

Outreach and Early Warning Systems (EWS) for the prevention of Intensive Care admission and death of critically ill adult patients on general hospital wards (Review)

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[Intervention Review]

Outreach and Early Warning Systems (EWS) for the prevention of Intensive Care admission and death of critically ill adult patients on general hospital wards

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ABSTRACT

Background

Despite the fact that outreach and early warning systems (EWS) are an integral part of a hospital wide systems approach to improve the early identification and management of deteriorating patients on general hospital wards, the widespread implementation of these interventions in practice is not based on robust research evidence.

Objectives

The primary objective was to determine the impact of critical care outreach services on hospital mortality rates. Secondary objectives included determining the effect of outreach services on intensive care unit (ICU) admission patterns, length of hospital stay and adverse events.

Search strategy

The review authors searched the following electronic databases: EPOC Specialised Register, The Cochrane Central Register of Controlled Trials (CENTRAL) and other Cochrane databases (all on *The Cochrane Library* 2006, Issue 3), MEDLINE (1996-June week 3 2006), EMBASE (1974-week 26 2006), CINAHL (1982-July week 5 2006), First Search (1992-2005) and CAB Health (1990-July 2006); also reference lists of relevant articles, conference abstracts, and made contact with experts and critical care organisations for further information.

Selection criteria

Randomised controlled trials (RCTs), controlled clinical trials (CCTs), controlled before and after studies (CBAs) and interrupted time series designs (ITS) which measured hospital mortality, unanticipated ICU admissions, ICU readmissions, length of hospital stay and adverse events following implementation of outreach and EWS in a general hospital ward to identify deteriorating adult patients versus general hospital ward setting without outreach and EWS were included in the review.

Outreach and Early Warning Systems (EWS) for the prevention of Intensive Care admission and death of critically ill adult patients on general hospital wards (Review)

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Data collection and analysis

Three review authors independently extracted data and two review authors assessed the methodological quality of the included studies. Meta-analysis was not possible due to heterogeneity. Summary statistics and descriptive summaries of primary and secondary outcomes are presented for each study.

Main results

Two cluster-randomised control trials were included: one randomised at hospital level (23 hospitals in Australia) and one at ward level (16 wards in the UK). The primary outcome in the Australian trial (a composite score comprising incidence of unexpected cardiac arrests, unexpected deaths and unplanned ICU admissions) showed no statistical significant difference between control and medical emergency team (MET) hospitals (adjusted P value 0.640; adjusted odds ratio (OR) 0.98; 95% confidence interval (CI) 0.83 to 1.16). The UK-based trial found that outreach reduced in-hospital mortality (adjusted OR 0.52; 95% CI 0.32 to 0.85) compared with the control group.

Authors' conclusions

The evidence from this review highlights the diversity and poor methodological quality of most studies investigating outreach. The results of the two included studies showed either no evidence of the effectiveness of outreach or a reduction in overall mortality in patients receiving outreach. The lack of evidence on outreach requires further multi-site RCT's to determine potential effectiveness.

PLAIN LANGUAGE SUMMARY

Ward and organisational practices to recognise and manage patient deterioration in hospital

Research has shown that patients in general hospital wards often show early signs and symptoms, such as changes in breathing and pulse, when their condition is getting worse. If treatment for these patients is delayed they could die or require admission to intensive care (ICU). It is thought that if hospital staff could identify and manage these patients earlier then there would be less deaths and ICU admissions. One way to identify and treat patients who are deteriorating is to introduce outreach services. This usually includes 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.

This summary of a Cochrane review presents what we know from research about the effect of outreach services for patients on general hospital wards. The review found two studies which were of good quality. One study compared 12 hospitals with outreach services to 11 that did not. Another study compared 16 wards with outreach to general wards without outreach.

One of the studies showed that outreach reduced the number of hospital deaths, while the other study found no differences between hospitals with outreach and those with no outreach. It is not clear whether outreach reduces hospital deaths or ICU admissions. High quality research is needed to determine the effect of outreach services.

BACKGROUND

Many hospital deaths are potentially predictable and preventable ([Goldhill 1999a](#); [McGloin 1999](#); [Smith 1998](#)). Observational studies suggest that clinical deterioration of patients on general hospital wards is often preceded by changes in physiological observations that are recorded by clinical staff six to 24 hours prior to a serious adverse event ([Franklin 1994](#); [Hillman 2002](#); [Kause 2004](#); [Schein 1990](#); [Smith 1998](#)). The most common physiological abnormalities are changes in basic vital signs of respiration, pulse, oxygenation and mental function ([Goldhill 1999a](#); [Schein 1990](#)), however, these changes in clinical signs are often missed,

misinterpreted or mismanaged ([Goldhill 2000](#); [McQuillan 1998](#); [Smith 1998](#)). The main reasons for staff failing to manage basic vital signs can be attributed to delays in seeking advice, failure to recognise clinical urgency, lack of knowledge and skills in resuscitation, inadequate supervision or organisational problems within the hospital setting ([McQuillan 1998](#)).

Delays in treatment or inadequate care of patients on general hospital wards often results in unanticipated admissions to the intensive care unit (ICU), increased length of hospital stay, cardiac arrest or death. [McQuillan](#) showed that up to 50% of ward based

patients received substandard care prior to ICU admission and that up to 41% of ICU admissions were potentially avoidable (McQuillan 1998). This is reflected in other studies (Bristow 2000; Goldhill 1999a; Hillman 2001; McGloin 1999). It has major implications for critically ill patients on general wards as unanticipated ICU admissions are twice as likely to develop cardiac arrest and are associated with an increased ICU and hospital mortality (Goldhill 1998; McGloin 1999; McQuillan 1998). This provision of sub-optimal care on general wards has significant consequences not only for in-hospital morbidity and mortality, but also ICU requirements and cost (McQuillan 1998).

The findings from this research suggest that the number of preventable deaths and unanticipated ICU admissions could be reduced if deteriorating patients on general hospital wards were identified earlier. This led to the introduction of a number of innovations for early detection and treatment of deterioration in ward based patients, namely an Early Warning System (EWS), the 'Acute Life-threatening Early Recognition and Treatment' (ALERTTM) course (Smith 2000), or similar educational programme, and a Critical Care Outreach Service (CCOS) (DOH 2000; NCEPOD 2005). EWSs are simple algorithms (plans of action) based on bedside observations that have been recommended to identify patients at risk on general hospital wards (DOH 2000; ICS 2002). These EWS are tools that have been developed to record physiological parameters of systolic blood pressure, heart rate, respiratory rate, urinary output, temperature and level of consciousness (Goldhill 1999b; Morgan 1997; Smith 2004; Subbe 2001;). A number of EWSs exist which are either based on exceeding any one of the set criteria or on the allocation of points to physiological observations which are then added to give a score. This criteria or score provides a mechanism for action in order for early intervention and treatment to be initiated. The action depends on the score or mechanisms in place within the hospital for referral of patients for review.

