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Co-design of a patient and family-initiated escalation of care intervention to detect and refer patient deterioration: Research protocol

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Abstract
Aim: To co-design a patient and family-initiated intervention to improve the detection and escalation of patient deterioration on acute adult hospital wards in Northern Ireland and the Republic of Ireland.

Design: The design is a collective case study approach in an acute hospital in Northern Ireland and the Republic of Ireland using an adapted co-design approach and Medical Research Council framework guidelines.

Methods: Data will be collected from key stakeholders (patients, relatives, and healthcare professionals) using individual and focus group interviews and a review of patients' records. This will inform the development of a co-designed intervention and implementation strategy. The developed prototype will be further refined and optimized following a feedback session with stakeholders from each hospital site. This study was funded in February 2018 and Research Ethics Committee approval was granted in March 2019.

Discussion: This study will contribute to the growing knowledge base in relation to the interventions that improve the escalation of patient deterioration. It will also contribute to the intelligence, evidence and understanding of the role of patient and family participation in the detection and referral of clinical deterioration in acute adult hospital settings.

Impact: There is an ongoing need to introduce systems or mechanisms in acute care hospital settings which allow patient or family members to have a greater role in escalating care when they are concerned about patient deterioration. To date there is limited evidence of rigorous studies examining this area and this study will use stakeholder engagement and involvement to co-design an intervention which will...
provide patients and families with a mechanism to address concerns which can be tested in practice.

**KEYWORDS**
clinical deterioration, family-initiated escalation of care, family-initiated rapid response, healthcare staff, hospital and experiences, nurses/midwives/nursing, patient, rapid response system

1 | INTRODUCTION

Clinical deterioration and more specifically failures relating to the recognition and response to deterioration is an area of significant concern internationally in acute healthcare settings (Donaldson, Panesar, & Darzi, 2014; Institute for Healthcare Improvement [IHI], 2006). In-hospital clinical deterioration that is not promptly recognized or responded to can lead to serious consequences such as increased length of hospital stay, intensive care unit (ICU) admission, cardiac arrest, and increased mortality (Bing-Hua, 2014; Donaldson et al., 2014). Early recognition, response, and treatment of clinical deterioration is therefore essential to the successful management of the acutely ill patient on general hospital wards.

It is increasingly recognized that patients and/or families may have a role to play in detecting and responding to clinical changes (IHI, 2006; WHO, 2013). This has led to several patient and family-initiated escalation of care interventions being implemented which enable patients and relatives to have a greater voice in calling for help. However, robust research in this area appears limited.

2 | BACKGROUND

Patients who deteriorate on general hospital wards frequently exhibit changes in vital signs prior to adverse events (Hillman et al., 2000; Kause et al., 2004). These vital sign changes are physiological alterations in respiratory rate, conscious level, heart rate, and blood pressure observed and recorded at the bedside by nurses regularly on patients in hospital. Early identification, interpretation, and response to these physiological changes has been shown to improve patient outcomes, reduce ICU admissions, and prevent adverse events (Beitler, Link, Bail, Hurdle, & Chong, 2011; Chen et al., 2014; Maharaj, Raffaele, & Wendon, 2015; Mitchell et al., 2010; Moon, Cosgrove, Lea, Fairs, & Cressey, 2011). As a result several systems have been implemented internationally to improve patient safety based on evidence-based guidelines (ACHS, 2012; IHI, 2006; NICE, 2007). In the United Kingdom (UK), Australia and United States of America (USA) several adult and paediatric patient and family-initiated interventions have been introduced which allow concerned patients, families or carers to trigger escalation of care either through an integrated RRS protocol or separate system (Gill, Leslie, & Marshall, 2016a; Greenhouse, Kuzminsly, Martin, & Merryman, 2006; IHI, 2006; Odell, Gerber, & Gager, 2010). These interventions include the provision of information, calling criteria, and education about when to call for help if they are concerned a patient or relative is deteriorating (Clinical Excellence Commission, 2017; Clinical Excellence Division, 2018).

