Interventions to increase patient and family involvement in escalation of care for acute life-threatening illness in community health and hospital settings (Protocol)


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Interventions to increase patient and family involvement in escalation of care for acute life-threatening illness in community health and hospital settings (Protocol)

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Interventions to increase patient and family involvement in escalation of care for acute life-threatening illness in community health and hospital settings

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ABSTRACT

This is a protocol for a Cochrane Review (Intervention). The objectives are as follows:

To assess the effects of interventions designed to increase patient and family involvement in escalation of care for acute life-threatening illness on patient and family outcomes, treatment outcomes, clinical outcomes, patient and family experience and adverse events.

BACKGROUND

Despite the rise of the global patient safety movement which was triggered by the publication of ‘To Err is Human’ (Kohn 2000), two decades later avoidable patient harm continues to be a burden on healthcare systems across the world (Landrigan 2010; Leistikow 2011; Wachter 2010). In addition to longstanding issues, new threats to patient safety are emerging. Patients are increasing in age, have more complex needs, and are often affected by multiple chronic conditions. The increased complexity of care creates new risks of error and harm to patients (Yu 2016).

While the potential role of patients to contribute to their safety was acknowledged in To Err is Human (Kohn 2000), until recently patient safety was largely seen as a technical and professional matter (Ocloo 2016). This position is changing. There is now a rising global commitment for providers to work together with patients and families to improve the delivery of safe care (Vincent 2016; Yu 2016). The World Health Organization has advocated that patients should become active partners in improving the safety, quality and efficiency of health service delivery (WHO 2013). Contributory roles for patients have been identified in processes such as hand hygiene, hospital rapid response systems, surgical checklists, medication safety, prevention of falls, prevention of medical errors after discharge and care transitions (Berger 2013).

There is also a strengthening evidence base that interventions are needed at provider and health system level to enable healthcare staff to engage effectively with these activities (Hor 2013; Rance 2013).
Patient involvement in safety can be difficult to achieve in practice, as this role challenges established hierarchies, power differentials and social and institutional norms (Draper 2015; Johnson 2015; Keogh 2013; Kirkup 2015). It can bring with it challenges such as the need to raise awareness amongst patients of potential problems without instilling anxiety and fear, and preventing a shift of responsibility for safer care and avoidance of harm from providers to families (Entwistle 2005; Lawton 2012). Some safety activities over which they have more control (e.g. medication safety) may be perceived by patients as more acceptable to participate in than others (e.g. hygiene practices). These beliefs are linked to the social meaning and value attached to these activities, and to patient and professional expectations about responsibilities for care (Entwistle 2010; Schwappach 2010).

It is clear from the literature that patient involvement in safety encompasses different models of application and mechanisms of action, and conflating these is unlikely to be helpful (Entwistle 2006; Johnson 2009). One type of model - patient involvement in escalation of care for acute (serious) life-threatening conditions (i.e. helping secure a step-up to urgent or emergency care) - has been receiving increasing policy and practice attention. Patient involvement can be defined on the micro-level in relation to patients, clinicians, processes, interactions and recurring patterns in practice as distinct from meso-level (in relation to organisations) and macro-level (in relation to the health system) (Nelson 2002; Nelson 2008).

**Description of the condition**

Patient and family involvement in escalation of care depends on a complex interplay of personal factors, lay and professional encounters, and contextual influences (Snyder 2016). Safety is an ongoing achievement which largely involves patients in interaction with family, friends and peers (Greenhalgh 2015) and healthcare staff (Hor 2013). Relationships underpin safety production, and patient involvement can be facilitated by partnership building and supportive communication (Snyder 2016). Trust is also linked to safety as it captures the non-technical, interpersonal and social nature of health care. Ethnographic accounts suggest that trust is contingent on a particular context and a set of relationships, including trusting oneself, one’s own body, healthcare staff and the health service (Cohn 2015).

Key requisites for patient-initiated escalation of care, as with other safety activities, are that patients need to (1) know how to participate (i.e. patients need to know how to recognise there is a problem, what action they can take, and why), (2) have the ability to participate which is derived not only from the patient’s knowledge, and physical and cognitive capacity, but also linked to self-efficacy, social status and the patient’s role within the family or community, and (3) be willing to participate (Davis 2012; Schwappach 2010).

Evidence shows that there is considerable scope to improve the patient and family contributory role to detection and management of acute illness. Delayed recognition and treatment of conditions such as pneumonia and meningitis in childhood (Wolfe 2011), pre-eclampsia and reduced foetal movements during pregnancy and after childbirth (Draper 2015; Warland 2015), and heart disease and stroke in adulthood (AHA 2005; ISWP 2010; Schwappach 2010), contribute significantly to the mortality and morbidity burden in low-, middle- and high-income countries. These conditions typically present with a time-critical window for early recognition and response, and are associated with red flag signs and symptoms (such as breathlessness and pain) which can signify a serious underlying condition and act as potential markers to aid patient and family involvement in escalation of care. Delays in recognition and receipt of appropriate treatment are linked to economic, socio-cultural, health care system level and interpersonal factors. These factors are relevant across countries (low, middle and high income) although the relative influence of each will vary (Binder 2012; Chandrathvea 2010; Lawlin 2008; Mandelzweig 2006; Thaddeus 1994; Thureson 2007). Factors affecting patients’ level of involvement include perceptions of risk and the consequences of contributing to safety as well as not participating in monitoring, seeking help and speaking up (Doherty 2012; Entwistle 2010). The local environment can hinder a patient’s or family member’s ability to act (Thaddeus 1994). Some patients may choose to adopt a passive role rather than taking on explicit safety roles which may raise their anxiety and a sense of responsibility. They may therefore choose to avoid taking an active role as a means of actively protecting their personal safety (Doherty 2012). Particularly in low-income countries (LICs), norms of passivity are underpinned by power hierarchies between patients and healthcare staff, and reinforced by broader societal and gender inequities (Behague 2008; Grossmann-Kendl 2001). Judgements about personal ability to contribute to diagnosis have been shown to be significant (Entwistle 2010). The trajectory of deterioration (particularly the rapidity of onset and degree of debilitating symptoms) will influence patients’ ability to engage in the most basic of safety acts (Doherty 2012). Classic ‘red-flag’ features of serious illness may be absent, e.g. meningococcal disease in children, making diagnosis difficult (Thompson 2006). Language and health literacy will impact on patients’ and families’ contributions to their safety, as will existing or previous relationships with staff and provider organisations, perceptions of trust and safety, and knowledge and experience of navigating the organisation (Entwistle 2010; Rainey 2013; Rance 2013).