Several educational programmes have been developed to provide basic knowledge and skills in acute care for ward nurses. The main generic and nationally available training provision for acute care in the United Kingdom (UK) is the ALERTTM course. It is a multiprofessional competency based training programme which is well established and provided by UK Trusts for trained nurses and doctors. The course focuses on systematic patient assessment, interprofessional teamwork, communication, documentation and an understanding of when to seek help (Smith 2000). Thus the course content attempts to address the main reasons highlighted by McQuillan and colleagues for suboptimal ward care (McQuillan 1998).

The concept of outreach has evolved in response to the recognised need for a more equitable hospital wide approach to the management of 'at risk' patients (Audit Commission; DOH 2000; DOHMA 2003; ICS 2002; NCEPOD 2005; RCP 2002). This approach redefines or classifies critically ill patients by need or level

of care required and not by the geographical boundaries of where the patient is located (DOH 2000). Levels of care classify patients according to the complexity of acute care required on a scale of zero (patients whose needs can be met through normal ward care in an acute hospital) to three (patients requiring advanced respiratory support in ICU). Outreach is generally intended to provide support across all levels of care within the hospital with specific support for level one patients on general wards that are at risk of deterioration.

The key component of the outreach service consists of multidisciplinary critical care teams, called critical care outreach teams (CCOT) or Patient At Risk Teams (PART) in the United Kingdom (Goldhill 1999b), Medical Emergency Teams (MET) in Australia (Lee 1995) and Rapid Response Teams in the United States (Berwick 2006). These critical care teams respond to call outs from general ward staff following identification of patients at risk based upon the EWS score. The purpose of outreach services is to ensure timely and appropriate management of deteriorating patients on general hospital wards. This could potentially avert the need for ICU admissions, enable more timely ICU discharges and provide educational support to extend the skills of general ward staff in identifying and managing deteriorating patients (DOH 2000; ICS 2002).

EWS have been introduced despite limited high quality evidence to demonstrate their sensitivity, specificity and usefulness (Goldhill 2000). To date the research evidence on EWS tools in predicting patient outcomes or impending critical illness is poor and the extent to which the existing tools are valid or reliable predictors of deterioration is unknown (McCrossan 2006; Moore 2006). It is clear from the available evidence that ensuring effective use of EWS is problematic (Sterling 2002) and that the adoption of EWS does not invariably result in improved clinical outcomes (Subbe 2003). The development and implementation of EWS are often decided locally which has resulted in a wide range of scoring systems that restrict comparison of outcomes and standardisation of care.

A recent systematic review on outreach found a lack of evidence to support the benefits of outreach as a result of the poor methodological quality of the included studies (Esmonde 2006). As considerable resources have been invested in outreach it is imperative that further robust evidence is provided on the effectiveness of these services. The aim of this systematic review is to provide up-to-date and robust evidence on the impact of outreach on patient outcomes of critically ill adult patients on general hospital wards.

OBJECTIVES

The primary objective of this review was to determine the impact of outreach services on hospital mortality rates. Secondary objectives were to determine the effects of outreach services on ICU admission patterns (admissions and readmissions), length of hos-

pital stay and the number of adverse events (unexpected cardiac or respiratory arrest) in adult patients who deteriorate on general hospital wards before and after the introduction of outreach services.

METHODS

Criteria for considering studies for this review

Types of studies

All randomised controlled trials (RCTs), Controlled Clinical Trials (CCTs), controlled before and after studies (CBAs) and interrupted-time-series designs (ITS) of outreach utilising EWS with no outreach and EWS. ITS studies with fewer than three data points before and three data points after the intervention were not included in the review. Published and unpublished data were included.

Types of participants

All patients who deteriorated on general adult wards in hospital.

Types of interventions

The implementation of outreach using an EWS in an acute hospital setting to identify deteriorating patients on general wards versus general ward based care without outreach and EWS. Outreach included the terms Critical Care Outreach Team (CCOT), Patient At Risk Team (PART), Medical Emergency Team (MET) or Rapid Response Team (RRT) and EWS included the terms Modified Early Warning System (MEWS) or Patient At Risk (PAR) score. Subgroup analysis for comparison of MET, which is medically led, versus CCOT, which is nurse led, was not possible due to the heterogeneity and limited number of included studies.

Types of outcome measures

Primary outcomes

The impact of outreach services on hospital mortality rates, unanticipated ICU admissions, ICU readmissions, length of hospital stay or adverse events (cardiac or respiratory arrest) in adult patients on general hospital wards.

Search methods for identification of studies

Electronic searches

The Database of Abstracts of Reviews of Effectiveness (DARE) (*The Cochrane Library* 2006, Issue 3) was searched for related reviews.

The following electronic databases were searched for primary studies:

a)The EPOC Register and the database of studies awaiting assessment (see SPECIALISED REGISTER under GROUP DETAILS) were last reviewed in July 2006.

b)The Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library*, 2006, Issue 3), Cochrane NHS Economic Evaluation Database (*The Cochrane Library*, 2005, Issue 2), and Cochrane Health Technology Assessment Database (*The Cochrane Library* 2005, Issue 2)

c)Bibliographic databases, including MEDLINE (1996-June week 3 2006), EMBASE (1974-week 26 2006), CINAHL (1982-July week 5 2006), First Search (1992-2005) and CAB Health (1990-July 2006).

The search strategy for electronic databases used the methodological component of the EPOC search strategy combined with selected MeSH terms and free text terms relating to EWS and outreach. The search strategy was translated into each database using the appropriate controlled vocabulary related to outreach and EWS.