Evaluation of these RRS patient and family-initiated interventions found that a small number of relatives identified patient deterioration and escalated a subset of patients missed by healthcare staff (Brady et al., 2015), were highly valued by patients and families, improved quality of care and enhanced patient and family experience and empowerment (Gerdik et al., 2010; Greenhouse et al., 2006; Odell, 2019; Odell et al., 2010). However, more robust evaluation of these schemes by systematic review highlighted the overall poor quality of the included studies and the lack of evidence on which to determine the impact of patient- and family-initiated schemes (Albutt, O’Hara, Conner, Fletcher, & Lawton, 2017; Gill et al., 2016a). Specifically, the reviews stated that these schemes were largely implemented as quality improvement interventions, audit or practice development initiatives without robust testing (Albutt et al., 2017;...
Gill et al., 2016a) and mainly focused on evaluating the effectiveness of implementation strategies using non-clinical outcomes (Albutt et al., 2017; Gill et al., 2016a). Furthermore, the systematic reviews suggested there was limited detail in the studies about the context of the intervention, the most appropriate strategies to inform patients, families, and healthcare staff of the process, no agreement on outcome measures and limited reports identifying patient and family preferences for involvement (Albutt et al., 2017). As a result the systematic reviews concluded that to date there are few studies that justify study design with underpinning theory, data collection methods, sample size or patient outcomes (Albutt et al., 2017; Gill et al., 2016a). This lack of evidence is more prominent in the adult setting compared with paediatrics (Gill, Leslie, & Marshall, 2016b, 2018). It was recommended that further research is required which uses a structured systematic approach, includes advisory groups and consumer involvement in the development of activation programme content, calling criteria, consumer education, and ongoing education of healthcare staff in the delivery of educational materials (Vorwerk & King, 2015). The purpose of this research study is to explore patient, family and healthcare professional perceptions of family involvement in escalating care and co-design a patient/family-initiated escalation of care intervention and implementation strategy.

3 | Methods

3.1 | Aim

To co-design a patient and family-initiated intervention to improve the detection and escalation of patient deterioration on acute adult hospital wards in Northern Ireland and the Republic of Ireland.

3.2 | Objectives

1. To collate research evidence, via a systematic review, on patients’, relatives’, and healthcare staffs’ experiences of deterioration and their perceptions of the barriers and facilitators to patient and family-initiated escalation of care in acute adult hospital settings.
2. To explore patients’, relatives’, and healthcare staffs’ experiences of deterioration and perceptions of a patient and family-initiated escalation of care intervention.
3. To use a co-design approach to develop, optimize and refine a patient/family-initiated escalation of care intervention and implementation strategy.

3.3 | Study design

The research design involves a collective case study approach in an acute hospital in Northern Ireland (NI) and the Republic of Ireland (ROI). A collective case study approach provides a structure that facilitates insight into the focus of interest across settings as it allows comparison across and between cases in their real-world contexts (Adams, Jones, Lefmann, & Sheppard, 2014; Baxter & Jack, 2008; Crowe et al., 2011). It is a particularly useful research design when the research aims to explore contextual or complex multivariate conditions and not just isolated variables and ensures that the phenomena of interest are not only explored through one lens but rather multiple lenses (Yin, 2018). It therefore provides useful insights to both develop interventions and/or explain ‘how’ or ‘why’ a given intervention worked (or not) (Stake, 2005; Yin, 2018).

The proposed study follows the development phase of the Medical Research Council (MRC) framework for developing and evaluating complex interventions (Craig et al., 2008) to determine the evidence base, identify underlying theory and to model process and outcomes prior to introducing and evaluating a patient and family-initiated escalation of care intervention. In this study, the developmental phase includes conducting a systematic review to establish the evidence base; undertaking focused interviews with patients, relatives, and healthcare staff to identify the underlying theory of how such interventions might work; and engaging key stakeholders to co-design an intervention and implementation strategy. As a result, this study will provide an important theoretical and evidence base about some of the mechanisms and contextual factors which are important to consider when co-designing, developing, and implementing a complex intervention such as this in health care (Craig et al., 2008; Schaalma & Kok, 2009). Patient and family-initiated interventions may be considered complex because they rely on several components working together including: understanding of patients and relatives’ ability to recognize deterioration and call for help, staff who are open to listen and be engaged and a mechanism of action. Hence, the MRC framework with its focus on proper development and testing of component parts is an ideal framework to draw from. To overcome the lack of pragmatic instruction on intervention development and delivery methods by the MRC (Aventin, Lohan, O’Halloran, & Henderson, 2015; Hawkins et al., 2017) an experience-based co-design approach (EBCD) (Kings Fund, 2019) and an action research cycle to co-design health interventions and delivery methods with key stakeholders will be used to facilitate this process (Hawkins et al., 2017). The collective case study approach will involve three phases: Phase 1: involves identifying the evidence base, Phase 2: gathering evidence to ascertain views of stakeholders, Phase 3: co-design of the intervention and implementation strategy (Figure 1).