Social codes of conduct of ‘appropriate use’ of emergency services influence help-seeking; patients and families fear making the ‘wrong’ judgement about calling for help and display uncertainty about when to seek help (Cheyne 2007; Ehrich 2003; Eri 2009; Houston 2000; Mackintosh 2012; Neil 2014). Patients’ previous experiences of the health service can influence help-seeking both positively and negatively (e.g. broken trust during a clini-
Access barriers to help-seeking are linked to lack of infrastructure (transport), poor signposting, gaps in the provision of services and gate keeping. Lack of resources and technology can lead to delays in appropriate response. Once in receipt of care from health professionals, involvement in escalation of care necessitates vigilance from patients and family members, and may require them to take a proactive and interactive role with staff with potentially some degree of confrontation, particularly if challenging the appropriateness of decisions taken (Entwistle 2010). Helping to secure a timely response may involve speaking up about concerns about the appropriateness of care received and seeking a second tier of professional staff or a different access route to acute care. This work involves negotiating hierarchies and boundaries. Considerable cognitive and emotional resources may be required from patients and families to carry out these types of safety behaviours (Davis 2012). Differentials in social and economic capital can lead to difficulties in voicing concerns freely (Béhague 2008). Patients report wanting to be seen by staff as ‘good’ patients by not bothering, challenging or criticising them (Hrisos 2013). Patients need to defend their ‘good patient status’ in the face of a whole social structure - a powerful biomedical system, inequities in healthcare delivery and fear of differential treatment - that drives underlying debates about culpability and blame (Béhague 2008; Davis 2008; Enrwistle 2005; Ocloo 2010; Schwappach 2008). The nature of professional cultures and institutional power, knowledge and politics can inhibit knowledge sharing (DoH 2013; Draper 2015; Johnstone 2009; Kohn 2000; Scott 2012; Waring 2009).

There are also a number of factors that moderate staff’s ability to listen to patients’ concerns and respond appropriately. Staff have to balance the trade-off between inappropriate reassurance (potentially leading to catastrophic delay in diagnosis and treatment), versus creating unnecessary additional anxiety for patients (Almond 2009). Emergency departments and triage clinics are characteristically unbounded, where staff have little control over workload. Staff shortages, limited resources, overcrowding and long waiting times contribute to poor communication and diagnostic errors (Eisenberg 2005; Roscoe 2016; Wears 2003). It is evident that there are differences in the (1) scale of avoidable morbidity and mortality between high- and low-income countries, (2) timelines and presentation of trajectories of deterioration for particular conditions, and (3) facility and professional help accessibility across the emergency care escalation pathway. However, it is important to move beyond condition-specific models and to utilise learning from both high- and low-income contexts, in order to understand generic processes which influence recognition and emergency response. Conceptually we draw distinction between patient and public health behaviours which occur prior to contact with healthcare professionals which include: self-monitoring; self-diagnosis; the decision to seek help; and the negotiation process that starts when patients (and families) come into contact with staff and start working with staff to ensure timely recognition and response. This review is concerned with this negotiation work i.e. patient and family involvement across the emergency care escalation pathway, once contact has been made with healthcare professionals. It includes patients presenting with new onset of conditions as they make contact with community health and hospital services for urgent/emergency care and timely treatment, and patients already in the healthcare system who are negotiating a step-up in care to receive urgent/emergency treatment.

**Description of the intervention**

Interventions will be considered eligible if they aim to change individual behaviour in relation to increasing patient and family involvement in escalating care for acute life-threatening illness in community health and hospital settings. These interventions can be aimed at patients, families, professionals, or combinations of the three.

The interventions could include one or more of these components.

- Those aimed at enabling patients and families to detect changes in patients’ conditions and to speak up about these changes to staff.
- Those aimed at empowering patients and families to feel confident about their contribution and role in negotiating a step-up in care.
- Those aimed at enabling staff to provide opportunities for patients and families to share concerns and to listen actively to these during urgent/emergency consultations.
- Those aimed at equipping staff with the skills to respond appropriately to patients and families when they raise concerns about diagnosis, treatment and management.

These interventions could aim to raise patients’ awareness of their role in facilitating timely emergency response and the importance of actively contributing to escalation of care. Interventions could include educational and motivational coaching programmes. These could be individualised to the patient’s specific needs to address cognitive and emotional effects impacted by involvement in escalation of care. Educational interventions aim to enhance patients’ and families’ self-efficacy to contribute to recognition and response. Patients are taught communication techniques to help them escalate their concerns (Denham 2008). Methods might include role play, use of written materials and workshops (See 2014; Weingart 2009).

Interventions could also teach patients how to call for help while in hospital (Hueckel 2012). Interventions may target both patient and provider behaviours with joint training programmes (Tait-Seale 2016; Weingart 2009). Patient-initiated rapid response systems provide a direct means for patients and families to contact an outreach team if they are concerned about a deterioration in condition and feel the clinical team are not taking their concerns seriously (Albutt 2016; Berger 2013; Vorwerk 2015). Programmes
could include information and training for patients and families to encourage them to access the service, and training or support for ward-based staff to address their concerns about patients seeking alternative help. Skills-based training to promote open and reciprocal communication between patients and staff in order to aid escalation of care could also include use of structured communication tools. For instance, the 'SBAR' tool ('situation', 'background', 'assessment' and 'recommendation') is a situational briefing tool to help patients convey, in less than a minute, vital information needed by the doctor or next caregiver (Denham 2008; Mackintosh 2010).

To summarise, increasing patient and family involvement in escalation of care for acute life-threatening illness might involve a range of different approaches, which could include any of the following.

**Patient- and family-focused interventions**
- One-to-one acute education session to increase confidence in speaking up about changes in condition and concerns using role play and motivational coaching (e.g. Mooney 2014).
- Adoption of a communication tool for patients in emergency situations, providing them with guidance on what information to share with clinical staff.

**Healthcare professional-focused interventions**
- Team skills-based programme providing information and training on how to listen and respond to patients' narratives about acute life-threatening illness.
- Training on cultural competence with regards to patients and families speaking up about clinical deterioration and challenging professional diagnosis and decision making.

**Joint interventions**
- Hospital-based training to improve patients' understanding of how and why to activate a patient-activated critical care outreach service, together with a staff programme to inform them of their role in encouraging patients and families to speak up about concerns.