Database: Ovid MEDLINE(R) <1996 to June week 3 2006>

Search Strategy:

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1. Point-of-Care Systems/
2. (warning system\$ or early warning).tw.
3. outreach.tw.
4. exp Emergency Service, Hospital/
5. patient care team/
6. medical emergency team.tw.
7. or/1-6
8. exp Critical Care/
9. Postoperative Care/
10. critical care.tw.
11. intensive care.tw.
12. (postoperative care or post-operative care).tw.
13. or/8-12
14. 7 and 13
15. randomized controlled trial.pt.
16. controlled clinical trial.pt.
17. intervention studies/
18. experiment\$.tw.
19. (time adj series).tw.
20. (pre test or pretest or (posttest or post test)).tw.
21. random allocation/
22. impact.tw.
23. intervention?.tw.
24. chang\$.tw.
25. evaluation studies/

26. evaluat\$.tw.
27. effect?.tw.
28. comparative studies/
29. or/15-28
30. 14 and 29

Searching other resources

1. The journal *British Journal of Anaesthesia* (1999-2005) was handsearched for conference abstracts from the Proceedings of the Intensive Care Society 'State of the Art' meetings.
2. Reference lists of all papers and relevant reviews were identified.
3. Eighty-three experts in Outreach, which included eleven authors of relevant papers, were contacted for further published and unpublished data.
4. Authors of other reviews in the field of effective professional practice were contacted regarding relevant studies of which they may be aware.
5. We searched ISI Web of Knowledge, BIOSIS Previews, ISI conference proceedings (2001 - 1st Nov 2006) and Zetoc databases for relevant conference abstracts (1990-26th Oct 2005).

Search strategies for the other databases can be found in the Appendices ([Appendix 1](#), [Appendix 2](#), [Appendix 3](#)). We did not apply any language restrictions.

Data collection and analysis

JM reviewed all of the search results, conference abstracts and reference lists of relevant articles and reports independently to make an initial identification of potentially relevant studies. Once the abstracts of all potentially relevant studies for inclusion had been identified, full copies of them were obtained. All abstracts and full text studies were independently assessed for inclusion by three review authors (JM, RF, AK). Disagreement or lack of consensus between review authors regarding inclusion or exclusion was resolved through discussion or arbitration by another review author (AM). All studies that initially appeared to meet our inclusion criteria and were not included in the review are detailed in the 'Characteristics of excluded studies' table.

Data extraction was performed independently by three review authors (JM, RF, AK) using an adapted version of the EPOC Data Collection checklist (see METHODS USED IN REVIEWS under GROUP DETAILS on *The Cochrane Library*). The data were checked for any discrepancies and were then collated. Any discrepancies identified were resolved through discussion until consensus was reached among the review authors. Eleven review authors were contacted about missing data.

Two independent review authors (JM, RF) assessed the methodological quality of each included study using the EPOC Data Col-

lection checklist. We collected information about concealment of allocation, baseline measurements, follow up of professionals, follow up of patients, intention-to-treat analysis, blinding, reliability of primary outcomes and protection against contamination for all randomised controlled trials. Discrepancies in quality ratings were resolved by discussion between review authors.

In the results, we report the pre-intervention and post-intervention statistical tests used for both study and control groups. Meta-analysis was not possible for the following reasons: the included studies did not measure the same outcome; their study designs were different; one study included all admissions while the other included admissions to certain wards; and the treatment and follow-up periods varied between the studies. Information on each study design, participants, type of intervention, setting, methods, outcomes and results are listed and significant research data from each RCTs are presented.

Sensitivity analysis

Originally we planned to conduct sensitivity analyses based on the quality of the included studies, however, given the small number of studies included, this was not possible.

Subgroup analysis

Originally we planned to conduct a subgroup analysis of the intervention by nurse led outreach or physician led MET based on the quality of the included studies, however, given the small number of included studies this was not possible.

Ongoing studies

No ongoing studies were identified.

RESULTS

Description of studies

See: [Characteristics of included studies](#); [Characteristics of excluded studies](#).

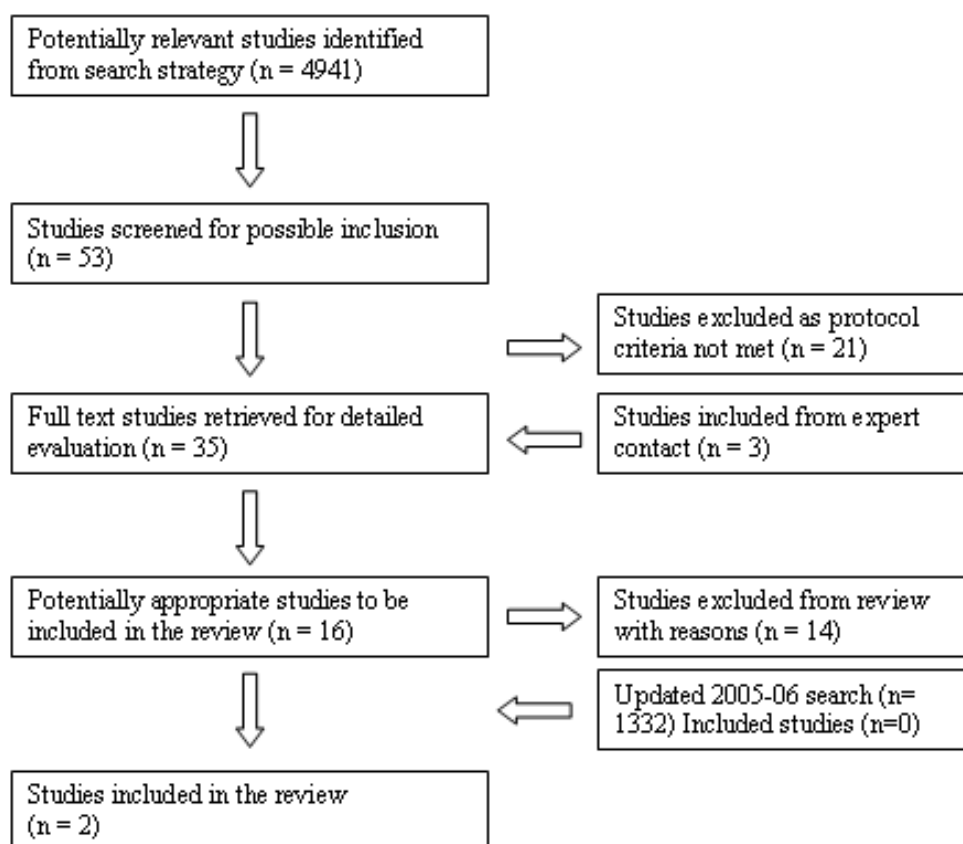
Results of the search

The initial database search in 2005 identified 4941 studies and the updated 2005-2006 search identified a further 1332 studies. Full text copies of 35 potentially relevant studies, which included published and unpublished data - from contact with 83 experts in outreach - were independently reviewed by three review authors (JM, RF, AK). Sixteen studies were identified as being potentially eligible, but fourteen were excluded because the study designs did not meet the inclusion criteria.

