confirm. Further details are given in Appendix B - Summary of HRA assessment.

It is critical that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. This is the case even where some or all participating NHS organisations in England are not required to provide formal confirmation of capacity and capability, as the HRA expects the organisations’ research management functions to confirm by email to the CI and sponsor that the research may proceed in advance of the no-objection deadline (where one is given). Contact details and further information about working with the research management function for each organisation can be accessed from http://www.hra.nhs.uk/hra-approval.

For guidance on how you and the sponsor should work with participating NHS organisations in England, please see Appendix B (Participating NHS Organisations, Capacity and Capability and Agreement sections).

After HRA Approval

The attached document “After HRA Approval – guidance for sponsors and investigators” gives detailed guidance on reporting requirements for studies with HRA Approval, including:

- Working with organisations hosting the research
- Registration of Research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics and is updated in the light of changes in reporting requirements or procedures.

New Participating Organisations

Plans to include any new participating organisations in the study in addition to those listed in the application should be notified to the HRA as an amendment. The study should not start at the new participating organisation until:

- For Clinical Trials of Investigational Medicinal Products (CTIMPS), the HRA has acknowledged that the amendment has been received by the Research Ethics Service.
• For NHS organisations in England, the organisation has confirmed capacity and capability, where required to do so, in line with the guidance provided by the HRA in the HRA categorisation email for the amendment.
• For NHS organisations in Northern Ireland, Scotland or Wales, management permission has been obtained.
• For non-NHS organisations, management permission has been obtained and SSA has been obtained from the REC where necessary.

Appendices
The HRA Approval letter contains the following appendices:
• A – List of Documents reviewed during HRA assessment
• B – Summary of HRA Assessment

User Feedback
The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please email the HRA at hra.approval@nhs.net. Additionally, one of our staff would be happy to call and discuss your experience of HRA Approval.

HRA Training
We are pleased to welcome researchers and research management staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

Your IRAS project ID is 193034. Please quote this on all correspondence.

Yours sincerely

Nicola Gilzeane
Assessor

Email: hra.approval@nhs.net

Copy to:  
Ms Nicole Palmer, University of Kent (Sponsor Contact)  
N.R.Palmer@kent.ac.uk
Ms Sarah Martin, Royal Surrey County Hospital Foundation Trust (Lead NHS R&D Contact)  
sarah.martin33@nhs.net
# Appendix A - List of Documents

The final document set reviewed during HRA assessment is below.

<table>
<thead>
<tr>
<th>Document</th>
<th>Version</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contract/Study Agreement [ELC Contract and funding]</td>
<td></td>
<td>01 February 2015</td>
</tr>
<tr>
<td>Evidence of Sponsor insurance or indemnity (non NHS Sponsors only)</td>
<td>vs.1</td>
<td>01 June 2015</td>
</tr>
<tr>
<td>Interview schedules or topic guides for participants [Topic guide vs. 2]</td>
<td>vs.2</td>
<td>27 November 2015</td>
</tr>
<tr>
<td>IRAS Application Form [IRAS_Form_10022016]</td>
<td></td>
<td>10 February 2016</td>
</tr>
<tr>
<td>Letter from funder [Funding confirmation email]</td>
<td></td>
<td>09 March 2016</td>
</tr>
<tr>
<td>Letter from sponsor [RESGov sponsorship confirmation]</td>
<td>vs.1</td>
<td>01 June 2015</td>
</tr>
<tr>
<td>Other [EI and PL to whom it may concern]</td>
<td>vs.1</td>
<td>01 June 2015</td>
</tr>
<tr>
<td>Other [Professional Indemnity Insurance]</td>
<td>vs.1</td>
<td>01 June 2015</td>
</tr>
<tr>
<td>Other [email confirming ethics ELC SRC ethics review and approval]</td>
<td>vs.1</td>
<td>25 January 2016</td>
</tr>
<tr>
<td>Other [Ugochi_Nwulu summary CV 2016]</td>
<td>vs.1</td>
<td>22 January 2016</td>
</tr>
<tr>
<td>Other [Summary Curriculum Vitae July AMK 2015]</td>
<td>vs.1</td>
<td>07 August 2015</td>
</tr>
<tr>
<td>Other [Certificate of Employers' Liability Insurance]</td>
<td>vs.1</td>
<td>01 June 2015</td>
</tr>
<tr>
<td>Other [CV DL]</td>
<td>vs.1</td>
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</tr>
<tr>
<td>Other [NELA database information]</td>
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<tr>
<td>Other [Schedule of Events]</td>
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<td>18 March 2016</td>
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<tr>
<td>Other [Statement of Activities]</td>
<td>1.3</td>
<td>14 March 2016</td>
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<td>Participant consent form [Participant Consent Form]</td>
<td>2</td>
<td>24 February 2016</td>
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<tr>
<td>Participant information sheet (PIS) [Participant Information Sheet]</td>
<td>2</td>
<td>24 February 2016</td>
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<tr>
<td>Participant information sheet (PIS) [Information Sheet Observations]</td>
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<td>09 March 2016</td>
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<tr>
<td>Research protocol or project proposal [ELC Implementation Protocol vs. 1]</td>
<td>vs.1</td>
<td>15 December 2015</td>
</tr>
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</table>
Appendix B - Summary of HRA Assessment