### How the intervention might work

Interventions designed at the level of individual behaviour change tend to be developed from the fields of psychology and behavioural science (Davis 2012; Schwappach 2009). Interventions draw on social cognitive theory (Bandura 1986); motivational interviewing (Miller 2012); stages of change (Prochaska 1983); the theories of reasoned action (Fishbein 1980) and planned behaviour (Ajzen 1991); and the self-regulatory model of health and illness (Leventhal 1998). These theories focus on the importance of self-control and empowerment. In this context, interventions aim to build on patients' and families' confidence and motivation to become involved, and instil new knowledge and skills for them to know how to contribute to safety (i.e. what signs and symptoms mean, how to self-monitor, what to do when concerned, what to expect from healthcare professionals). Interventions targeted at changing behaviours of healthcare providers aim to address personal values, beliefs and professional goals. Behaviour change initiatives could also target both patients' and staff's communication behaviours using methods such as user-experience design (Tai-Seale 2016).

### Why it is important to do this review

While there is increasing policy emphasis on patients as co-producers of safety, there is a paucity of evidence regarding effectiveness of interventions to aid involvement (NPSA 2015). The research that has been conducted is generally of poor methodological quality (Berger 2013; Peat 2010). Concerns have been raised regarding the poor conceptualisation of the intended mechanisms and causal chain in many safety interventions, making it difficult to elicit how and where they are designed to act (Peat 2010).

Currently, notions of 'expertise', 'involvement' and 'partnership' are mostly used in the context of patients with long-term conditions, and reflect their participation in treatment and care management decisions. It is less clear how these concepts apply to patient involvement in safety, particularly in the context of escalating care during acute life-threatening episodes of illness. This review is distinct from others that have explored the effectiveness of chronic disease education or management programmes for patients and families (Peytreau-Brivdeaux 2015). It also adds to existing research on patient involvement in safety which has tended to be based in hospital or hospice settings, and has typically focused on error prevention (e.g. prompting staff to wash hands and detecting medication errors) (Doherty 2012).

The review is timely given concerns about poor patient experiences in securing professional response for serious safety concerns and increasing consumer interest in the potential for a greater role in being able to safely escalate care (European Patients' Forum 2017; NFWI-NCT 2017; Scott 2012; Walton 2016). Existing research and effectiveness reviews on recognition of, and response to, acute life-threatening illness have tended to focus on interventions for specific conditions e.g. stroke (Lecouturier 2010). This review will offer the opportunity to assess commonalities and differences across conditions, settings and interventions. The focus is across the escalation of care pathway, including both community health and hospital settings, in recognition of the difficulties experienced by patients with new onset of a condition negotiating access to emergency care; and patients already in the health care system who require a step-up in care to receive emergency treatment.

Research into the effectiveness of interventions aimed at patient and family involvement in safety has often focused at the patient level rather than at the point of interaction between patients and staff i.e. acknowledging that safety is co-produced by patients and providers. This review will widen the lens' angle to include those interventions targeted at the collaborative local level of interactions between patients, families, and staff. The conceptual model...
The review is required to assess the effectiveness of different approaches to increasing patient and family involvement in escalation of care. Individual behaviour-change models focusing solely on information exchange may fail to recognise the impact of socio-cultural factors (Crossley 2001; Dutta-Bergman 2005). The mortality and morbidity burden of acute life-threatening illness is often more significant amongst members of black, minority and ethnic communities, and the socially disadvantaged (Flenady 2016; Heuschmann 2008). Information processing requires effort and the burden may be greater in those with lower levels of education, literacy and health literacy (WHO 2008). Health communication research demonstrates the importance of addressing cultural differences in order to optimise intervention effectiveness (Alden 2014). Cultural competency training for staff may help address problems influenced by patient-provider cultural and language differences (Johnstone 2006).

There is also a need to assess unintended consequences of interventions. Involvement in escalation of care may heighten patient and family anxiety, and their feelings of responsibility for safety or the outcomes of treatment, or both (Davis 2012; Warland 2013). Interventions may inappropriately burden families with responsibilities for the safe provision of care that are beyond their abilities and intentions (Johnstone 2009). There may be negative effects on patient-provider communicative trust (Brown 2008). This review is related to, but distinct from, other Cochrane Reviews in the following respects.

- Several reviews focus on the provision of interventions to reduce acute care utilisation for long-term conditions such as COPD and asthma (Boyd 2009; Howcroft 2016; Tapp 2007; Walters 2010). These reviews included interventions, such as action plans as well as education, which were aimed at enabling...
patient self-management and timely help-seeking for an acute exacerbation of the condition. These reviews are distinct from ours as the focus was on community-based preventative action (e.g. adherence to treatment), and self-initiated interventions (e.g. taking medication early during an asthma attack) as well as help-seeking (knowing when to seek medical assistance). Primary outcomes were hospital admission rates and emergency department visits. Our review in contrast is concerned with patient and family contributions to diagnosis and response once in contact with health professionals such as the GP or emergency services, and whether individual behaviour change interventions can enable effective patient-provider team-working in escalation of care for life-threatening illness.

- McGaughey 2007 assessed the impact of outreach services - including the introduction of an Early Warning System to record physiological observations, training of hospital staff to recognise signs, or creating special teams to respond to calls when a patient is deteriorating - on hospital mortality rates. Our review adds to this in terms of making explicit the patient and family contribution to escalation of care. McGaughey 2007 included training for nurses and doctors on systematic patient assessment, inter-professional teamwork, communication, documentation and an understanding of when to seek help, but the patient and family role within this was not considered. Our review also adds to an ongoing review of paediatric early warning systems including the role of families in escalation of care (Hood 2015).

- Similarly Opiyo 2015 investigated in-service training for health professionals to improve the care of seriously ill newborns and children in low-income countries. Family contribution to the recognition and management of seriously ill newborns and children in-service was not included in the training.

- Dwamena 2012 investigated the effects of interventions for healthcare providers that aimed to promote a patient-centred approach in clinical consultations. Their review is relevant in that it focused on behaviours that reflect a philosophy of care that encourages shared control of the consultation, decisions about interventions or management of the health problems with the patient. They found that interventions directed at providers and patients that include condition-specific educational materials have beneficial effects on health behaviour and health status, outcomes not assessed in studies reviewed previously. Our review will build on this and add important specificity to patient and provider behaviour measures regarding escalation of emergency care.

- Horvat 2014 investigated the effects of cultural competence education for health professionals on patient-related outcomes. While our review is focused on the specific process of escalation of care for life-threatening illness, sensitivity to cultural competence may be necessary for effective patient-provider communication. The Horvat review found positive, albeit low-quality evidence, showing improvements in the involvement of patients from culturally and linguistically diverse backgrounds with delivery of cultural competence education.

