Detailed project description

Full title of project

Evaluation of a national surveillance system for mortality alerts

Summary of Research

Background

Since 2007, the Dr Foster Unit at Imperial (DFU) has generated monthly mortality alerts based on statistical process control charts using routinely collected hospital administrative data on 122 diagnoses and procedures for all English acute non-specialist NHS hospital trusts (Bottle et al, 2008). A mortality alert is sent to an NHS hospital trust at no charge, irrespective of whether they have a commercial relationship with Dr Foster Intelligence (and copied to the Care Quality Commission, CQC) if the mortality rate exceeds a high threshold (less than 0.001 probability of a statistical false alarm in a year). CQC also run their own mortality alerting system on quarterly data using Healthcare Resource Groups, HRGs (CQC, 2012a). CQC writes to a trust alerting from either system and asks for a response, which are then logged by CQC. This joint mortality surveillance system was pivotal in alerting the then Healthcare Commission (HCC) to problems at Mid Staffordshire NHS Foundation Trust. As recommended in the resulting Public Inquiry, trusts should have systems that provide real-time information on mortality, patient safety and quality of care (Department of Health, 2013a).

Overall aims

Our proposal, in collaboration with Professor Aneez Esmail from the University of Manchester and supported by the CQC, sets out to improve understanding of these mortality alerts and to evaluate their impact as an intervention to reduce avoidable mortality within English NHS hospital trusts (hereafter referred to as trusts). We will achieve these aims by applying multiple methods across two workstreams. This approach will enable us to provide a comprehensive assessment of the quality of care and potentially avoidable mortality for alerting conditions, focusing on two conditions commonly attributed to mortality alerts - acute myocardial infarction and septicaemia.

Workstream 1. Descriptive analysis of all alerts, their relationships with other measures of quality and their impact on reducing avoidable mortality.
Workstream 2. Understanding the impact of mortality alerts at 12 trusts through visits and interviews, including organisational response to alerts and contextual and related factors which influence how trusts/hospitals act upon alerts.

Outputs

- Guidelines for trusts on how to respond to mortality alerts (template for action).
- Recommendations on improvements to the surveillance system (e.g. suggestions on which types of alerts are often driven by data quality and/or casemix rather than quality of care).

- Interim progress reports.
- Final research report, including executive summary.
- Papers published in academic peer-reviewed journals and professional NHS management journals.
- Conference presentations..
- Seminars, workshops and meetings.

Benefits and impact of research

Findings from our research will:

- Assist in better understanding mortality surveillance systems and their interpretation
- Inform health policies on service planning for the two conditions investigated.
- Support national quality improvement initiatives such as the Public Health Outcomes Framework.
- Improve the joint national surveillance system and public trust in it, with potential for methodological replication in other countries including the rest of the UK.
- Increase understanding of administrative data use (suitability and usability) for mortality monitoring.
- Deliver learning from hospitals/trusts with effective responses to mortality alerts, evidenced by reduced or consistently low mortality rates.

Background and Rationale

The HS&DR call invites research leading to a better understanding of which strategies are effective in identifying and reducing excess mortality in hospitals. The mortality alerting systems run by CQC and DFU have already had some success in detecting hospitals delivering poor quality care (The Mid Staffordshire NHS Foundation Trust Inquiry, 2010). However, uncertainty exists about the sensitivity of systems based on analysis of routinely collected hospital data and healthcare providers' responses following alerts.

The mortality alerts provided by DFU and CQC are for specific diagnoses or procedures. These alerts lend themselves to our analyses as they are potentially more actionable than summary (overall) measures of mortality such as the Hospital Standardised Mortality Ratio (HSMR) or Summary Hospital-level Mortality indicator (SHMI). The mortality alert system demands significant resources from CQC and DFU. Although CQC is continually evaluating its surveillance programme, this project would both complement and build upon CQC's activity.

There have been 447 closed mortality outlier alerts as of 30th September 2012, including 292 alerts followed up with trusts (CQC, 2012b). There has been no systematic empirical research to determine whether the DFU and CQC joint national mortality surveillance system is any better at detecting quality of care issues than other less focused approaches (e.g. HSMR, SHMI), or if alerts are

associated with reductions in avoidable deaths. It is also unclear what the most appropriate actions are for trusts after receiving an alert. Our project aims to address these gaps in knowledge.

Workstream 1 will describe trends in mortality alerts and also examine the relationships between these alerts, outcomes following investigation as reported to CQC and other measures of quality of care through statistical analyses of national hospital administrative data on admissions (Hospital Episode Statistics, HES).

Workstream 2 will employ qualitative methods to illuminate the mechanisms by which mortality alerts are used at trusts and translated into action and will focus initially on acute myocardial infarction and septicaemia alerts. Research demonstrates that many quality improvement interventions are context dependent, and we expect the response to mortality alerts to vary as a result of local structural, cultural and contextual factors. This workstream will provide valuable insight from key informants and stakeholders on how current alerting processes interacts with the local organisational context, on the barriers and enablers for effective local use of mortality alerts and on the unintended consequences of alerting. Through analysis of end-users' experiences of the current alerting system, we will develop guidance and recommendations to promote more effective and actionable feedback from national mortality surveillance programmes.

As a result of work across the two workstreams, we will be able to produce a trust-level template for action on how to respond to mortality alerts and suggest how mortality surveillance systems can be improved. While this project focuses on English trusts, the findings have far wider implications for healthcare systems both in the UK and internationally. The methodology applied in this project can be replicated in other countries either entirely or from individual workstreams depending on data availability and quality.