Included studies

Two RCTs met the inclusion criteria for this review (Figure 1). One study was from Australia and the other was from the UK. The two studies were published in 2004 and 2005 and included all adult patient admissions (14 years of age and over) to general hospital wards.

Figure 1. QUORUM Diagram



One study was a prospective cluster randomised controlled trial of general inpatient wards in 23 hospitals over a 12-month period (Hillman 2005). The 23 hospitals were randomised as either intervention hospitals (12) or control hospitals (11). In order to conceal the randomisation sequence or study treatment from project investigators and participating hospitals, an independent statistician randomly assigned hospitals to receive standardised MET implementation or to be controls.

The other study was a prospective stepped-wedge randomised controlled trial which phased in the introduction of CCOT in 16 acute adult general wards in one hospital (Priestley 2004). Wards were paired (high risk and low risk pairings) using professional judgement to match for overall risk of death and serious adverse

outcomes. Each of the matched and randomised pairs of wards was then randomised to introduce outreach following a four week training period. On completion of the training the paired wards moved from control to intervention wards. The sequence of outreach intervention was randomised over the 32-week study period. Randomisation was undertaken by one investigator based on ward pairings and risk estimates provided by the rest of the study team. General wards were either inpatient wards across hospitals or specifically surgical, medical or elderly patient wards in one hospital. A 'general ward' in both studies did not encompass ICUs, high dependency units, coronary care units, operating theatres, post-operative recovery areas or emergency departments that had intensive care specialist supervision. One study included all patients

admitted to hospital and the other study included patients admitted to specific wards over the research period (excluding those who died on admission). The settings varied from a single non-teaching acute 800 bed hospital in England to a variety of urban and rural Australian hospitals which differed in size and organizational characteristics (stratified by teaching and non-teaching and blocked by number of hospital beds).

The intervention hospitals or wards in both studies introduced a standardised educational strategy to prepare for the introduction of outreach. This was the implementation period of the study. The educational strategy in both studies included information on the calling criteria (i.e., when to contact the outreach team), relevance of the criteria to at-risk patients, and when and how to call the outreach team. In one study, the educational process included training in care of the acutely ill patient for ward staff (Priestley 2004) which was not a part of the educational process in the other study (Hillman 2005). The provision of outreach services in one study included practical advice and help with an emphasis on collaboration and sharing of skills (Priestley 2004). The educational strategies utilised in one study included lectures, video, written information and visual reminders displayed on identification badges and posters throughout the hospitals (Hillman 2005).

The implementation period for MET was four months (Hillman 2005) and four weeks for each pair of wards introducing outreach (Priestley 2004). Both studies introduced MET or CCOT on a 24 hour, 7 day-a-week basis. The composition of the MET varied among participating hospitals but required a minimum inclusion of cardiac arrest team, one doctor, one ICU nurse or Accident and Emergency nurse (Hillman 2005). The composition of the CCOT was led by a nurse consultant with a team of experienced nurses and medical support when required (Priestley 2004). The early identification of deteriorating ward patients was assessed in both studies either through use of a PAR score or by the use specific MET calling criteria. The EWS tools differed in that the PAR score was a multiple parameter scoring system (Priestley 2004) and the MET utilised a single parameter system to provide calling criteria (Hillman 2005) for a response to patient deterioration.

Both studies utilised the objective criteria to trigger outreach but emphasised the importance of staff calling the outreach team if they had concerns regardless of the calling criteria.

The two studies introduced MET or CCOT in the intervention hospitals or wards and the control hospitals or wards continued standard practice of care. One study indicated that the cardiac arrest team was maintained as standard practice in control hospitals (Hillman 2005) while it was not clear whether the cardiac arrest team was maintained as standard practice in the control wards during the implementation period of the other study (Priestley 2004). The control groups were either patients admitted to one of two paired wards (Priestley 2004) or 11 matched hospitals and their patients (Hillman 2005). The control hospitals and wards did not receive education in outreach calling criteria or education on identifying patients at risk.

The patient outcomes measured in the two studies varied. The primary outcome of the MERIT study (Hillman 2005) was a composite score based upon the incidence of cardiac arrests without a pre-existing not-for-resuscitation order (NFR), unplanned ICU admissions and unexpected deaths (deaths without a pre-existing NFR order). These were reported as a rate of incidence per 1,000 admissions and adjusted P values to account for cluster and individual level differences. The items comprising the composite score were examined individually and treated as secondary outcomes. Hospital mortality and length of stay were the outcomes measured in the other study (Priestley 2004) and the findings were analysed and compared using multivariate logistic regression.

Risk of bias in included studies

The methodological quality of included studies are summarised in the 'Characteristics of Included studies' table using Cochrane Handbook for Systematic Reviews of Interventions' criteria of adequate (A), unclear (B), inadequate (C) and not used (D). Quality was independently assessed by two review authors using a modified version of the EPOC Data Collection checklist (see METHODS USED IN REVIEWS under GROUP DETAILS in *The Cochrane Library*) (Table 1).

Table 1. Quality Assessment

Study ID	Allocation concealment	Baseline measurement	Patient follow up	Intention to treat	Outcomes blinded	Reliable outcomes	Protection /contamin	Risk of bias	Footnotes
Priestly 2004	Not Done Randomisation done	Done Calculated the Simplified Acute	Done Follow up of wards was com-	Done Patients were allo-cated	Done Objective outcomes. Blinding	Done Outcomes obtained from hos-	Unclear Randomisati of wards in one hospi-	Medium: One or two criteria scored as	Done* - Unclear - Not done - Not sure**

Table 1. Quality Assessment (Continued)

by investigator based on ward pairings and risk estimates provide by study team. Wards matched and randomised for overall risk of death and other serious adverse outcomes. V paired (high and low risk) by professional judgement based on the number of cardiac arrests per ward. Randomisation of ward pairings and randomisation of wards to receive intervention w not explicitly described	Physiology Score II (SAPS II) as indicator of patient health within 24 hours of admission to a study ward.	plete and follow up of patients was complete for 80-90%	to the intervention, training and control groups based on admission ward regardless of subsequent ward transfers.	not possible.	pital database.	tal and potential for contamination.	Unclear or Not done.	* Assess and score each primary outcome variable separately. ** Unsure means that the review author is unsure, while Unclear means that the reviewer is sure that the paper is unclear on the criteria Risk of bias: Low: All criteria scored as Done (or if the ones that are not scored as Done are considered unimportant in this study). Medium: One or two criteria scored as Unclear or Not done. High: More than two criteria scored as Unclear or Not done (or if
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Table 1. Quality Assessment (Continued)