This appendix provides assurance to you, the sponsor and the NHS in England that the study, as reviewed for HRA Approval, is compliant with relevant standards. It also provides information and clarification, where needed, to participating NHS organisations in England on elements of the review that will assist in the determination of capacity and capability, where this assessment is required.

For information on how the sponsor should be working with participating NHS organisations in England, please refer to the, participating NHS organisations, capacity and capability and agreement sections in this appendix.

HRA assessment criteria

<table>
<thead>
<tr>
<th></th>
<th>IRAS application completed correctly</th>
<th>Compliant with Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1</td>
<td>Participant information/consent documents and consent process</td>
<td>Compliant with Standards</td>
</tr>
<tr>
<td>3.1</td>
<td>Protocol assessment</td>
<td>Compliant with Standards</td>
</tr>
<tr>
<td>4.1</td>
<td>Allocation of responsibilities and rights are agreed and documented (see Agreement section for further details)</td>
<td>Compliant with Standards</td>
</tr>
<tr>
<td>4.2</td>
<td>Insurance/indemnity arrangements assessed</td>
<td>Compliant with Standards</td>
</tr>
<tr>
<td>4.3</td>
<td>Financial arrangements assessed (see funding section for further details)</td>
<td>Compliant with Standards</td>
</tr>
<tr>
<td>5.1</td>
<td>Compliance with the Data Protection Act and data security issues assessed</td>
<td>Compliant with Standards</td>
</tr>
<tr>
<td>5.2</td>
<td>CTIMPS – Arrangements for compliance with the Clinical Trials Regulations assessed</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>
5.3 Compliance with any applicable laws or regulations | Not Applicable

6.1 NHS Research Ethics Committee favourable opinion received for applicable studies | Not Applicable

6.2 CTIMPS – Clinical Trials Authorisation (CTA) letter received | Not Applicable

6.3 Devices – MHRA notice of no objection received | Not Applicable

6.4 Other regulatory approvals and authorisations received | Not Applicable

Comments

The box below provides additional information and comments relating to the HRA assessment criteria above

Where applicable, independent contractors (e.g. General Practitioners) should ensure that the professional indemnity provided by their medical defence organisation covers the activities required of them for this research study.

Participating NHS Organisations

This provides detail on the types of participating NHS organisations in the study and a statement as to whether the activities at all organisations are the same or different.

All sites will submit patient data to the National Emergency Laparotomy Audit (NELA) online database, for most sites this will be routine activity. Between 10 and 12 of these sites will be selected as ‘case study’ sites where the research team will conduct staff interviews and meeting observations.

The Chief Investigator or sponsor should share study documents with participating NHS organisations in England in order to put arrangements in place to deliver the study. The documents should be sent to both the local study team, where applicable, and the office providing the research management function at the participating organisation. For further guidance on working with participating NHS organisations please see the HRA website.

If chief investigators, sponsors or principal investigators are asked to complete site level forms for participating NHS organisations in England which are not provided in IRAS or on the HRA website, the chief investigator, sponsor or principal investigator should notify the HRA immediately at hra.approval@nhs.net. The HRA will work with these organisations to achieve a consistent approach.
to information provision.

HR Arrangements

<table>
<thead>
<tr>
<th>A</th>
<th>Determination of the need for a Principal Investigator, a Local Collaborator, or neither and associated training requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>This confirms whether the sponsor position on the need for a PI, LC or neither is correct for each type of participating NHS organisation in England and the minimum training requirements PIs should meet.</td>
</tr>
<tr>
<td></td>
<td>No Local Collaborator or Principal Investigators will be required unless the research team conduct interviews or observations in a care setting where a local collaborator would be required to facilitate access.</td>
</tr>
<tr>
<td></td>
<td>GCP training is not a generic training requirement, in line with the HRA statement on training requirements.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>B</th>
<th>HR Good Practice requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>This confirms the HR Good Practice requirements for the study and the pre-engagement checks that should and should not be undertaken.</td>
</tr>
<tr>
<td></td>
<td>A letter of access will be required for external staff where interviews and observations are being carried out within a care setting on the premises of participating NHS organisations. No Disclosure and Barring Service or Occupational Health checks will be needed where a letter of access is required.</td>
</tr>
</tbody>
</table>