Evidence explaining why this research is needed now

The mortality alerting system has been operating since 2007 and has accrued enough alerts over time for any impact on quality of care and mortality rates to become apparent. As this system contributed to the identification of problems at Mid Staffordshire NHS Foundation Trust and in light of the findings and recommendation for real-time monitoring systems from the Public Inquiry (Department of Health, 2013a; Department of Health, 2013b), it is both important and timely that this research is carried out to better understand the meaning of these alerts and how best to respond to them.

Previous studies on effective interventions have tended to be small scale and descriptive, with methodological limitations restricting control of confounding factors, interpretation of results or causality. Research evaluating interventions to reduce mortality have highlighted difficulties in attributing effects to specific interventions due to multiple concurrent schemes, and produced equivocal results (Wright et al, 2006; Rogers, 2008).

National mortality surveillance could be potentially efficient to manage as data are routinely collected. Computer algorithms are adaptable and can be refined more easily than employing additional and/or training staff for similar activities. The surveillance system requires minimal specialist equipment and it is not affected by potential delays due to policy changes in the provision or commission of health services.

Aims and objectives

Our proposed project aims to improve understanding of a national hospital mortality surveillance system. We intend to also evaluate its impact as an intervention to reduce avoidable mortality within English NHS hospital trusts.

Research questions

To meet the project's aims, we will answer three research questions:

1. Do mortality indices reflect anything about avoidable deaths and wider quality of care?
2. How do trusts respond to mortality alerts?
3. How can current responses to mortality alerts be improved?

The objectives of the project are to:

1. Comprehensively describe the findings and impact of a national mortality surveillance system as a feedback mechanism for quality improvement.
2. Determine the relationship of alerts to other potential indicators of quality e.g. Staff to bed ratios, acute bed occupancy, overall hospital mortality (SHMI and HSMR), Trust financial data (from the National Audit Office and the Audit Commission), the National Inpatient Survey, NHS Litigation Authority risk assessment data, and the Patient Safety Thermometer. Other sources of information such as Quality Accounts, Myocardial Ischaemia National Audit Project (MINAP) and the GMC National Training Survey will have information more relevant to specific conditions.
3. Determine the temporal patterns of alerts and whether they are associated with subsequent changes in mortality rates at trusts.
4. Describe trusts' responses to receiving mortality alerts and the impact on safety/quality improvements, including organisational and staff behaviour.
5. Determine whether there are differences in the delivery of care at frequently alerting trusts compared with trusts that alert rarely, for two conditions commonly generating mortality alerts - acute myocardial infarction and septicaemia.
6. Determine at trusts where mortality decreased after alerts whether they were more likely to apply common safety/quality interventions (e.g. care bundles, guidelines or early warning systems) compared with trusts that repeatedly alert.

Research Plan / Methods

The following table presents an overview of our proposed two workstreams and how they connect to the research questions and objectives outlined previously.

Table 1 Mapping of study methods to the project's research questions and objectives

Research question (Q)	Research objective (O)	Workstream (W)
Q1. Do mortality indices reflect anything about avoidable deaths and wider quality of care?		
	O1. Comprehensively describe the findings and impact of a national mortality surveillance system as a feedback mechanism for quality improvement.	W1-W2
	O2. Determine the relationship of alerts to other potential indicators of quality e.g. Staff to bed ratios, acute bed occupancy, overall hospital mortality (SHMI and HSMR), Trust financial data (from the National Audit Office and the Audit Commission), the National Inpatient Survey, NHS Litigation Authority risk assessment data, and the Patient Safety Thermometer. Other sources of information such as Quality Accounts, Myocardial Ischaemia National Audit Project (MINAP) and the GMC National Training Survey will have information more relevant to specific conditions.	W1
Q2. How do trusts respond to mortality alerts?		
	O3. Determine the temporal patterns of alerts and whether they are associated with subsequent changes in mortality rates at trusts.	W1-W2
	O4. Describe trusts' responses to receiving mortality alerts and the impact on safety/quality improvements, including organisational and staff behaviour.	W2
Q3. How can current responses to mortality alerts be improved?		
	O5. Determine whether there are differences in the delivery of care at frequently alerting trusts compared with trusts that alert rarely, for two conditions commonly generating mortality alerts - acute myocardial infarction and septicaemia.	W2
	O6. Determine at trusts where mortality decreased after alerts whether there are commonly applied safety/quality interventions (e.g. care bundles, guidelines or early warning systems) compared with trusts that repeatedly alert.	W2

Key:

Workstream 1 (W1). Statistical analysis of alerts, their relationships with other measures of quality and their impact on reducing avoidable mortality.

Workstream 2 (W2). Understanding the impact of mortality alerts at 12 trusts through interviews, including organisational response to alerts and contextual and related factors which influence how trusts/hospitals act upon alerts.

Workstream 1. Descriptive analysis of alerts

Study design

Statistical analysis of national hospital administrative data on admissions (Hospital Episode Statistics, HES).

Study sample

The DFU at Imperial holds HES data from 1996/7 financial year to date, augmented monthly from the Secondary Uses Service data warehouse, and has records of all monthly mortality alerts generated and sent to trusts since 2007. We will sample from alerts generated during the three most recent years (2011-2013).

Data analysis

We will first describe the epidemiology of alerts from the national mortality surveillance system in terms of numbers of alerts by patient group, time and hospital trust, giving the numbers of patients and deaths involved in those alerts using descriptive statistics. Simple comparisons among units flagged as high of their post-alert outcome rates with their pre-alert outcome rates (simple "before-after" comparisons) are subject to regression to the mean when the "before" rate that is estimated to be high simply due to sampling error then falls to its "after" level, thereby giving the impression of a reduction in mortality. Such comparisons also fail to account for pre-existing time trends in those rates – hospital mortality, for example, has in general been falling over time. Ignoring such pre-existing trends will wrongly give the impression that the hospital's interventions have worked. Interrupted time series with a control group can deal with both problems. "Alerting" trusts will be defined as those whose CUSUM chart crosses the threshold during the previous 3 years with statistical false alarm rate of 1 in 1000 per year for any of the patient groups monitored. Thresholds are tailored according to volume and expected mortality rate for the trust and patient group as described elsewhere (Bottle and Aylin 2011). The use of such a high threshold also helps guard against regression to the mean, as it reduces the chance of a short bad run signalling and immediately returning to normal. We will use all non-alerting acute non-specialist trusts as the control group. The outcome here will be any in-hospital death; we will analyse crude and then casemix-adjusted mortality, the latter via our existing published models (Bottle and Aylin, 2008). We will also focus on organisations that have had repeat alerts.