**OBJECTIVES**

To assess the effects of interventions designed to increase patient and family involvement in escalation of care for acute life-threatening illness on patient and family outcomes, treatment outcomes, clinical outcomes, patient and family experience and adverse events.

**METHODS**

**Criteria for considering studies for this review**

**Types of studies**

We will include randomised controlled trials (RCTs) and cluster-randomised controlled trials only as this is an effectiveness review and randomisation is the only way to prevent systematic differences between baseline characteristics of participants in different intervention groups in terms of both known and unknown (or unmeasured) confounders.

**Types of participants**

All patients (adults aged 18 or over) and family members with potential to contribute to timely response for acute deterioration in the context of a life-threatening illness will be included. No exclusions will be made based on gender, ethnicity, or specific condition.

Family is defined as parents, relatives, partners, friends or caregivers who are able to act as ‘close as kin’ in order to recognise changes in patients’ conditions and seek help on patients’ behalf. We will include interventions if they target individuals or groups e.g. ethnic minority groups or specific subcategories, e.g. parents, the elderly and pregnant women.

The review will include interventions designed for patients and families in community health and hospital settings, in both low- and high-income countries. This will include community health centres, medical practices, emergency departments, clinics and wards.

We will exclude interventions that are targeted at lay health workers (paid or voluntary) including community health workers, village health workers and birth attendants. We define lay health worker as any health worker who: (1) assists with diagnosis of, referral to and securing of professional help for patients with life-
threatening conditions; (2) is trained in some way in the context of the intervention but has received no formal professional or para-professional certificate or tertiary education degree.

We will include interventions that are aimed at enabling professionals to engage effectively with patients and families when they seek help or speak up about concerns. Professionals are defined as those who undertake remunerated work for which formal tertiary education is required e.g. nurse aides, medical assistants, physician assistants, paramedical workers in emergency services, and other self-defined health professionals or health paraprofessionals. We will exclude trainees of any of the professions or paraprofessions listed above.

We define acute life-threatening illnesses as ‘time critical’ serious illnesses where avoidance of death is reliant on early detection and instigation of appropriate management. These conditions involve threats to a patient’s life, imminent risk of clinical deterioration, or potential to progress to a serious problem. They require aggressive, rapid clinical intervention accessed via urgent or emergency care. This review focuses on those physical illnesses where there is scope for patients and families to contribute to the process of securing a rapid response, for example stroke, myocardial infarction, pre-eclampsia, reduced foetal movements, sepsis and meningitis. Interventions escalating care for seizures in epilepsy or anaphylaxis in allergy will be included as well as previously undiagnosed conditions such as new-onset asthma. We will exclude mental health conditions because of the additional problems presented by serious mental health conditions in terms of patients’ capacity to act and contribute to escalation of care.

We will exclude interventions that are solely aimed at enabling patients to self-manage chronic long-term conditions such as asthma unless the interventions include an identifiable focus on working with staff to ensure timely response to an acute life-threatening deterioration in condition.

Types of interventions

This review will evaluate any intervention (informative, educational, behavioural) intended to improve patients’ and families’ ability to participate in escalating care for a life-threatening illness. We will include interventions aimed at patients and families as well as those aimed at healthcare professionals. The interventions could be designed at individual or group level. The interventions may include access to informational resources, oral presentations, one-on-one or group classes or seminars, or skills-based workshops. An intervention may have taken place at a single time point or involve a short series of events (e.g. a set of workshops). We define patient and family involvement in escalation of care as working with healthcare professionals to ensure care received for acute deterioration is timely and appropriate, including raising concerns about diagnosis, treatment and management. Studies will be included if an intervention aims to do any of the following: increase knowledge in patients, their family, or both, about what signs and symptoms of acute life-threatening illness to report to health professionals, why and how, and what care or treatment to expect from health professionals; aid patient and/or family motivation and behavioural intent to work with health professionals; increase patient’s or their family’s ability to act, including speaking up about concerns about deterioration in a patient’s condition and care decisions; or to increase staff motivation, capability and ability to listen and respond to patients’ and families’ concerns.

The review is likely to include complex interventions with potential for different factors to contribute to effectiveness. The considerable scope for variation makes it useful to describe these interventions in terms of the main domains using the TIDieR checklist (Hoffmann 2014). Description of interventions in included papers will detail (i) rationale and content; (ii) mode of delivery; (iii) type of provider; (iv) location/context; (v) participant characteristics or who is involved; (vi) dose - tailoring and fidelity. We will include the following comparisons.

- Interventions to promote patient and family escalation of care versus no intervention.
- Interventions to promote patient and family escalation of care versus standard or usual care; i.e. where active involvement of patients and families in escalation of care for acute life-threatening conditions is not explicitly attempted.

Types of outcome measures

Outcomes will relate to patients and family members, health care professionals, and health service use. The listed outcomes will not be used as criteria for including studies. See Figure 1 for the conceptual model underpinning the review (showing only primary outcomes).

Primary outcomes

Patients or family members, or both

1. Patient and family outcomes: changes in capabilities to negotiate access to care and escalate care, measured by self-reports or observations, captured by the following potential outcomes.
   i) Knowledge: knowledge of danger signs and appropriate care-seeking behaviours.
   ii) Behavioural intent: motivation to take an active role in escalation of care.
   iii) Willingness to participate: willingness to raise concerns and escalate care.
   iv) Self-efficacy: confidence in one’s own ability to self-diagnose, seek help and work with staff to secure professional help.
   v) Skills acquisition: skills in reporting changes in condition, asking for professional help and working with professionals.
2. Treatment outcomes: timeliness, appropriateness and effectiveness of response, measured by self-reports or proxy reports (professionals' or family members') captured by the following outcomes.
   i) Time from start of symptoms to delivery of professional treatment.
   ii) Appropriateness and effectiveness of treatment given.
3. Clinical outcomes.
   i) Mortality, measured by mortality rates including failure-to-rescue rates (patient death following post-operative complications).
   ii) Morbidity, burden associated with delayed recognition and treatment of condition: measured by objective measures e.g. number of events; or presence of and severity of symptoms e.g. heart failure after acute myocardial infarction or disability after stroke.
4. Patient and family experience: measured by self-reports captured by the following measures.
   i) Perceptions of safety and trust in care providers.
   ii) Perceptions of involvement in escalation of care.
   iii) Perceptions of timeliness and appropriateness of healthcare professionals' response (including being given opportunities to share concerns and help with escalation of care).
   iv) Satisfaction with healthcare professionals' response.
   v) Satisfaction with care received.
5. Adverse events.
   i) Patient harms: any reports of harms or adverse events associated with patient and family involvement in escalation of care.