3.4 | Phase 1: Identifying the evidence base

3.4.1 | Qualitative systematic review

A systematic review was undertaken to uncover the existing qualitative evidence base about patients’, families’, and healthcare staffs’ experiences of deterioration and their perceptions of the barriers and facilitators to patient and family-initiated escalation of care in acute adult hospital settings. The methodology for this systematic
review is outlined in a previously published systematic review protocol (McKinney, Fitzsimons, Blackwood, & McGaughey, 2019). The review protocol was registered prospectively with PROSPERO (CRD42018106952) and the review was conducted using Cochrane methodology. Phase 1 of establishing the evidence base via a qualitative systematic review has now been completed.

3.5 | Phase 2: Ascertaining the views of stakeholders

Phase 2 will involve building on the results of the systematic review to further explore patients’, relatives’, and healthcare professionals’ experiences of deterioration and their perceptions of a patient and family-initiated escalation of care intervention in a local context. It has been argued that complex interventions are inextricably linked to context and therefore understanding the views of key stakeholders from a local context is extremely important as it holds implications for the sustainability, acceptability, and feasibility of the intervention (Booth et al., 2019).

3.5.1 | Sample selection

An acute care teaching hospital in Northern Ireland and the Republic of Ireland which have implemented RRS will be identified via steering group members and hospitals willing to participate will be included. In each hospital a local collaborator and members of the care team will facilitate recruitment and access to patients, relatives, and healthcare professionals. Patients and relatives will be recruited from acute adult medical or surgical wards that trigger the highest number of critical care outreach referrals as identified from the critical care outreach database or critical care outreach records/manager in each hospital.

In each participating hospital, patients (N = 6), relatives (N = 6), ward nurses (N = 6), critical care outreach staff (4–8), and key informants (ward manager, critical care outreach team manager, ward doctor, critical care doctor, hospital at night manager) (N = 1) will be purposively recruited to take part in individual semi-structured interviews (key informants) or focus group interviews (patients, relatives, critical care outreach, and ward staff). Where recruitment of insufficient numbers of patients, relatives or healthcare professionals for focus groups occurs, individual semi-structured interviews will be facilitated. Estimate of sample size is based on recommendations of six to eight participants for focus group interviews and homogenous groups (Kuzel, 1992) and recommendations that data saturation is likely to occur after approximately 12 interviews (Guest, Bunce, & Johnson, 2006).

3.5.2 | Inclusion/exclusion criteria

Patient and relatives who meet specific inclusion criteria will be included; patient triggered an urgent medical and/or critical care outreach team response according to local hospital policy, patient had a critical care outreach team review, was 18 years of age or over, English speaking and physically and cognitively able to communicate. Patients and relatives will be excluded if patient was known to be approaching end-of-life or cognitive/physical impairment affects their ability to communicate. Relatives of deceased patients will also be excluded. Healthcare staff with greater than 6 months acute care experience will be eligible for inclusion.