Among the alerting trusts, different mortality patterns are possible. Some trusts will have a rate that is fairly constantly above average: their CUSUM chart will gradually rise before crossing the threshold and alerting. Others will have a rate that is average or even below average (their CUSUM chart will hover along the Y=0 line) before experiencing a short, bad run that rapidly leads to an alert. Each of these may or may not alert further. With over 15 years of HES data in the Unit, we are well placed to look for and define such patterns by plotting monthly crude and adjusted rates. It is preferable to have at least ten time points from which to estimate any trend. We will plot each alerting trust separately at first before incorporating into ITS models; these will firstly compare each alerting trust against each

other categorised by reported outcomes to CQC, before combining the alerting trusts and comparing against the control group. Such models typically test for both a step change and a change in slope post-alert. As any change in mortality following the alert may not happen in the next time period, we will need to test for lagged effects. However, it may not be possible to neatly summarise post-alert mortality patterns due to different contextual effects. We will also examine whether there is a relationship with the outcomes of any local investigations as reported to CQC.

We will also examine the relationship between frequently alerting, single-alerting and non-alerting trusts and alternative indicators of care such as staff to bed ratios, acute bed occupancy, overall hospital mortality (SHMI and HSMR), Trust financial data (from the National Audit Office and the Audit Commission), the National Inpatient Survey, NHS Litigation Authority risk assessment data, and the Patient Safety Thermometer. Other sources of information such as Quality Accounts, Myocardial Ischaemia National Audit Project (MINAP) and the GMC National Training Survey will have information more relevant to specific conditions.

Some of these are institution level indicators, but others (such as MINAP, the GMC National Training Survey, Quality Accounts and the Patient Safety Thermometer) have more condition or specialty specific information. This information will provide useful context when comparing trusts. These statistical associations will be analysed for the three types of trusts (defined by their alerting status) in different ways depending on the frequency and duration of reporting for the indicator. Those such as HSMRs that are available monthly or quarterly for a number of years can be calculated alongside the mortality rates for the specific patient groups and the two readily compared. Those that are available only as annual snapshots may be matched more approximately in time to the alert, but for those trusts whose mortality rates are fairly constant leading up to the alert, this will be less important. If the indicator is only available for the year containing the alert and the year afterwards, then analysis will not be able to account for any pre-existing trends in the indicator. We will use generalized linear models with year and trust type (alerting status) as predictors together with the indicator; the mortality for the alerting patient group will be the dependent variable. If the indicator is only available for one year, then we will do pairwise correlations among the three trust types if we think an analysis of the indicator is still worthwhile.

Workstream 2. Understanding the impact of mortality alerts through interviews

Study design

This workstream will employ mixed methods to investigate the mechanisms by which mortality alerts are assimilated at local Trust level and translated into strategies for action, including description of any specific remedial responses to improve quality of care and reduce hospital mortality. Workstream 2 will be divided into two phases, comprising semi-structured, in-depth institutional case studies (Phase A) and structured cross-sectional surveys (Phase B). Phase A will achieve an in-depth

understanding of the processes governing institutional responses to alerts and avoidable mortality, whilst Phase B will contribute a broader cross-sectional perspective on the extent of specific categories of behavioural response (identified in the first phase) within the national population of alerted trusts in England. The two phase structure will provide rich information on both the depth and breadth of organisational responses to alerts, which will provide a rounded investigation and evaluation of the current mortality alerting system and its local impact upon health care organisations.

Study Phases

Phase A case studies - overview

Phase A will employ comparative institutional case studies, in which multiple methods of data collection, including documentary analysis and interviews with stakeholders and key informants, will be used to describe organisational behaviour. The case study design is selected due to its flexibility of focus, facility for in depth investigation of mechanism and capacity to explore interactions between a phenomenon and its context (Yin, 2001). The approach taken will comprise analysis of individual organisational cases followed by cross-case comparative analysis to provide rich perspectives upon strategic and behavioural responses at organisational level.

Phase B survey study - overview

Qualitative analysis of the data emerging from phase A will inform the development of a structured evaluative instrument to categorise and quantify organisational behavioural and contextual aspects of the response to alerts in Phase B. Using this approach, the key mechanisms by which the alerting system impacts upon delivery of care will be described and the variations and extent of specific responses to alerts investigated. The inclusion of cross-sectional, structured data collection within phase B affords the opportunity to conduct quantitative analysis of variations in organisational response to alerts and to synthesise key findings from work stream 1 and work stream 2 through analysis of trends in hospital mortality as a function of variations in organisational behaviour attributable to the mortality alerting system as a health informatics and regulatory intervention. Data collection in phase B will be based upon a piloted and standardised survey instrument developed from analysis of the Phase A data with specific response items based upon emergent categories of response to alerts. Data collection in phase B will utilise site-level surveys administered to each alerted trust. We draw upon expertise in survey design and multi-site data collection developed during our previous work in the Safer Patients Initiative (e.g. Benn, 2012).