									at least one criteria that is essential in that study is scored as Unclear or Not done). Fatally flawed: Untrustworthy results
Hillman 2005	Done Randomisation of hospitals was done by independent statistician who had no other involvement in the study. Randomisation concealed from investigators and participating hospitals. Hospitals were stratified by teaching status and block by number of beds with a group of	Done Outcome and process measures obtained for all hospitals over a 2 month period.	Done Follow up of hospitals was complete. No hospitals lost to follow up	Done Statistical analysis was undertaken on an intention to treat analysis.	Done Objective outcomes. Blinding not possible.	Unclear Data collectors trained with a standardised data collection manual. Kappa not stated. Three data audits were done during the study to ensure accuracy of data (source documentation, outcomes of the study and automated optical scanning data entry. Source	Done Allocation by institution	Medium: One or two criteria scored as Unclear or Not done.	Done* - Unclear - Not done - Not sure** * Assess and score each primary outcome variable separately. ** Unsure means that the review author is unsure, while Unclear means that the reviewer is sure that the paper is unclear on the criteria Risk of bias:

Table 1. Quality Assessment (Continued)

	4 using SAS version 6.12					of outcome data not explicitly stated. Additional data was requested from authors but was not provided at time of going to press.			Low: All criteria scored as Done (or if the ones that are not scored as Done are considered unimportant in this study). Medium: One or two criteria scored as Unclear or Not done. High: More than two criteria scored as Unclear or Not done (or if at least one criteria that is essential in that study is scored as Unclear or Not done). Fatally flawed: Untrustworthy results
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Both studies matched and randomised either hospitals or wards to receive outreach or no outreach and adjusted for clustering of outcomes. One study undertook baseline measurements over a two-month period prior to the introduction of MET system (Hillman 2005) while the other study included patient characteristics on admission as baseline data (Priestley 2004). There was no loss to follow up in either study. Intention-to-treat analysis and a power

calculation to detect clinically significant effects and sample size was undertaken in both studies (Hillman 2005; Priestley 2004). Blinding of primary outcomes was not undertaken in either study as all outcomes were measured objectively. Reliable outcome measures were obtained from hospital databases in one study, (Priestley 2004) and the method of attaining outcome measures was unclear in the other study (Hillman 2005). Protection against contamination was controlled by institutional allocation in one study (

Hillman 2005) and unclear in the other study (Priestley 2004). The studies were rated as medium risk of bias, as one criterion was scored as unclear in the MERIT study (Hillman 2005) and two criteria were scored as either not done or unclear in the Priestley study (Priestley 2004).

Effects of interventions

The results indicate that at baseline in the MERIT study (Hillman 2005), the number of patients with the primary outcome (a composite score comprising incidence of unexpected cardiac arrests, death (without NFR) and unplanned ICU admission) in the MET hospitals (6.58 patients per 1000 admissions) was slightly lower than control hospitals (7.07 patients per 1000 admissions). In the Priestley study (Priestley 2004), the mean Simplified Acute Physiology Score (SAPS) II death probability estimate at baseline in the matched and randomised patients was slightly lower in the control wards (17.3; 95% confidence interval (CI) 16.8 to 17.8) compared with the outreach wards (19.9; 95% CI 19.4 to 20.3).

Composite outcomes

The primary outcome in the MERIT study (Hillman 2005) was a composite score consisting of incidence of unexpected cardiac arrests, death (without NFR) and unplanned ICU admissions. The findings showed a similar incidence of the composite primary outcome in both the control and the MET hospitals (5.86 versus 5.31 per 1000 admissions; adjusted P value 0.640; adjusted odds ratio (OR) = 0.98; 95% CI 0.83 to 1.16) during the six-month study period. The Priestley study did not measure a composite score (Priestley 2004).

Mortality rates

Priestley had hospital mortality as a primary outcome (Priestley 2004), whereas the MERIT study had mortality (deaths without NFR) as a secondary outcome (Hillman 2005). The findings of the Priestley study showed that outreach reduced in-hospital mortality (adjusted OR = 0.52; 95% CI 0.32 to 0.85) (Priestley 2004). The secondary outcomes at the patient level in the MERIT study found no significant difference in the rate of unexpected death (without NFR) in the control hospitals compared with MET hospitals (1.18 versus 1.06 patients per 1000 admissions; adjusted P value 0.752).

Unplanned ICU admissions

The MERIT study was the only study to measure ICU admissions as a secondary outcome at the patient level (Hillman 2005). The study found no significant difference in the incidence of unplanned ICU admission in the control hospitals compared with MET hospitals (4.68 versus 4.19 patients per 1000 admissions; adjusted P value 0.60).

Length of stay

The MERIT study did not measure length of stay (LOS) (Hillman 2005). LOS was a primary outcome in the Priestley study (Priestley

2004), which showed an increased mean length of stay (hazard ratio 0.91; 95% CI 0.84 to 0.99) in the outreach group compared with the control group, although sensitivity analysis and adjustment for clustering showed no significant difference in LOS between outreach and control groups.

Adverse events (cardiac or respiratory arrest)

Priestley did not measure adverse events (Priestley 2004). The secondary outcomes at the patient level in the MERIT study showed an increased incidence of unexpected cardiac arrests in the control hospitals compared with MET hospitals (1.64 versus 1.31 patients per 1000 admissions, adjusted P value 0.74) (Hillman 2005).

The documentation of EWS charts and the number of calls were indicated in the process data of one study (Hillman 2005). The documentation of EWS charts 15 minutes before a cardiac arrest was significantly higher in control hospitals compared with MET hospitals (44% versus 30%; P value 0.031). This increased rate of recording was not statistically significant for either unplanned ICU admissions (55% versus 51%; P value 0.59) or unexpected deaths (55% versus 50%; P value 0.66) between the control and MET hospitals. The call rates for the arrest team or the MET team showed a statistically significant increased mean calling rate in the MET hospitals compared with the control hospitals (mean 3.1 (SD 1.3) versus 8.7 (SD 3.5); P value < 0.001). The number of calls not associated with an event was greater in the MET hospital compared with control hospitals (1329/1886 patient (70%) versus 194/528 (37%), P value < 0.001). The Priestley study did not measure process outcomes (Priestley 2004).