3.5.3 | Data collection

In each participating ward a gatekeeper (ward manager/clinical staff, critical care outreach team manager or local collaborator) will identify, approach, and distribute information packs to patients, relatives, and healthcare professionals who meet specific inclusion criteria. Patient and relative participants will be approached when the patient is considered to be physically and emotionally stable by ward staff following the period of deterioration before hospital discharge. Those who express an interest in participating will be asked to complete a reply slip to be returned to the researcher. The participants will then be contacted by the researcher to discuss the study, answer any questions and agree a convenient interview date and time ensuring that there is a 24 hr cooling off period. All interviews

FIGURE 1 Flow diagram of study phases [Colour figure can be viewed at wileyonlinelibrary.com]
will be conducted in a quiet room in the hospital or convenient location. Individual and focus group interviews will last approximately 60 min. The research literature (Gill, Leslie, & Marshall, 2018; Rainey, Ehrich, Mackintosh, & Sandall, 2013) and the Theoretical Domains Framework (TDF) (Atkins et al., 2017; Cane, O’Connor, & Michie, 2012) will be used to inform the development of the interview guides. The TDF is a comprehensive framework that is considered to be particularly suitable for implementation researchers as it addresses the behaviour change factors that are relevant for the successful implementation of an intervention (Atkins et al., 2017). A review of patient’s medical and nursing records to contextualize the clinical deterioration and referral will also be undertaken. This information will help to inform the interviews as it will give background clinical information. Informed consent will be obtained prior to each interview and review of documents.

3.5.4 | Data analysis

Interview data will be transcribed verbatim and entered into NIVO 11 to assist the organization of data into themes and categories. Sensitivity to the data will be achieved through close listening to/reading of each interview. The use of digital recording and verbatim typing of transcripts will assure consistent and accurate recording of data. Data will be analysed using thematic analysis as per the six-phase guide outlined by Braun and Clarke (2006). Review of case notes will be analysed to label and classify what led to the deterioration and how it was managed after and this information will be tabulated.

3.6 | Phase 3 – Co-design of the intervention

Co-design is defined as the voluntary or involuntary involvement of key users or stakeholders in the design, management, implementation and/or evaluation of services (Clarke, Jones, Harris, & Robert, 2017). It is argued that involving stakeholders in the design and development of interventions is one of the best ways to ensure that the intervention meets the needs of the target population and also has the potential to increase intervention effectiveness (O’Brien et al., 2016). Consequently, a co-design approach, drawing on elements of the experience-based co-design (EBCD) approach (Kings Fund, 2019) will be incorporated throughout this study. A three-stage framework for the co-design and prototyping of public health interventions (Hawkins et al., 2017) will be used to guide the development of an All-Ireland patient and family escalation of care intervention (Figure 2). A Steering group comprising of patient, relative and healthcare representatives from each hospital site, academic supervisors and commissioning and policy makers will be actively involved during each stage.

3.6.1 | Evidence review and stakeholder consultation

As previously outlined a qualitative evidence review and stakeholder consultation with patients, relatives, and healthcare professionals will be conducted in Phases 1 and 2 and forms the initial part of the co-design framework. The purpose is to explore experiences of deterioration, perceived facilitators and barriers to escalation and attitudes about the acceptability of potential interventions.

![Figure 2: Co-design framework for development of a patient and family-initiated escalation of care intervention.](wileyonlinelibrary.com)
3.6.2 | Co-design

The review and interview findings will be collated and presented to Steering group members to inform the development of a prototype intervention. Action research, as advocated by Hawkins et al. (2017) will be employed during the co-design stage. This will involve organizing several meetings during which feedback on findings and ideas will be discussed, refinements to a potential intervention will be made, presented, and discussed again until agreement on a final proposed intervention has been reached. Face to face meetings will be supplemented with communications by email and/or telephone where required.

3.6.3 | Prototyping

A prototype of the adopted intervention or resource will be developed by the research team and members of the Steering group based on the consensus agreement reached in the co-design stage. In keeping with the modified EBCD approach (Kings Fund, 2019) a joint feedback session will be facilitated at each hospital with patients, relatives, and healthcare professionals to gain their perceptions and recommendations on the prototype to optimize the intervention. Key stakeholders will be purposively selected from those who consented in Phase 2 to be contacted again to obtain a range of perspectives from all stakeholder groups and to consider whether the developed prototype is reflective of their previous views. Feedback sessions will be recorded, transcribed and thematically analysed and the findings will be presented to the Steering Group. This will facilitate refinement of the intervention to optimize utility and fidelity. An implementation strategy will also be developed to deliver the intervention based on implementation science models (Damschroder et al., 2009; May, 2013).