Study recruitment and sampling

Phase A sampling (organisational level)

Using stratified and theoretical sampling methods, we will draw our sample for phase A of workstream 2 from trusts alerted in two disparate areas requiring varying scope of local response: septicaemia and AMI (referred hitherto as “conditions”). 12 healthcare organisations will be selected for case studies in Phase A. All selected study sites will have received an alert in one of the targeted condition areas within the last 36 months. Our sampling strategy has the following aims:

- To provide comparative perspectives on responding to mortality alerts through selection of 6 trusts that were alerted for septicaemia-related mortality and 6 trusts that alerted for AMI. These conditions were selected due to their relatively high frequency of alerting and due to their potential for providing interesting relative challenges for trusts. Septicaemia cases are likely to be dispersed across an institution’s clinical unit structure, with more complex causality and therefore requiring multifaceted/multi-site intervention methods.
- To sample variation in the responses to alerts This will be achieved by examination of trends in mortality within workstream 1 and stratification of organisations by patterns of repeat alerting. Within each condition, we will select 3 organisations which received only a single alert within the past 36 months and which subsequently showed a positive trend towards reduced mortality. The comparative stratum will comprise 3 organisations which received 2 or more alerts for the same condition (the last within the previous 36 month period) i.e. sites where mortality did not reduce despite the alerts.
- Where opportunities exist within the confines of the above sampling framework to select disparate trusts in terms of size or academic status, this will be incorporated into the sampling strategy in order to further maximise variation in study sites for in-depth case study.

The research groups within Phase A case studies will therefore possess the following structure (see table). This approach will allow in-depth comparisons of organisational behavioural responses between organisations with different levels of repeated alerting within the same condition area and between comparable organisations (in terms of intensity of alerting) across conditions.

Condition area:	**Level of repeat alerting**	**Number of site case studies**
Septicaemia	Single alert	3
	Repeating alert	3
AMI	Single alert	3
	Repeating alert	3
		12 in total

Phase B survey target sample

Phase B of work stream 2 will seek to investigate the extent and variation of categories of organisational response to mortality alerts identified within the in-depth phase A work. Survey responses will be obtained at the level of the alerted health care organisation (i.e. one response per site). The target survey respondent will be a representative of the organisational body with oversight responsibility for the local response to the mortality alert. Instructions will be provided to each organisation contacted to aid in identification of an appropriate respondent and which outline the required response criteria, which includes details of the organisation (e.g. size and type metrics) and historical knowledge of the local response to the alert and its outcome. We have set a target response rate of 60% of prior alerted sites that fit our inclusion criteria. We base this figure upon our experience in data collection for a recent national survey of perioperative units for the National Institute of Academic Anaesthesia in which a response rate of 59% of registered sites was achieved. Through the networks and contacts linked to the mortality outlier monitoring programme maintained by CQC, we will have means to issue prompts and reminders to promote responding.

In terms of organisational level sampling for the survey component, based upon historical data, approximately 50 individual organisations are alerted each year, representing up to 70 separate alert instances. For the Phase B work, we constrain the time-period of interest to the last three years giving a potential study sample of 150 - 210 cases (depending upon whether the instrument is administered on the basis of organisations or alerts as cases). The recent time period specified will ensure a level of organisational structural and staffing stability required to provide meaningful responses to questions concerning events in the organisation's history. Where practicable and where valid cases are available, we will prioritise the most recent periods of alerting in our analysis to improve recall, relevance and accuracy.

Data collection and analysis

Phase A case studies

The target dataset for the qualitative case studies in Phase A will be based upon interviews with key informants at the 12 selected organisations. Each case study will comprise initial telephone/email contact with key informants, followed by a maximum of two separate site visits, undertaken by two researchers within a two-week period, in which qualitative data will be collected via in-depth research interviews with local stakeholders.

Within each case study, our data collection and informant sampling procedures will be informed by experience in multi-site qualitative research projects funded by the EU (QUASER study) and the Health Foundation (evaluation of the Safer Patients Initiative). It is anticipated that up to 12 in-depth interviews will be undertaken at each site, over the course of either a single or repeated site visit. Sampling of interviewees will be stratified by level and relevance to the clinical area implicated by the alert, as well as driven by our evaluative frame and emergent information from key informants (i.e.

theoretical sampling). Initial contact will be made via the organisation's chief executive's office and an initial contact sought familiar with the local strategic response to mortality alerts. This individual is likely to be the medical director or head of risk/governance. Sampling will then proceed from meso-level (strategic/organisational) to micro-level systems (clinical division or unit level) and will include representation of any organisational body or task group established to respond to the implicated care issue. Due to variation in alerts, local structures and local responses, it is difficult to pre-specify the exact sample, but the target stakeholder knowledge for the case study data collection concerns the strategic response to the mortality alert and its operational implementation and governance. We expect to include information from varied stakeholders with corporate, managerial and clinical perspectives upon the actions taken to address the quality of care issue. In terms of timescales for case study data collection, the focus is retrospective rather than longitudinal and so the focus of the investigators will move from site to site during the course of the case study data collection period, with the aim of completing the required data collection (interviews and documentary review) within a concise period before moving onto the next. Whilst some case studies will overlap, the overall timeline of data collection will be sequential rather than contemporaneous across sites. Where possible, maximum variation will be sought in the onset of "early" and "late" case studies and their respective site visits during the data collection period.