Secondary outcomes

Patients or family members, or both
1. Receptiveness to, and acceptability of, intervention to patients and families: measured by self-reports.

Health care professionals
1. Healthcare professionals' psychological well-being and capability/capacity to respond to patient and family concerns: measured by self-reports (e.g. empathy, self-compassion, self-efficacy, communication with patients).
2. Healthcare professionals' experience of clinical encounter: measured by self-reports captured by the following potential measures.
   i) Healthcare professionals' experience of patient and family contribution to safety.
   ii) Healthcare professionals' satisfaction with patient and family involvement.
3. Receptiveness to, and acceptability of, intervention to healthcare professionals: measured by self-reports.

Service use
1. Attendance and use of health care services: measured by call-outs, attendance, admission and readmission rates e.g. emergency services, GP surgeries, clinics, emergency departments, critical care.
We will include validated measures where possible. Non-validated measures will be recorded but excluded from the meta-analysis. The outcomes listed above are broad categories. Two authors will independently assign the outcomes reported in each included study to the review's outcome categories and resolve any differences in categorisation, if they occur, by the involvement of a third author. In the case of studies that report more than one outcome within each of these groupings, we will adopt the following process: two authors will independently list the outcomes for the trial (without considering either the size of the effect or its statistical significance) and make a decision about which is most 'clinically' important. We will describe this process clearly, including the need for involvement of a third author for further discussion and decision.
We will pool outcome data from studies examining different clinical conditions providing they consider similar constructs, e.g. changes in knowledge, even if the measures are slightly different. We will report on those constructs that are very different or measured in very different ways narratively and will not include them in the meta-analysis.

Timing of outcome assessment
We will group the outcomes into short-term (less than 3 months), medium-term (3 to 12 months) and long-term (more than one year). Where outcomes are collected at more than one time point, we will choose the one most clinically relevant for inclusion in analysis and provide a rationale. Longer-term follow-up is more likely to be clinically relevant.

Main outcomes for summary of findings table
We plan to report results for the following outcomes in 'Summary of findings' tables in the review.
- Patient and family knowledge of danger signs and appropriate care-seeking behaviours.
- Patient and family self-efficacy (confidence in one's own ability to self-diagnose, seek help and work with staff to secure professional help).
- Time from start of symptoms to delivery of professional treatment.
- Mortality, measured by mortality rates including failure-to-rescue rates (patient death following post-operative complications).
Patient and family perceptions of involvement in escalation of care.

- Patient and family satisfaction with care received.
- Patient harms (reports of harms or adverse events associated with patient and family involvement in escalation of care).

Search methods for identification of studies

See the Cochrane Handbook chapter 4.5 and chapter 6.

Electronic searches

We will search the following electronic databases.

- The Cochrane Central Register of Controlled Trials (CENTRAL, in the Cochrane Library, latest issue).
- MEDLINE (OvidSP) (2000 to present).
- Embase (OvidSP) (2000 to present).
- PsycINFO (OvidSP) (2000 to present).

We present the strategy for MEDLINE (OvidSP) in Appendix 1. We will tailor strategies to other databases and report them in the review. There will be no language restrictions. We will restrict searches from 2000, the year that ‘To Err is Human’ was published (Kohn 2000).

Searching other resources

We will search relevant grey literature sources such as the Dissertations and Theses database, OpenGREY and The Grey Literature Report as well as relevant conference proceedings. We will contact experts in the field, our advisory group and authors of included studies for advice as to other relevant studies. We will also search reference lists of included studies and relevant systematic reviews. We will also search online trial registers (ClinicalTrials.gov and the World Health Organization (WHO) International Clinical Trials Registry Platform) for ongoing and recently completed studies.

Data collection and analysis

Selection of studies

Two authors will independently screen all titles and abstracts identified from searches to determine which meet the inclusion criteria. We will retrieve in full text any papers identified as potentially relevant by at least one author. Two review authors will independently screen full text articles for inclusion or exclusion, with discrepancies resolved by discussion and by consulting a third author if necessary to reach consensus. We will list all potentially relevant papers excluded from the review at this stage as ‘excluded studies’, with reasons provided in the ‘Characteristics of excluded studies’ table. We will also provide citation details and any available information about ongoing studies, and collate and report details of duplicate publications, so that each study (rather than each report) is the unit of interest in the review. We will report the screening and selection process in an adapted PRISMA flow chart (Liberati 2009).

Data extraction and management

Two review authors will extract data independently from included studies. They will resolve any discrepancies by discussion until consensus is reached, or through consultation with a third author where necessary. We will develop and pilot a data extraction form using the Cochrane Consumers and Communication Group Data Extraction Template (available at cccrg.cochrane.org/author-resources). Data to be extracted will include the following items.

Methods

We will extract data about the study design, the methods of recruitment of participants, the inclusion and exclusion criteria for participants, information on funding of the study, declaration of interests for the primary investigators, statistical methods used and consumer involvement. We will assess the risk of bias of included studies as described below (see Assessment of risk of bias in included studies).

Participant characteristics

From each study we will record the following information: description of participants (patients and/or family members), number of participants, age, gender, ethnicity and life-threatening condition. We will record the following information on the study: setting (community health or hospital), income of the country (high, middle or low).

Intervention

We will use the template for intervention description and replication (TIDieR) guidelines for describing interventions in the included studies (Hoffmann 2014). We will record rationale and content; description of intervention and intervention components; mode of delivery; type of provider; location/context; intervention level (individual, group, patient and provider); dose; tailoring and fidelity; description of comparison group. We will report whether the interventions and control treatments were described in sufficient detail to replicate, investigate most relevant causal factors, and report these factors.
Outcomes
We will list all primary and secondary outcomes reported in each included study and describe how they were assessed. We will report on the timing of follow-up. Our analyses will be confined to those outcomes selected a priori as described in Types of outcome measures.

All extracted data will be entered into Review Manager 5 (RevMan 5) by one review author, and will be checked for accuracy against the data extraction sheets by a second review author working independently (Review Manager 2014).