DISCUSSION

In this systematic review we found that the evidence to determine the effectiveness of critical care outreach and EWS on reducing hospital mortality, unplanned ICU admissions and readmissions, length of hospital stay and adverse events is inconclusive. Only two RCTs met the inclusion criteria. The findings from these two RCTs showed either no significant difference in the incidence of composite outcomes between MET and control hospitals (adjusted P value 0.640; adjusted OR = 0.98; 95% CI 0.83 to 1.16) (Hillman 2005) or that outreach reduced in-hospital mortality (adjusted OR = 0.52; 95% CI 0.32 to 0.85) compared with wards with no outreach (Priestley 2004). The increased length of stay (hazard ratio 0.91; 95% CI 0.84 to 0.99) found in the Priestley study was consistent with a reduction in hospital mortality (Priestley 2004), though additional analyses did not provide consistent support for this finding.

The methodological quality of these two studies was assessed as being a medium risk of bias. Comparison across studies was not possible due to heterogeneity in terms of interventions, settings, outcomes and study designs. In both studies the implementation

and follow-up periods were relatively short and this may have influenced the findings. The overall strength of evidence to inform decisions regarding the implementation and funding of CCOS is inconclusive.

The findings from this systematic review are important as they demonstrate the need for further high quality research in the area before the widespread promotion of outreach can be recommended. The larger part of the available research evidence on outreach is based on before and after designs which either lack randomisation or use historical controls. Future RCTs should be multicentred hospital comparisons which measure standardised outcomes in order to facilitate comparison across studies. A broad range of process and outcome measures are recommended to evaluate the impact of outreach (DeVita 2006). Qualitative studies should address subjective end points (medical and nursing ward staff and management opinions) and the factors (communication, professional boundaries) which hinder or support the introduction of a complex healthcare intervention in practice. Measurement of alternative objective end-points (time to first assessment, records of action taken and follow-up) may provide evidence to support the decision-making of whether EWS are useful.

Comparison of these findings with those of a recent systematic review published on outreach (Esmonde 2006) highlight similar issues of poor quality of research and a lack of evidence to support the benefits of outreach. The two systematic reviews differ in the quality of the inclusion criteria, which influenced the number of included studies. Esmonde included 23 studies of which 16 were uncontrolled before and after studies (Esmonde 2006). The review concluded that the evidence in the review was weak as a result of the poor methodological quality of the included study designs. The strength of our study is the rigorous inclusion criteria which highlights evidence on the basis of two RCTs.

The limitations of our study should be noted; this review found only two good quality RCTs. The findings from one study are inconclusive with the other study finding a reduction in hospital mortality rates. As a result no strong recommendations can be made based on the available evidence currently available. It is hoped that the direction of future research in this area in the UK will be guided by recommendations following the conclusion of the ongoing evaluative research on outreach in England commissioned by the Service Delivery Organisation (SDO 2004) and the National Institute for Health and Clinical Excellence (NICE) guidelines on caring for the acutely ill patient in hospital (NICE 2007).

To date the evidence from the two studies highlight the different models of CCOS that predominate in the UK and Australia. The Australian MET model is doctor-led whilst in the UK the CCOT model is nurse-led. There is no evidence to suggest that there are any differences between a nurse-led or doctor-led outreach team, however, the research design by Priestley implemented outreach

across 16 wards ensuring that the CCOT nurse visited every patient admitted within 24 hours (Priestley 2004). The frequent presence of the outreach nurse within the ward environment may have allowed relationships across the wards to be established as the role of outreach emphasises support and collaboration. This study also included staff training in the care of the acutely ill patient which may have had an impact on the ward nurses' decisions to utilise the calling criteria. In the MERIT study (Hillman 2005) patients were not visited on admission and the MET teams were only in contact with ward staff when alerted via the calling criteria. The role of the MET team was not explicitly stated although the focus would appear to be patient intervention management. It could be that the follow up of patients, training in acute care and the introduction of specific calling criteria to help identify deteriorating ward patients had an impact on outcomes by breaking down traditional hierarchical organisational barriers which may impede the communication process. Clear terminology and guidelines in relation to each model are required to provide standardisation of practices which would allow for more robust comparisons between models.

The studies used both objective and subjective EWS assessment criteria to trigger outreach. The MET hospitals utilised a single-parameter system (Hillman 2005), whereas the CCOT used a multiple-parameter system (Priestley 2004). There is no evidence to suggest that one early warning tool is better than the other. It was assumed that all patients admitted to the intervention hospital or wards in both studies had an EWS chart to record physiological deterioration, however, documentation of the EWS charts in the 15-minute period before an event were absent or incomplete for 50% of unplanned ICU admissions and unexpected deaths (Hillman 2005). This has serious implications for the total number of patients that can be identified as 'at risk' if the predetermined criteria for evaluating deterioration are not being recorded. Process data from the MERIT study found a significantly higher call rate prior to cardiac arrest or unplanned ICU admissions, and an increased mean number of calls not associated with a cardiac arrest or death in MET hospitals (Hillman 2005). The increased number of calls may have been as a result of heightened awareness or issues of low EWS sensitivity in particular wards.

The short timeframe for the implementation and evaluation of outreach and the absence of an enforcement policy across both studies may have had an impact on the findings. The change process requires both time and reinforcement to ensure ownership of the change, however, in the Priestley study (Priestley 2004), the critical care outreach nurse's presence may have been more prominent, and acted as a reinforcement policy, as each patient was visited within 24 hours of admission. Continued support and reinforcement from the investigators could have resulted in an increased number of calls from general ward staff on the intervention wards or hospitals. This is important as the low rate of MET calls preceding unplanned ICU admissions and unexpected deaths were

evident in patients who had documented calling criteria in the MERIT study (Hillman 2005). It suggests that even when EWS or calling criteria are met, nurses were reluctant to call for help. In future, in order to determine the effect of enforcement policies, or the reasons for a low rate of calls, the number of outreach calls needs to be audited. Information on the following points: who, predominately, made the calls; the response time; and intervention or action administered; as well as the patient outcome, would provide information on the process of outreach and not just patient outcomes. An understanding of the process is imperative in order to understand how the end point was reached.

The MERIT study had major limitations that may have resulted in the negative findings (Hillman 2005). The first of these was the risk of contamination between intervention and control hospitals as result of increased media attention in hospital quality and safety issues in Australia that highlighted the benefits of outreach. This may have increased staff awareness regarding the clinical signs of deterioration in patients and as a result they identified and responded to deteriorating patients earlier in the control hospitals. Secondly, MERIT investigators suggested that the cardiac arrest team in the control hospitals may have acted to some extent as MET teams, as 48% of cardiac calls in the control hospitals were not associated with a cardiac arrest or unexpected death. Thirdly, the study was underpowered for detection of a significant difference in the incidence of primary outcomes, and, finally, the inter-hospital variability was also higher than anticipated. Limitations of the Priestley study included possible contamination of the study wards similar to the MERIT study and limited generalisability (Priestley 2004).