In addition to interviews with trust employees, qualitative data will be sought in the form of documentary evidence in the form of Trust reports of key actions and the formal organisational responses to the alerts sent to the CQC. Documentary evidence sought will include Trust board reports, relevant organisational policies, internal communications and CQC records of actions and their respective sign-offs. In accordance with qualitative research principles, a purposive sampling method will be employed to identify a core set of informants at each site, with subsequent sampling driven by consideration of theoretical sampling and saturation to ensure capture of maximum variation in response to alerts and organisational behaviour across study sites. As a minimum, a core sample representing the strategic board level perspective, senior governance, clinical and nursing perspectives will be sought. Key roles involved in local interpretation of mortality data and alerts will then be sought, including key informants responsible for the local response to feedback and actioning quality improvement responses. In addition to Trust personnel at alerted organisations, additional interviews will be undertaken with both CQC informants and patient representative bodies, in order to ensure that the aims of regulators and the expectations of patient groups are represented in our analysis of service level responses to mortality alerts. In terms of the types of questions that will be asked of informants at each site, the following criteria are illustrative:

SAMPLE INTERVIEW PROMPTS FOR CASE STUDY DATA COLLECTION

Experience of the alerting mechanism

- *Understanding of the statistical basis of the alert*
- *Perceived credibility of the alert: confidence in the validity and reliability of the data*

- *Comparability with local data*
- *Support offered as part of the alert*
- *Characteristics and specific processes of alerting, including responsibilities of different agents, information flows (periodicity) and guidance issued with the feedback on expected local responses.*

Organisational and strategic responses to alert:

- *How was the intelligence received and disseminated within the organisation*
- *What are the perceived consequences of not responding, from different stakeholder perspectives?*
- *What was the initial internal response to the alert, how was the information locally investigated and validated*
- *Which organisational and committee structures were tasked with responsibility for responding to the alert; which professional sub-groups were involved*
- *Was the issue escalated to board level?*
- *Short term/initial response & dissemination strategy*
- *Resource allocation*
- *Comparability between strategic and operational/clinical response*
- *Reception amongst different professional groups/organisational levels*
- *Characterisation of the strategic response: e.g. acquiescence, compromise, avoidance, defiance or manipulation*
- *Degree of anticipation/expectation for alert – had they been alerted before and how recently*
- *Long term response and remedial strategy: internal response and external response*
- *Assignment of roles and responsibilities for mounting the response – which organisational structures would be accountable, what local reporting mechanism would be set up*

Interventional and operational responses to alert:

- *Resource utilisation*
- *What specific clinical process/quality improvement intervention was undertaken*
- *How was any quality improvement initiative structured and governed*
- *Was further monitoring/evaluation undertaken*
- *What was the process of implementation?*
- *What were the aims and intended outcomes of the intervention?*
- *What was the intended timescale for achievement of the initiatives goals?*
- *How was this evaluated/reported?*
- *Were there any organisational change implications?*

Evaluation of response to alert (mechanism – context interactions)

- *What was the overall outcome?*
- *What were the key enablers/barriers?*

- *How did organisational/contextual factors influence the response?*
- *What are the different professional perspectives upon the adequacy of the response to the mortality alert?*
- *Ensure that any "interventions" or examples of best practice in local responses to alerts are clearly described.*
- *Local and external perceptions of whether the alerts were effective (or ineffective) in stimulating local action.*
- *Was there experience of repeated alerts and what is the likely impact of repeated alerts?*

Evaluative stance

We conceptualise mortality alerting as a specific intervention mechanism in the broader area of health surveillance informatics, which aims to transform hospital administrative data into meaningful and actionable signals, alerting trusts to any significant mortality trends requiring local investigation and local action. Although the actual transmission of alerts to trusts is a relatively straightforward operation, we theorise that it is appropriate to conceptualise the whole surveillance and alerting system, within its institutional regulatory role, as a complex intervention for the purposes of research and evaluation (Ovretveit, 2002). This is because the mechanism of intervention involved encompasses both the informatics system itself (the characteristics of the alert as a form of performance feedback) and the local organisational response to receiving an alert, the latter likely to be variable as a function of a range of contextual and organisational preconditions (Benn, 2009). Public and governmental interest in above-expected mortality adds a social and inter-institutional dimension for alerted trusts, which may be experienced as external social and regulatory pressure from an institutional standpoint (DiMaggio & Powell, 1983).

The conceptual approach adopted here suggests specific features of the analytic stance and evaluative frameworks that can be productively employed in this area. Due to our hypothesis that the effectiveness of alerting as a quality improvement intervention is likely to be driven by variations in context and response, as much as the features of the alerting process itself, a realist evaluative perspective is likely to be most productive (Tilley & Pawson, 1997). The realist position provides a framework for identifying not only what outcomes are produced by an intervention, but how they are produced and how the intervention interacts with varying local conditions to produce the outcomes. In this sense the focus of investigation encompasses three interacting facets: mechanism, context and outcome. In the case of mortality alerting, mechanism refers to the active characteristics of the alerts and the alerting process. Context refers to the important features of the organisational setting which govern how the information is assimilated into organisational structures, behaviour, norms and strategy. Outcomes relate both to the local consequences of organisational responses to alerting, in

terms of system change, and their impact upon process and quality of care indicators and ultimately hospital mortality.

In terms of the organisational response to mortality alerts, when viewed as a regulatory mechanism, alerting may be conceptualised as a process of external institutional pressure. Institutional theory may be invoked to account for internal strategic responses to institutional pressure (Oliver, 1991). Organisational responses are thus constrained by external demands and expectations. Both regulatory agencies and public opinion may serve as external pressures for internal responses and the internal strategic response may vary along a number of dimensions, including conformity-resistance, passivity-activeness and acceptance-manipulation (Oliver, 1991). Of particular relevance to the internal dynamics of strategic and behavioural responses to mortality alerts are the potential repertoire of responses to conflicting institutional demands described by Pache & Santos (2010). According to theory in this area, response types include: acquiescence, compromise, avoidance, defiance and manipulation.