Assessment of risk of bias in included studies
We will assess and report on the methodological risk of bias of included studies in accordance with the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2011) and the guidelines of the Cochrane Consumers and Communication Review Group (Ryan 2011), which recommends the explicit reporting of the following individual elements for RCTs: random sequence generation; allocation sequence concealment; blinding (participants, personnel); blinding (outcome assessment); completeness of outcome data; and selective outcome reporting. We will consider blinding separately for different outcomes where appropriate (for example, blinding may have the potential to differently affect subjective versus objective outcome measures). For cluster-RCTs we will also assess and report the risk of bias associated with an additional domain: selective recruitment of cluster participants. Other sources of bias include baseline imbalances for both individual and cluster-RCTs and comparability with individually randomised trials for cluster-RCTs. We will judge each item as being at high, low or unclear risk of bias as set out in the criteria provided by Higgins 2011, and provide a quote from the study report and a justification for our judgement for each item in the 'Risk of bias' table.

Studies will be deemed to be at the highest risk of bias if they are scored as at unclear risk of bias for the sequence generation domain, or at high or unclear risk of bias for the allocation concealment domain, based on growing empirical evidence that these factors are particularly important potential sources of bias (Higgins 2011). We will therefore exclude all studies rated at a high risk of bias for the random sequence generation item of the 'Risk of bias' tool, since these studies are categorised as quasi-RCTs (Higgins 2011). In all cases, two authors will independently assess the risk of bias of included studies, with any disagreements resolved by discussion to reach consensus. We will contact study authors for additional information about the included studies, or for clarification of the study methods as required. We will incorporate the results of the risk of bias assessment into the review through standard tables, and systematic narrative description and commentary about each of the elements, leading to an overall assessment of the risk of bias of included studies and a judgement about the internal validity of the review's results.

Measures of treatment effect
For dichotomous outcomes, we will analyse data based on the number of events and the number of people assessed in the intervention and comparison groups. We will use these to calculate the risk ratio (RR) and 95% confidence interval (CI). For continuous measures, we will analyse data based on the mean, standard deviation (SD) and number of people assessed for both the intervention and comparison groups to calculate mean difference (MD) and 95% CI. If the MD is reported without individual group data, we will use this to report the study results. If more than one study measures the same outcome using different tools, we will calculate the standardised mean difference (SMD) and 95% CI using the generic inverse variance method in Review Manager 5. Time from symptom onset to professional response will be measured as MDs or standardised MDs between groups.

Unit of analysis issues
In the case of individual randomised controlled trials the unit of analysis will be individual patients with acute life-threatening illness. The analysis must take into account the level at which randomisation occurred.

If cluster-RCTs are included we will check for unit-of-analysis errors. If errors are found, and sufficient information is available, we will re-analyse the data using the appropriate unit of analysis, by taking account of the intracluster correlation (ICC). We will obtain estimates of the ICC by contacting authors of included studies, or impute them using estimates from external sources. If it is not possible to obtain sufficient information to re-analyse the data we will report effect estimates and annotate ‘unit-of-analysis error’.

Dealing with missing data
We will attempt to contact study authors to obtain missing data (participant, outcome, or summary data). For participant data, we will, where possible, conduct analysis on an intention-to-treat basis; otherwise data will be analysed as reported. We will report on the levels of loss to follow-up and assess this as a source of potential bias.

For missing outcome or summary data we will impute missing data where possible and report any assumptions in the review. We will investigate, through sensitivity analyses, the effects of any imputed data on pooled effect estimates.

Assessment of heterogeneity
We anticipate heterogeneity in terms of intervention modalities, life-threatening conditions, populations, settings, degree of bias, outcome measures and timing of outcome assessment. Where studies are considered sufficiently similar, based on an assessment of the above factors, to allow pooling of data using meta-analysis,
we will assess the degree of heterogeneity by visual inspection of forest plots and using the Chi² test for heterogeneity. We will quantify heterogeneity using the I² statistic, interpreting an I² value of 50% or more as representing a substantial level of heterogeneity. We will interpret the I² value in light of the size and direction of effects and the strength of evidence for heterogeneity based on the P value from the Chi² test and number of contributing studies (Higgins 2011).

If too few trials are included in the meta-analysis, the Chi² test has little power to detect heterogeneity. In these cases we will interpret non-significant results of the test of heterogeneity with care. Where heterogeneity is present in pooled effect estimates we will explore possible reasons for variability by conducting subgroup analysis. Where we detect substantial clinical, methodological or statistical heterogeneity across included studies we will not report pooled results from meta-analysis but will instead use a narrative approach to data synthesis. In this event we will attempt to explore possible clinical or methodological reasons for this variation by grouping studies that are similar in terms of populations, setting, intervention features, methodological features, or other factors to explore differences in intervention effects.

**Assessment of reporting biases**

We will assess reporting bias qualitatively based on the characteristics of the included studies (e.g. if only small studies that indicate positive findings are identified for inclusion), and if information that we obtain from contacting experts and authors of studies suggests that there are relevant unpublished studies.

If we identify sufficient studies (at least 10) for inclusion in the review we will construct a funnel plot to investigate small-study effects, which may indicate the presence of publication bias. We will formally test for funnel plot asymmetry, with the choice of test made based on advice in Higgins 2011, and bearing in mind that there may be several reasons for funnel plot asymmetry when interpreting the results.

**Data synthesis**

We will decide whether to meta-analyse data based on whether the interventions in the included trials are similar enough in terms of participants, settings, intervention, comparison and outcome measures to ensure meaningful conclusions from a statistically pooled result. Due to the anticipated variability in the populations, settings and interventions of included studies, we will use a random-effects model for meta-analysis.

If meta-analysis is possible, we will investigate possible sources of heterogeneity through subgroup analyses, and group the data based on the category that best explores the heterogeneity of studies and makes most sense to the reader (for example by interventions, populations or outcomes).

If we are unable to pool the data statistically using meta-analysis we will conduct a narrative synthesis of results. We will present the major outcomes and results, organised by intervention categories according to the major types and/or aims of the identified interventions. Depending on the assembled research, we may also explore the possibility of organising the data by population or setting. Within the data categories we will explore the following main comparisons of the review.

- Intervention versus no intervention.
- Intervention versus usual care.

Where studies compare more than one intervention, we will compare each separately to no intervention/control.

**Subgroup analysis and investigation of heterogeneity**

If sufficient data are available, we will conduct three subgroup analyses.

1. Setting (high-income countries versus low- and middle-income countries as defined by the World Bank (World Bank 2016)): due to differences in infrastructure such as transportation and health facility, and access/care pathways.
2. Focus of intervention (patient/family, healthcare professional, relational including both patient and staff).
3. Content (addressing knowledge, attitude or skills).

**Sensitivity analysis**

We will conduct sensitivity analyses with studies restricted to those at low risk of bias. We will investigate, through sensitivity analyses, the effects of any imputed data on pooled effect estimates.