The limitations and findings of both these studies highlight that, to date, there is no evidence to suggest that the introduction of outreach contributes to improved patient outcomes. Equally, there is no evidence to suggest that outreach is associated with adverse healthcare events. We were unable to determine the economic implications of implementing outreach from either study. The cost may vary substantially, depending on the staffing, resources and content of the intervention implemented. Since outreach incurs opportunity costs, it is reasonable to suggest that healthcare funders and the public should expect that large numbers of reliable, well-designed, prospective studies should be conducted either before widespread implementation or alongside it. As a result, no recommendations for the introduction of outreach to improve patient outcomes can be made at this time. Further RCTs are required to demonstrate the value and benefit of outreach that is currently recognised by many who have participated in it, and who are reluctant to give it up without clear evidence to the contrary.

AUTHORS' CONCLUSIONS

Implications for practice

There is minimal evidence at this time to recommend the adoption of outreach to support the identification and management of acutely ill patients in hospital.

Implications for research

There is a need for further prospective RCTs. The feasibility of these studies has been shown in two different RCT designs evaluating outreach. The poor quality of current research evidence and the heterogeneity across studies requires that planning of future RCTs should aim to standardise measures of outcomes to allow for comparisons across studies. There is a need to clarify similarities or differences in the role and intervention strategies of the MET and CCOT models and to undertake a subgroup analysis to indicate any differences between the two models. This would provide clarification on the implementation of outreach services to facilitate standardisation of practice so that comparisons can be made across studies.

The use of EWS systems or MET calling criteria in the practice setting needs to be evaluated. This would provide an understanding of the factors associated with poor documentation of EWS charts and the reluctance of ward staff to utilize the calling criteria.

Educational programmes which provide a basic understanding of patient assessment and immediate management of physiological derangements is imperative to empower ward staff to feel confident in managing critically ill patients. Evaluation of the ALERTTM course has shown beneficial effects on doctors' knowledge of acute care and increased confidence levels of healthcare staff to the recognition and management of acutely ill patients (Featherstone 2005; Smith 2004). To date there is no evidence on the impact that these educational programmes have had on clinical practice or patient outcomes. It is recommended that the ALERTTM best practice guidelines should be utilised to evaluate the standard of practice in wards in relation to the appropriateness of interventions and the documentation of care following identification of an 'at risk' patient.

The implementation of any complex healthcare intervention will have certain factors supporting and hindering the change process. We suggest further research which focuses specifically on those barriers identified by McQuillan (McQuillan 1998) as the reasons for suboptimal care. This area of research is important in order to identify and explain the complex processes and mechanisms within a hospital which support or hinder the change process in identifying and managing deteriorating patients on general hospital wards.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Hillman 2005

Methods	Prospective cluster randomised controlled trial (RCT). Randomisation was concealed from the project investigators and participating hospitals. 2 month baseline period, 4 month implementation period and 6 month after period in both control and intervention hospitals.	
Participants	23 hospitals General inpatient wards, coronary care units and high dependency units which were not under direct supervision of an intensive care unit specialist. A general ward included any inpatient ward within the study hospitals. The study excluded events in patients < 14 years, patients who died on arrival to hospital, or patients who had not been formally admitted to hospital.	
Interventions	12 intervention hospitals introduced hospital-wide Medical Emergency Teams (MET). Standardised education and implementation strategy was used to introduce the MET. 11 control hospitals did not receive MET education. Cardiac arrest teams continued unchanged during implementation and study period.	
Outcomes	Primary: composite outcome of the incidence (events divided by the number of eligible patients admitted to the hospital during the study period) of cardiac arrests without a pre-existing not for resuscitation order (NFR), unplanned ICU admission, and unexpected deaths (deaths without a pre-existing NFR). Secondary outcomes: individual patient data (cardiac arrests without pre-existing NFR, unplanned ICU admissions, unexpected deaths and length of hospital stay).	
Notes	Staff designated to form MET varied between participating hospitals. If a patient had more than one event during their hospital stay, only one event was included in the composite measure.	
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

Priestley 2004

Methods	Prospective stepped wedge RCT. Critical care outreach team (CCOT) sequentially introduced to each paired ward over a 4 week training period. All wards received the intervention in equal time periods over the 32 week study period. Randomisation done by one author based on ward pairings and risk estimates provided by the rest of the study team.	
Participants	All patients admitted to 16 acute adult wards of one-general hospital over a 32 week period.	
Interventions	Critical Care Outreach Service (CCOS) 24 hours a day, 7 days a week, across 16 study wards which had an average of 30 beds each and included 8 surgical, 5 medical and 3 elderly medicine wards. In each ward, 4 weeks of training was provided, after which outreach was fully operational. The control wards moved from control to intervention wards via the training period.	
Outcomes	Rate of in-hospital deaths. Length of hospital stay.	
Notes		
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	No	C - Inadequate

A - Adequate
B- Unclear
C- Inadequate
D- Not used

Characteristics of excluded studies [ordered by study ID]

Bakalar 2004	Study design does not meet with EPOC criteria for controlled before and after (CBA) study (no control arm after intervention) or interrupted time series analysis (ITS) (3 data points before and after intervention). Retrospective data
Ball 2003	Study design does not meet with EPOC criteria for CBA study (no control arm after intervention) or ITS (3 data points before and after intervention).
Barnes 2003	Study design does not meet with EPOC criteria for CBA study (no control arm after intervention) or ITS (3 data points before and after intervention).

(Continued)

Bellomo 2003	Study does not meet study eligibility criteria as defined by EPOC for CBA study (no control arm after intervention) or ITS (3 data points before and after intervention).
Bellomo 2004	Study does not meet study eligibility criteria as defined by EPOC for CBA study (no control arm after intervention) or ITS (3 data points before and after intervention).
Buist 2002	Study does not meet study eligibility criteria as defined by EPOC for CBA study (no control arm after intervention) or ITS (3 data points before and after intervention). Only one data point available post 1999.
DeVita 2004	Intervention was the introduction of protocolised calling criteria to enhance MET system which had been introduced. Intervention was predetermined calling criteria and not outreach.
Garcea 2004	Study does not meet study eligibility criteria as defined by EPOC for CBA study (no control arm after intervention) or ITS (3 data points before and after intervention).
Jones 2005	Study does not meet study eligibility criteria as defined by EPOC for CBA study (no control arm after intervention) or ITS (3 data points before and after intervention). Figure 1 displays data over six years for after but data not available for pre intervention.
Leary 2003	Study does not meet study eligibility criteria as defined by EPOC for CBA study (no control arm after intervention) or ITS (3 data points before and after intervention).
Pittard 2003	Study does not meet study eligibility criteria as defined by EPOC for CBA study (no control arm after intervention) or ITS (3 data points before and after intervention).
Story 2004	Study does not meet study eligibility criteria as defined by EPOC for CBA study (no control arm after intervention) or ITS (3 data points before and after intervention).
Subbe 2003	Intervention was an Assessment Score for Sick Patient Identification and Step-up in Treatment (ASSIST) and education on early recognition of patients (ALERT) rather than assessing the effect of an intervention.
Young 2002	Study does not meet study eligibility criteria as defined by EPOC for CBA study (no control arm after intervention) or ITS (3 data points before and after intervention).