Case study data analysis and development of survey evaluative framework

Analysis of empirical data from the case studies will employ best practice in qualitative research, including elements of grounded theory (iterative coding, constant comparative method and theoretical saturation) in order to ensure emergent categories of information are grounded in the perspectives and experiences of informants. Organisational cases will initially be described and analysed thematically using a framework analytic approach, drawing upon both inductive and deductive (theory-driven) approaches. The later phases of analysis will employ cross-case analytic methods to further explore the boundaries and applicability of emergent categories. In addition to social sciences research, health informatics, patient safety and health services management research perspectives, we will bring "expert" lay/patient perspectives to bear upon the interpretation of qualitative data pertaining to organisational responses to alerts, particularly as they relate to public expectations. This will be achieved through collaboration with the CQC which maintains a network of lay/patient representatives for site inspections.

In addition to providing in-depth analysis linked to the core research question concerning the nature of effective organisational responses to mortality alerts, an important outcome from the qualitative work will be a theoretically- and empirically-informed evaluative framework for investigation of the overall effectiveness of the mortality alerting system (including data feedback and local response elements). The resulting evaluative framework will be used to structure both the Phase B survey instrument and the final synthesis of research findings across the study components. Examples of the categories of data items which will be included within the survey instrument are included below:

CANDIDATE DATA ITEMS FOR CROSS-SECTIONAL SURVEY OF ALERTED ORGANISATIONS
(final version to be developed based upon output from WS2 qualitative analysis)

Respondent demographics

- *Location and role within the organisation*
- *Role relative to the local mortality alert response (e.g. project lead, chair of oversight committee, executive sponsor)*

Organisational descriptors

- *Organisation size, type, structure and academic status*

Organisational structure, process and policy relating to quality governance (informed by improvement science and organisational theory)

- *Internal organisational reporting mechanisms for monitoring hospital mortality*
- *Organisational structures and processes in place for responding to intelligence relating to local quality of care*

Circumstances surrounding the mortality alert and local response (informed by literature on data feedback interventions and organisational sociology)

- *Medical conditions and procedures implicated by the alert*
- *Divisional structures, units and roles assigned with responsibility for responding to the alert*
- *Actions taken in response to the alert (categories of organisational behaviour and quality improvement/assurance activity to be derived from qualitative analysis of case study data)*
- *Timescale set for response*
- *New structures/processes/policies created*
- *Sustained effects of the response to the alert*
- *Final resolution of the alerting process and corresponding CQC case*

Evaluation of the mortality outliers surveillance and alerting process

- *Adequacy of the monitoring system as a means of detecting local care issues from an end-user's perspective*
- *Rated accuracy, timeliness, credibility, urgency and local relevance of the data feedback*
- *Degree to which the alert and its accompanying guidance was facilitative of local positive action*

Evaluation of the local response to the mortality alert

- *Experienced barriers and challenges to effective response*
- *Comparison of intended to actual outcomes/changes to care provision*
- *Ratings of the efficacy and sustainability of the local response*

Several areas of established research and theory may be invoked as analytic lenses to inform the study data analysis and development of the evaluative framework. In terms of intervention mechanism, theoretical perspectives and research evidence on the characteristics of effective data feedback interventions at institutional level (e.g. De Vos, 2013; Van Der Veer 2010) will be used to inform the analytic framework and generation of categories. We have experience of applying theory in this area to analyse data feedback interventions to improve quality of perioperative care (Benn, 2012). Research suggests, for example, that the characteristics of effective feedback for quality improvement

are timeliness, specificity to local context, non-punitive content and continuous provision (Bradley, 2004). Similarly, effective feedback from medical registries is considered to be trusted (in terms of data quality) by local users and implemented within an environment in which end-users are motivated to act upon the feedback, are supported by a conducive organisational context and have positive expectancy regarding outcome from changing local systems and processes (Van Der Veer, 2010). The analytic approach adopted will investigate the degree to which these characteristics interact with the local context and response to mortality alerts, through comparative cases. For example, it is important to capture the views of a broad range of relevant clinical and managerial informants within each case study regarding the perceived credibility and utility of the alert as a signal of potential underlying problems in care and therefore as a valid reason for allocation of resource and effort. The perceived consequences of not responding to the alert will additionally be explored from both institutional and societal perspectives. Data collection and analysis will be informed by appropriate organisational sociological theory, such as institutional theory (DiMaggio & Powell, 1983) and its derivatives (Scott, 1987) as previously outlined.

In terms of mechanism-context interactions, it will be particularly important for the practical aim of describing variation and best practice in responding to alerts, to capture the range of local interventional responses developed in response to alerts. This will be achieved through adoption of a multilevel view of the health care organisation, taking into account the strategic, managerial and operational (clinical) response to alerts. Several specific areas of organisational and improvement science theory will help to structure our enquiry in these areas. Process evaluation (Hulscher, 2003), for example, offers a framework for assessment of the intervention development and implementation process, including description of the intervention model and goals, checking local exposure to the intervention and investigation of the experience of implementing the intervention, including local barriers and enabling factors. In terms of an organisational perspective on structural and behavioural responses to quality issues within quality improvement initiatives, Bate (2008) provides a framework for analysis of the challenges inherent in this type of complex intervention, including structural, political, cultural, emotional, educational and technological perspectives. Our team has experience of using this framework for analysis (Robert, 2011).

Phase B survey piloting and final data analysis

We are aware of the challenges inherent in collecting reliable and valid data in national/multi-site survey studies from our previous work on the safer patients initiative. As in our previous work, we have similarly allocated time in the work plan to iterate and develop a valid and reliable measurement instrument for deployment in a national survey study of alerted sites. Survey development will be informed by the findings from the qualitative work and our emergent evaluative framework. Item development will be theoretically informed and early iterations of the survey instrument will be piloted using model respondents at the researchers' institutions to ensure relevance and consistency in interpretation of items.