**Summary of findings table**

We will prepare a ‘Summary of findings’ table to present the results of analysis, based on the methods described in chapter 11 of the Cochrane Handbook for Systematic Reviews of Interventions (Schünemann 2011). We will present the results of meta-analysis for the major comparisons of the review, for each of the major primary outcomes, including potential harms, as outlined in the ‘Types of outcome measures’ section. We will provide a source and rationale for each assumed risk cited in the table(s), and will use the GRADE system to rank the quality of the evidence using the GRADE profiler (GRADEpro GDT) software (Schünemann 2011). If meta-analysis is not possible, we will present results in a narrative ‘Summary of findings’ table format, such as that used by Chan 2011.

**Ensuring relevance to decisions in health care**

We have established an advisory group early on in the review process, to ensure that the review is of relevance and will inform policy, planners, providers and service users. We have convened a group of eight stakeholders (4 users and 4 providers). These include Carolyn Canfield (independent citizen-patient), Helen Haskell (Mothers...
We plan to hold three teleconferences which will be structured around 1) protocol development in terms of its scope, outcomes; 2) findings/analysis; 3) key conclusions and dissemination plan. We will also consult the advisory group to help with resolving discrepancies around selection of studies and data extraction and management. In addition the protocol and review will receive feedback from at least one consumer referee in addition to a health professional as part of Cochrane Consumers and Communication's standard editorial processes.

ACKNOWLEDGEMENTS

We thank our advisory group members (Carolyn Canfield, Helen Haskell, Tommy's baby charity, Sands, Sarah Neill, Rebecca Lawton, David Schwappach and Rohit Ramaswamy) for their valuable help with the protocol development. We also thank the Cochrane Consumers and Communication editors and staff, particularly the managing editor, Bronwen Merner, and our contact editor, Anneliese Synnot, for their input.

REFERENCES

Additional references

AHA 2005  


Bandura 1986  

Berger 2013  

Binder 2012  


CCCRG 2014  


Cheyne H, Terry R, Niven C, Dowding D, Hundley V, McNamee P. ‘Should I come in now?’ A qualitative investigation of how women’s experiences in early labour against medical error), Tommy’s baby charity, and Sands (Stillbirth and neonatal death charity); and four academics with expertise in patient involvement in safety (Sarah Neill, Rebecca Lawton, David Schwappach) and global health (Rohit Ramaswamy). As part of Cochrane Consumers and Communication’s standard at least one consumer referee in addition to a health professional for their valuable help with the protocol development. We also thank the Cochrane Consumers and Communication editors and staff, particularly the managing editor, Bronwen Merner, and our contact editor, Anneliese Synnot, for their input.

Cohn 2015

Craig 2008

Crossley 2001

Davis 2008

Davis 2012

Denham 2008

DoH 2013

Doherty 2012

Draper 2015

Dutta-Bergman 2005

Dwamena 2012

Ehrich 2003

Eisenberg 2005

Entwistle 2005

Entwistle 2006

Entwistle 2010

Eri 2009

European Patients’ Forum 2017

Fishbein 1980

Flenady 2016

Greenhalgh 2005

Grossmann-Kendall 2001
Interventions to increase patient and family involvement in escalation of care for acute life-threatening illness in community health and hospital settings (Protocol)

Heuschmann 2008

Higgins 2011

Hoffmann 2014

Hood 2015

Hor 2013

Horvat 2014

Houston 2000
Houston, AM, Pickering AJ. 'Do I or don't I call the doctor': a qualitative study of parental perceptions of calling the GP out-of-hours. *Health Expectations* 2000;3(4):234–42.

Howcroft 2016

Hrisos 2013

Hueckel 2012

ISWP 2010

Johnson 2015

Johnstone 2006

Johnstone 2009

Keogh 2013

Kirkup 2015

Kohn 2000

Landrigan 2010

Lawton 2012

Lecouturier 2010

Leistikow 2011
Leistikow JP, Kalkman CJ, de Bruijn H. Why patient safety is such a tough nut to crack. *BMJ* 2011;342:d3447.

Leventhal 1998
Interventions to increase patient and family involvement in escalation of care for acute life-threatening illness in community health and hospital settings (Protocol)

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Interventions to increase patient and family involvement in escalation of care for acute life-threatening illness in community health and hospital settings (Protocol)

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### ADDITIONAL TABLES

#### Table 1. Logic model

<table>
<thead>
<tr>
<th>Nature of the problem</th>
<th>Included conditions</th>
<th>Access to help</th>
<th>Intervention level / strategies</th>
<th>Moderating factors</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Problem: avoidable harm</td>
<td>Deterioration in condition due to new onset (e.g. stroke, meningitis, heart attack, sepsis, croup, epiglottitis)</td>
<td>New - via GP/out of hours/emergency/urgent care centres/ambulatory care Already receiving routine care - step up via GP/week of hours/emergency department/ambulatory care</td>
<td>The interventions could be designed at individual, or group level Informative (e.g. posters). Educational (workshops). Behavioural (e.g. health coaching, skills training). The interventions may be aimed at: patients and families; and/or professionals</td>
<td>Patient Presentation and trajectory of illness. Complexity of condition and diagnosis. Vagueness of symptoms. Cognitive, emotional and physical state. Education and socio-economic status. Language and health literacy. Social connectedness/social exclusion. Perceptions of risk</td>
<td>Primary outcome: Patient and/or family outcomes (knowledge, attitudes, confidence, skills and involvement in escalation of care) Treatment outcomes (timeliness, appropriateness and effectiveness of treatment given) Clinical outcomes (morbidity and mortality). Patient and family experience (perceptions of safety and</td>
</tr>
</tbody>
</table>
Table 1. Logic model  (Continued)

<table>
<thead>
<tr>
<th>and safety.</th>
<th>Previous illness/pregnancy experience</th>
</tr>
</thead>
<tbody>
<tr>
<td>Family</td>
<td>Availability of family and 'close as kin'.</td>
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<tr>
<td></td>
<td>Availability of family health care professional for advice.</td>
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<tr>
<td></td>
<td>Education and socio-economic status.</td>
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<tr>
<td></td>
<td>Language and health literacy.</td>
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<td></td>
<td>Perceptions of risk and safety.</td>
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<tr>
<td>Professional</td>
<td>Staff motivation and capacity to respond.</td>
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<tr>
<td></td>
<td>Staff acceptability of and receptiveness to patient contribution to safety</td>
</tr>
<tr>
<td></td>
<td>Staff perceptions of risk and safety.</td>
</tr>
<tr>
<td></td>
<td>Staff specialisation, expertise, skills.</td>
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<tr>
<td>Relational</td>
<td>Prior experiences of clinical encounters/patient and providers</td>
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<td></td>
<td>Trust in patient and provider.</td>
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<td></td>
<td>Continuity of care.</td>
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<tr>
<td>Socio-cultural</td>
<td>Associations of symptoms/illness.</td>
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<tr>
<td></td>
<td>Racial and social class stereotyping.</td>
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<tr>
<td></td>
<td>Labelling.</td>
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<tr>
<td></td>
<td>Discrimination.</td>
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<tr>
<td></td>
<td>Stigma/fear.</td>
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<tr>
<td></td>
<td>Prior illness experiences of adverse events (patient harms, patient complaints).</td>
</tr>
</tbody>
</table>