Confirmation of Capacity and Capability

| This describes whether formal confirmation of capacity and capability is required by participating NHS organisations in England. |
|---|----------------------------------------------------------------------------------------------------------------------------------|
| The HRA has determined that participating NHS organisations in England do not need to formally confirm their capacity and capability to undertake their role in this research, because local staff at sites will only be required to submit existing data to the National Emergency Laparotomy Audit (NELA) online database. The only additional activity that will take place at selected ‘case study’ sites will be staff interviews and meeting observations conducted by members of the research team. It is expected that these organisations will become participating NHS organisations 35 days after the date of issue of this letter (no later than 22/04/2016) if they have not already confirmed participation, unless justification can be provided to the sponsor and the HRA as to why the organisation cannot participate, or the organisation requests additional time to confirm. Further details are given in the Agreement section below. |
**Agreement**

<table>
<thead>
<tr>
<th>This details the expected mechanism for NHS organisations in England to confirm their capacity and capability to undertake their role in the study.</th>
</tr>
</thead>
</table>

Although formal confirmation of capacity and capability is not required of all organisations participating in this study (see Confirmation of Capacity and Capability section for full details), and such organisations would therefore be assumed to have confirmed their capacity and capability should they not respond to the contrary, we would ask that these organisations pro-actively engage with the sponsor in order to confirm at as early a date as possible. Confirmation in such cases should be by email to the CI and Sponsor confirming participation based on the relevant Statement of Activities and information within this Appendix B.

**Funding**

| This details what funding is in place for participating NHS organisations in England and, where applicable, confirms if a validated industry costing template is in place. It does not give an indication as to the appropriateness of the funding for NHS organisations in England. |

As detailed in the Statement of Activities, the sponsor is not providing any funding for NHS organisations.

**Other Information to Aid Study Set-up**

| This details any other information that may be helpful to sponsors and participating NHS organisations in England to aid study set-up. |

The applicant has indicated that they do not intend to apply for inclusion on the NIHR CRN Portfolio.
Appendix G: Activity Sheet
<table>
<thead>
<tr>
<th>Name (fill in once)</th>
<th>Role in ELC (fill in once)</th>
<th>Date</th>
<th>Activity</th>
<th>with whom</th>
<th>Organisation</th>
<th>Purpose</th>
<th>outcome (if any)</th>
<th>Duration (if applicable)</th>
<th>other comments</th>
</tr>
</thead>
</table>

Appendix H: Legend to the anonymised interview transcripts
### Legend to the anonymised interview transcripts

<table>
<thead>
<tr>
<th>Sites</th>
<th>No of beds</th>
<th>Teaching hospital</th>
<th>Foundation trust status</th>
<th>CQC rating</th>
<th>ELC in split sites</th>
<th>EPOCH* participant</th>
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</thead>
<tbody>
<tr>
<td>AHSN 1</td>
<td>Trust A</td>
<td>272</td>
<td>No</td>
<td>No</td>
<td>Requires improvement</td>
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<td></td>
<td>Trust B</td>
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<td>No</td>
<td>No</td>
<td>Requires improvement</td>
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<tr>
<td></td>
<td>Trust C</td>
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<td>Requires improvement</td>
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<td>AHSN 2</td>
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<td>No rating</td>
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<tr>
<td></td>
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<td>No</td>
<td>Requires improvement</td>
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<tr>
<td></td>
<td>Trust F</td>
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<tr>
<td>AHSN 3</td>
<td>Trust G</td>
<td>1041</td>
<td>Yes</td>
<td>Yes</td>
<td>Requires improvement</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Trust H</td>
<td>541</td>
<td>No</td>
<td>Yes</td>
<td>Inadequate</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Trust I</td>
<td>901</td>
<td>Yes</td>
<td>No</td>
<td>Requires improvement</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Trust J</td>
<td>1,368</td>
<td>No</td>
<td>Yes</td>
<td>Outstanding</td>
<td>No</td>
</tr>
</tbody>
</table>

The three AHSN regions are referred to as AHSN 1, AHSN 2 and AHSN 3 and the hospitals within each are coded A – J.

To maintain anonymity:

Quotes from interview respondents from the central team are labelled: [Respondent, Central team]

Quotes from interview respondents from an AHSN project team are labelled: [Respondent, AHSN 1, 2 or 3]

Quotes from interview respondents from the hospital teams are labelled, for example: [Respondent, Trust A-AHSN 1]