The target response rate for the survey of alerted sites is 60%. Individual responses represent an organisational

In analysis of the final survey dataset, we will seek to classify and quantify the relationships between type and frequency of alerting, key contextual and organisational behavioural characteristics and intermediate outcomes such as the development of local interventions and quality improvement initiatives linked to the aim of reducing mortality. Key categories of response identified from the in-depth qualitative work in phase A and informed by appropriate theoretical and analytic frames will be used to develop a structured assessment instrument to capture the extent and range of organisational responses to alerts across the population of alerted sites. In the final report and research synthesis, variation will be described statistically, with correlational analysis undertaken to investigate relationships between context, processes and outcomes. For example, the association between organisational type and organisational response categories will be explored, along with the degree to which different categories of response predict alert outcome and effectiveness, drawing upon workstream 1 data. In this manner, trends in hospital mortality may be explored as a function of variations in organisational behaviour resulting from the alerting system and the survey component will contribute an important evaluative perspective upon the existing mortality outlier alerting system as a health informatics and regulatory intervention. Critically, the cross-sectional perspective in phase B will permit analysis of the extent to which locally applied patient safety and service quality interventions triggered in response to an alerting system are instrumental in addressing significant outlying in-hospital mortality.

Dissemination and projected outputs

Dissemination

With the support of patient groups, members of the project team including our external colleagues (Professor Aneez Esmail and CQC) and patient representative we will disseminate project findings. The outputs from individual studies within the project will be submitted for publication in leading journals such as the British Medical Journal (BMJ), Health Service Research and BMJ Quality and Safety. Wider dissemination of our research will include targeting national and international conferences:

- BMJ International Forum on Quality and Safety is the leading international conference on quality improvement in healthcare. The conference in 2013 was attended by 3,000 delegates from 90 countries. With such a large audience, it is possible to widely disseminate our project findings to clinicians, researchers and managers, and to also receive feedback from a varied audience. Results from the two workstreams may be presented in different formats at this conference, from posters, invited talks to workshops on the template for action and guidelines for improving surveillance systems.

- Patient Safety Congress is one of the largest annual patient safety conferences in the UK. New perspectives and experiences in safety improvement are presented. Our research would be shared with clinicians, service providers as well as other researchers and interested groups working in the UK.
- Health Services Research Network Symposium is intended for knowledge sharing of health services research. Thus is it directly relevant for all workstreams of our project. Discussion of the findings from workstream 2 (learning from mortality alerts) may be particularly relevant to the varied attendees (service leaders, service users and carers, researchers, practitioners, senior managers and policy makers).
- NHS Confederation Annual Conference is aimed at senior leaders, including chief executives and clinical leads, working in or on behalf of the NHS. Our findings to inform policies on service planning and the delivery of learning will be useful to the conference audience and will raise awareness of our research at the management level of the health service, as well as encourage adoption of recommendations and guidelines from the results.
- Healthwatch England National Conference. Healthwatch England is the independent consumer champion for health and social care in England and here we aim to reach the 152 local Healthwatch groups to raise awareness of the alerting process, to inform them of our findings, for example the questions local groups should be asking their local NHS organisations.

Through our links with the Collaboration for Leadership in Applied Health Research and Care for Northwest London, we will organise knowledge exchange workshops with key representatives at such events as the CLAHRC Monthly Research Meeting and Collaborative Learning and Delivery events. Regular project updates will be provided on the DFU webpage at Imperial College London. We will provide material appropriate for patient groups through patient forums and organisations such as the British Cardiac Patients Association and Surviving Sepsis Campaign. We will provide findings in the form of written reports (biannual and annual). Given the relevance and importance of mortality monitoring in healthcare internationally, we expect that there will also be significant interest in the outputs from the proposed evaluation by health organisations in other countries.

Outputs

We envisage a number of important outputs from this project:

- Guidelines for trusts on how to respond to mortality alerts (template for action).
- Guidance on how surveillance system could be improved (e.g. suggestions on which types of alerts are driven by data quality versus casemix).
- Papers published in academic peer-reviewed journals and professional NHS management journals.
- Interim progress reports.
- Final research report, including executive and lay summaries.
- Conference presentations, with PowerPoint slides.
- Seminars, workshops and meetings.

We will use methods of investigating avoidable mortality and wider quality of care issues which can be replicated locally and nationally, thus the impact of this research extends beyond the current remit for English NHS hospital trusts. Our understanding of the suitability and usability of administrative data for mortality monitoring will be improved. The findings will inform health policies on service planning and supplement national initiatives such as the Public Health Outcomes Framework. By identifying patient groups at greater risk of mortality, future interventions in these groups can be better tailored. Processes and organisational factors associated with elevated risk will also be identified, so that improvements in these areas can be targeted. Learning can be achieved from trusts that respond effectively to alerts (those with decreased mortality following alerts and those with consistently low mortality rates).

Plan of investigation and timetable

This project will run for 30 months. In the 3 months before project start, we will begin to liaise with trusts on research governance (we already have ethical permission to use our Hospital Episode Statistics to examine variations in delivery of healthcare) a. We will prepare for staff recruitment, which will begin in month -3 (3 months duration).The management group of investigators will meet every two months in year 1 and then quarterly thereafter, with the first meeting in month -3 before the project start. The Scientific Steering Committee will meet biannually, the first meeting in month 1.

Preparation for both workstreams will occur up to month -3 before the project starts. Workstream 1 will begin in month 1 although sampling will begin in month -2 before the project start for 6 months. Data collection will begin in month 4 for 6 months. Analyses will begin in month 6 for 16 months. Workstream 1 publications will be prepared and submitted in year 2, with final output by month 25.