**Secondary outcomes:**
Receptiveness to and acceptability of intervention to patients and families
Healthcare professionals’ psychological well-being and capability/capacity to respond to patient and family concerns
Healthcare professionals’ experience of clinical encounter.
Receptiveness to and acceptability of intervention to healthcare professionals
Attendance and use of health care services.
<table>
<thead>
<tr>
<th>Interventions to increase patient and family involvement in escalation of care for acute life-threatening illness in community health and hospital settings (Protocol)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Copyright © 2017 The Cochrane Collaboration. Published by John Wiley &amp; Sons, Ltd.</td>
</tr>
</tbody>
</table>
Appendix 1. MEDLINE search strategy

1 (Decision Making/ or Decision support techniques/ or exp Health Education/ or "Patient Acceptance of Health Care"/ or exp Patient Care Team/ or Family/ or Patients/ or exp Interpersonal Relations/) and (exp Health Facilities/ or Critical care/ or Critical Illness/ or exp Emergency Medical Services/ or exp Pregnancy/)

2 ((patient$ or consumer$ or family or families or relative$ or parent$ or child$ or partner$ or women$ or caret$ or caregiver$ or advocate$) adj5 (activat$ or involv$ or initiat$ or engag$ or participat$ or contribut$ or collaborat$ or role or cooperat$ or assist$ or champion$ or advoc$ or help-seek$) adj5 (deteriorat$ or escalat$ or "life threatening" or life-threatening or critical or emergenc$ or complication$ or "warning signs" or "danger signs" or adverse)).tw.

3 ("escalation of care" or "failure to rescue" or "rapid response" or "rapid-response" or "critical incident" or "early warning score" or "critical care outreach" or "calling for help" or "patient deteriorat$" or "deteriorating patient" or "medical emergency team" or "failure to escalate").tw.

4 1 or 2 or 3

5 (randomized controlled trial or controlled clinical trial).pt. or randomi?ed.ab. or placebo.ab. or randomly.ab. or trial.ti,ab. or groups.ab.

6 (randomized controlled trial or controlled clinical trial).pt. or randomi?ed.ab. or placebo.ab. or randomly.ab. or trial.ti,ab.

7 4 and 5

8 4 and 6

9 (((Decision Making/ or Decision support techniques/ or exp Health Education/ or "Patient Acceptance of Health Care"/ or exp Patient Care Team/ or Family/ or Patients/ or exp Interpersonal Relations/) and (exp Health Facilities/ or Critical care/ or Critical Illness/ or exp Emergency Medical Services/ or exp Pregnancy/)) or (((patient$ or consumer$ or family or families or relative$ or parent$ or child$ or partner$ or women$ or caret$ or caregiver$ or advocate$) adj5 (activat$ or involv$ or initiat$ or engag$ or participat$ or contribut$ or collaborat$ or role or cooperat$ or assist$ or champion$ or advoc$ or help-seek$) adj5 (deteriorat$ or escalat$ or "life threatening" or life-threatening or critical or emergenc$ or complication$ or "warning signs" or "danger signs" or adverse)) or ("rapid response" or rapid-response or "critical incident") adj3 (team$ or system$ or program$) adj5 (acute or emergency or critical)).tw. or ("escalation of care" or "failure to rescue" or "rapid response" or "rapid-response" or "critical incident" or "early warning score" or "critical care outreach" or "calling for help" or "patient deteriorat$" or "deteriorating patient" or "medical emergency team" or "failure to escalate").tw.) and (randomized controlled trial or controlled clinical trial).pt. or randomi?ed.ab. or placebo.ab. or randomly.ab. or trial.ti,ab.)

Contributions of Authors

NM is the review’s guarantor.

NM conceived the review question, wrote the first draft, and has managed the revision and submission process.

JS, RD and NS have helped develop the objectives and scope of the review, and the conceptual diagram.

SW has helped coordinate stakeholder involvement in the review.

All authors have contributed to the writing and editing of the protocol for publication.

Responsibilities for the full review are as follows:

<table>
<thead>
<tr>
<th>Task</th>
<th>Authors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Develop and run searches</td>
<td>NM, SW, AE, MA</td>
</tr>
<tr>
<td>Obtain studies</td>
<td>NM, SW, AE, MA</td>
</tr>
<tr>
<td>Select which studies to include (minimum of 2 people)</td>
<td>NM, JS, NS, RD, SW, AE, MA</td>
</tr>
</tbody>
</table>
Extract data from studies (minimum of 2 people)  NM, RD, SW, AE, MA, HR-J

Enter data into Review Manager 5  NM, RD, SW, AE, MA, HR-J

Analysis  NM, JS, NS, RD, SW, HR-J, AE, MA

Prep review report  NM, JS, NS, RD, SW, HR-J, AE, MA

Update review  NM, JS, NS, RD, SW, HR-J, AE, MA

**DECLARATIONS OF INTEREST**

Nicola Mackintosh: none known

Jane Sandall has a long standing interest in this topic from a patient and family, and professional and policy response viewpoint. She was a member of the WHO Expert advisory group member on patient participation in reducing healthcare-related safety risks, WHO Regional Office for Europe. She is a member of the National Childbirth Trust Research Advisory Group and RCOG SANDS Stillbirth Study Group Member and Obstetric Anaesthetists’ Association Maternal Critical Care Sub Committee.

Dr Nick Sevdalis is the director of London Safety & Training Solutions Ltd, which delivers team interventions, assessments and training to hospitals in the UK and internationally on a consultancy basis.

Rachel Davis: none known

Hannah Rayment-Jones: none known

Abigail Easter: none known

Sophie Williams: none known

Mary Adams: none known

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**Internal sources**

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External sources

- No sources of support supplied

NOTES

This protocol is based on standard text and guidance provided by Cochrane Consumers and Communication (CCCRG 2014).