DATA AND ANALYSES

This review has no analyses.

APPENDICES

Appendix I. EMBASE Search Strategy

Search Term

1. Hospital Information System/
2. (warning system\$ or early warning).tw.
3. outreach.tw.
4. Emergency Health Service/
5. Patient Care/
6. medical emergency team?.tw.
7. or/1-7
8. exp Intensive Care/
9. Postoperative Care/
10. critical care.tw.
11. intensive care.tw.
12. (postoperative care or post-operative care).tw.
13. or/8-12
14. 7 and 13
15. Randomized controlled trial/
16. (randomised or randomized).tw.
17. experiment\$.tw.
18. (time adj series).tw.
19. (pre test or pretest or post test or posttest).tw.
20. impact.tw.
21. intervention?.tw.
22. chang\$.tw.
23. Evaluation/
24. evaluat\$.tw.
25. effect?.tw.
26. compar\$.tw.
27. (controlled adj study).tw.
28. ((comparative or intervention) adj study).tw.
29. or/15-28
30. Nonhuman/
31. 29 not 30
32. 14 and 31

Appendix 2. Cochrane Search History

#1 MeSH descriptor Point-of-Care Systems explode all trees in MeSH Products
#2 warning system* in All Fields in all products
#3 early warning in All Fields in all products
#4 outreach in All Fields in all products
#5 MeSH descriptor Emergency Service, Hospital explode all trees in MeSH products
#6 MeSH descriptor Patient Care Team explode all trees in MeSH products
#7 medical emergency team in All Fields in all products
#8 (#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7)
#9 MeSH descriptor Critical Care explode all trees in MeSH products
#10 MeSH descriptor Postoperative Care explode all trees in MeSH products
#11 critical care in All Fields in all products
#12 intensive care in All Fields in all products
#13 postoperative care in All Fields in all products
#14 post-operative care in All Fields in all products
#15(#9 OR #10 OR #11 OR #12 OR #13 OR #14)
#16 (#8 and #15) (481)
#17 Randomized Controlled Trial [publication type] in all products
#18 Controlled Clinical Trial [publication type] in all products
#19 MeSH descriptor Intervention Studies explode all trees in MeSH products
#20 experiment in All Fields in all products
#21 time series in All Fields in all products
#22 pretest in All Fields in all products
#23 pre test in All Fields in all products
#24 posttest in All Fields in all products
#25 post test in All Fields in all products
#26 MeSH descriptor Random Allocation explode all trees in MeSH products
#27 impact in All Fields in all products
#28 intervention in All Fields in all products
#29 chang* in All Fields in all products
#30 MeSH descriptor Evaluation Studies explode all trees in MeSH products
#31 evaluat* in All Fields in all products
#32 effect in All Fields in all products
#33 comparative study [publication type] in all products
#34 (#17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33)
#35(#16 AND #34)
#36(#16 AND #34)
#37(#16 AND #34)

Appendix 3. Web of Science, Biosis previews and ISI Proceedings Databases Searches

#1 topic = ("point of care system*")
#2 topic = ("warning system*" or "early warning")
#3 topic = (outreach)
#4 topic = (hospital emergency service*)
#5 topic = (patient care team*)
#6 topic = (medical emergency team*)
#7 topic = (#1 or #2 or #3 or #4 or #5 or #6)
#8 topic = (critical care)
#9 topic = (postoperative care or post-operative care or post operative care)
#10 topic = (critical care)

#11 topic = (intensive care)
 #12 topic = (#8 or #9 or #10 or #11)
 #13 topic = (#7 and #12)
 #14 topic = (randomized controlled trial*)
 #15 topic = (controlled clinical trial*)
 #16 topic = (intervention studies or intervention study)
 #17 topic = (experiment*)
 #18 topic = ("time series")
 #19 topic = (pre test or pretest or pre-test)
 #20 topic = (posttest or post test or post-test)
 #21 topic = ("random allocation")
 #22 topic = (impact)
 #23 topic = (intervention*)
 #24 topic = (chang*)
 #25 topic = ("evaluation studies")
 #26 topic = (evaluat*)
 #27 topic = (effect)
 #28 topic = ("comparative studies")
 #29 topic = (#14 or #15 or #16 or #17 or #18 or #19 or #20 or #21 or #22 or #23 or #24 or #25 or #26 or #27 or #28)
 #30 topic = (#13 and # 29)

WHAT'S NEW

Last assessed as up-to-date: 22 May 2007.

12 November 2008	Amended	Minor changes
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HISTORY

Protocol first published: Issue 4, 2005

Review first published: Issue 3, 2007

22 April 2008	Amended	Converted to new review format.
23 May 2007	New citation required and conclusions have changed	Substantive amendment

CONTRIBUTIONS OF AUTHORS

All review authors have contributed to the protocol. JM lead the writing of the protocol, all other review authors provided comment and feedback. For the full review: JM ran the search strategy, JM, AK and RF screened records for eligibility. AM acted as arbitrator for any disagreements on the inclusion of studies. JM and AK abstracted data and disagreement were resolved by an independent arbitrator (RF). JM and RF assessed the quality of all eligible studies and AK acted as arbitrator for any discrepancies in quality ratings. JM undertook the analysis, interpretation of results and the writing up of the review. AK, RF, AM and MM contributed to the analysis, interpretation of results and provided feedback on the review. FA provided supervision and feedback on all aspects of the manuscript review.

DECLARATIONS OF INTEREST

None known.

SOURCES OF SUPPORT

Internal sources

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External sources

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INDEX TERMS

Medical Subject Headings (MeSH)

Critical Illness [*mortality]; Heart Arrest [*mortality]; *Hospital Mortality; *Intensive Care Units; Length of Stay; Patient Admission [statistics & numerical data]; Patients' Rooms; Randomized Controlled Trials as Topic

MeSH check words

Adult; Humans