Workstream 2 Phase A will begin in month 1 with onset of the majority of the individual work packages dependent upon recruitment of a full time researcher. The initial case study site sample will be established by month 4 with the option to subsequently iterate sampling if identified trusts drop out or based upon theoretical justification in accordance with qualitative analytic practices. Local research governance approval in each of the 12 sites is anticipated to be completed by month 7.
Case study data collection will require 12 months from month 6, with qualitative analysis beginning in parallel after 6 months and lasting for 12 months in duration. Workstream 2 Phase B will begin in month 15. The survey tool will be developed and piloted. The survey will be administered to alerted sites from month 18 with a 3 month data collection duration. Final analysis and synthesis of quantitative data will take place in months 22 - 24 in parallel with drafting of final report outputs. Preparation of publications based upon the qualitative work packages will begin in month 20 with outputs based upon the quantitative data developed subsequently.

Patient group contact will be maintained over 30 months, and before. Interim research reports will be published biannually (first publication in month 6). The final research report will be published in month 31 (3 month compilation time).

Project management

The project will be led by Dr Paul Aylin and managed by the academic team at Imperial College London. We will put in place a management group consisting of Aylin, Bottle, Benn, Vincent and Burnett. This group will meet every two months in the first year and quarterly thereafter. Formal minutes will be kept and outputs checked against the research plan.

A Scientific Steering Committee (as required by NIHR) consisting of external members will work closely with the project team to ensure that the research is conducted with intellectual objectivity and independence. The group will be chaired by an external academic and will meet biannually to consider progress reports from the PI and researchers. Membership will include:

- An independent academic chair
- Two invited patient representative.
- A representative from the Care Quality Commission.
- A further independent academic from the London School of Hygiene and Tropical Medicine
- Professor Aneez Esmail

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The principal investigator (PI), Dr Paul Aylin, and co-applicant Dr Alex Bottle, are employed by Imperial College London but receive some funding from a research grant to investigate variation in healthcare outcomes from Dr Foster Intelligence (DFI), an independent healthcare information company. However, DFI will not be directly involved in, nor directly benefit from, this project above and beyond that of any other organisation. Our methodology and results will be published publicly. The findings will have implications at local and national levels for the use of mortality monitoring by hospitals and trusts as part of their quality improvement systems. The project will use Hospital Episode Statistics (HES) and Secondary Uses Service (SUS) data received by DFU from an existing non-commercial research agreement with the NHS Health and Social Care Information Centre (NHSCIC), along with data collected by the CQC and directly from trusts.

Approval by ethics committees

For workstream 1, the principal investigator already has permission from the National Information Governance Board under Section 251 of the NHS Act 2006 (formerly Section 60 approval from the Patient Information Advisory Group) to hold confidential data and analyse them for research purposes (ref PIAG 2-05 (d)2007). Annual renewal of CAG approval will be applied for according to advised deadlines, if appropriate (Health Research Agency, 2013).We have approval to use them for research and measuring quality of delivery of healthcare, from the South East Ethics Research

Committee (ref 10/H1102/25) and have confirmation from our sponsor that this covers workstream 1.. Further permissions will be applied for, as appropriate. Under the harmonised governance arrangements for research ethics committees (GAfREC, 2011), workstream 2 does not require full REC approval due to its reliance upon service evaluation methods (surveys and interviews) and use of health service staff as the participant group. Again, we have confirmation from our sponsor that this is the case. Regardless of the requirement for REC approval, local trust R&D approval will be sought from all included sites or an appropriate centralised agency. A buffer has been incorporated into the project timeline to accommodate variations in the actual approvals process.

The PI and relevant co-investigators will liaise with research management and governance support colleagues via the Clinical Research Network to obtain advice about the ethical approval process. In addition, pre-application guidance will be sought from NRES and Health Research Agency (HRA). All members of the project team will adhere to trusts' research governance and Caldicott guidelines. This three year project will be led by the academic team (DFU) at Imperial College London, in collaboration with Professor Aneez Esmail from Manchester University, and supported by CQC and the Imperial Patient Safety Translational Research Centre (CPSSQ). DFU has considerable expertise in generating and analysing mortality alerts. CPSSQ has additional expertise in patient and clinician interviews.

Patient and Public Involvement

In preparing this application we asked our patient representative on the committee of the Imperial Patient Safety Translational Research Centre (CPSSQ) for comments on an early draft outline of the proposal. She saw the proposed research as a very useful project because any system requires regular evaluation which could reveal data beneficial to improving the system (particularly from the review of alerting trusts). The patient representative felt that the outlined research questions were valid and relevant from the patient perspective in terms of investigating safety, quality and resources. She commented that since the study appeared to consist primarily of a review of data already available, there may be limited areas for public involvement. She also thought that the involvement of patients as described in the draft proposal was appropriate and acceptable.

We have carefully considered how best to actively involve patients in as many aspects of the project as possible, indicated by early consultation of a patient representative in the design of the project on the first stage application. We are eager for patients to be active advocates, providing insights into expectations and reactions of public/patient populations. We will seek patients to inform and advise on research implementation and delivery, including methodological design and participation in workstream 2. Patient representatives will also be invited to comment on the research and its outputs, including recommendations on dissemination opportunities to the broader community. Two patient representatives will be recruited to sit on the Scientific Steering Committee and we have allocated funding for them to attend biannual meetings and participate in other activities. Patient representatives will be consulted in the development of participant information resources.

To effectively engage patients in the research, we will follow INVOLVE guidance for researchers. We will liaise with RDS London on recruitment of patients and our patient representative on the management board of the Imperial Patient Safety Translational Research Centre on opportunities to involve patients. We are interested in working with patient groups associated with the two conditions/groups of interest in this project, such as British Heart Foundation and the UK Sepsis Trust. We will make contact with such groups before the project start date to discuss involvement.