3.7 | Ethical considerations and dissemination

Ethical approval for the study was obtained from East of England – Cambridge East Research Ethics Committee (Ref:19/EE/0061), the ROI Hospital Research Ethics Board (Ref: C.A.2126) and individual governance approval for each hospital in NI and the ROI in March 2019. All participants will be provided with detailed information about the nature and purpose of the study, informed that participation is voluntary and that all personal/demographic data from interviews and all digital recordings and transcripts will be coded to ensure anonymity. Participants will be given the opportunity to ask questions and will be free to decide whether to take part. A gatekeeper, who is an experienced healthcare professional (ward manager/clinical staff, critical care outreach team manager or local collaborator) will identify and use their professional discretion to ensure that patients and relatives and healthcare professionals are approached at a suitable time to consider if they may wish to become involved in the study. Patients and relatives will be afforded the opportunity to have another individual attend the interview with them to support them if desired. A distress protocol will be implemented in the event that a participant becomes upset and a researcher safety protocol will also be followed to maximize researcher safety (Green & Thorogood, 2014). It will be made clear to participants that consent can be withdrawn at any time without prejudice (Edwards, 2005). It will also be made clear to participants that there may be exceptional circumstances whereby the researcher is morally and legally obliged to breach confidentiality and a Breach in Confidentiality protocol will be followed in such cases (Gray, 2017). Participants will be informed that the research study will be published in professional journals, but that data will be anonymized so no individual patient, relative or staff member can be identified. Access to review notes and records will be obtained via a gatekeeper. The patients’ hospital consultant and General Practitioner (GP) will be informed that the patient has given consent to take part in the study. All members of the research team will have undertaken training in General Data Protection Regulation (GDPR). Only the research team will have access to the data which will be stored securely, in a locked filing cabinet, in a locked office on university premises. Computers used to store data will be password encrypted to restrict access.

The systematic review protocol, research protocol and findings from the systematic review and qualitative phase of the study will be submitted for publication in high-quality peer-reviewed journals and will be presented at National and International conferences. Findings will also be presented to key stakeholders at Steering group meetings as they become available and on the School of Nursing and Midwifery websites, via Twitter and/or other social media platforms.

3.8 | Rigour

Several actions will be taken to ensure rigour in qualitative data collection and analysis. The use of digital-recording and verbatim typing of transcripts will assure consistent and accurate recording of data. Sensitivity to the data will be achieved through close listening to and reading of each interview. To further enhance the rigour and reduce investigator bias, the emerging categories will be cross-checked by other members of the research team following a pilot of interview transcripts to ensure credibility (Houghton, Casey, Shaw, & Murphy, 2013). Credibility will also be maintained through the use of digital recording of the interviews and the presentation of an accurate account of participants’ perspectives, using quotations as appropriate (Houghton et al., 2013). Member checking will also be employed. Participants will be offered the opportunity to receive a summary of their interview to check for accuracy to further enhance trustworthiness (Baxter & Jack, 2008).

4 | DISCUSSION

There is a pressing need for more robust research that considers the patients and relatives voice in recognizing deterioration and calling for help. This research will add to the growing body of knowledge in this area and will generate greater insights into the feasibility and
acceptability of a co-designed intervention whose aim is to support patients and relatives to escalate care. The significance of this research can particularly be considered from the choice of research design. A key strength of the design is that it considers the central role of patients, relatives and healthcare professionals across all stages of the research project, ensuring real collaboration with all stakeholders in the design, development, and implementation planning of the intervention. By using this approach, it will ensure that the developed intervention reflects the perspectives and realities of key stakeholders’ experience, which is crucial if, going forward this intervention is be used in practice in NI and the ROI.

4.1 | Limitations

Due to funding and time constraints, this is a small-scale study, consisting of a case study approach involving only two hospitals, one in NI and one in ROI. As the healthcare systems in NI and the ROI differ, it could be argued that inclusion of more than one hospital in each area could allow for similarities/differences to be more accurately compared. However, it is also a possibility that the inclusion of hospitals in different areas may also be an advantage as it may provide better insights into cultural differences that exist in two different healthcare jurisdictions.

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CONFLICT OF INTEREST

No conflict of interest has been declared by the authors.

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