An Roinn Sláinte
Department of Health

Irish Maternity Early Warning System (IMEWS) V2

National Clinical Guideline No. 4

Annex 1: Systematic review update

National Patient Safety Office
Oifig Náisiúnta um Shábháilteacht Othar

NATIONAL CLINICAL EFFECTIVENESS COMMITTEE

HRB Health Research Board

CICER Collaboration in Ireland for Clinical Effectiveness Reviews

Clinical effectiveness and cost-effectiveness of maternity early warning systems: systematic review update

The Irish Maternity Early Warning System (IMEWS) National Clinical Guideline No. 4

February 2018

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Particular thanks are due to the following members of the Guideline Development Group:

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About HRB-CICER

In 2016, the Department of Health requested the Health Research Board (HRB) to fund a dedicated multidisciplinary research group to support the activities of the Ministerial appointed National Clinical Effectiveness Committee (NCEC). Called HRB-CICER (Collaboration in Ireland for Clinical Effectiveness Reviews), a five-year contract (2017 to 2022) was awarded following a competitive process to the Health Information and Quality Authority (HIQA). The HRB-CICER team comprises a dedicated multidisciplinary research team (including expertise in health economics, qualitative and quantitative research methods and epidemiology) supported by staff from the Health Technology Assessment (HTA) team in HIQA and the HRB Centre for Primary Care Research at the Royal College of Surgeons in Ireland (RCSI), as well as national and international clinical and methodological experts.

Guideline development groups submit clinical guidelines for appraisal and endorsement by the NCEC as National Clinical Guidelines. HRB-CICER provides independent scientific support to guideline development groups tailored according to their specific needs. The main role of the HRB-CICER team is to undertake systematic reviews of the clinical effectiveness and cost-effectiveness of interventions included in the guidelines and to estimate the budget impact of implementing the guidelines. Additional support can be provided by HRB-CICER to guideline development groups including; providing tailored training sessions and working closely with the guideline development groups to develop clinical questions and search strategies; performing systematic reviews of international clinical guidelines; supporting the assessment of their suitability for adaption to Ireland and assisting in the development of evidence-based recommendations.

Membership of the evaluation team

Members of the HRB-CICER Evaluation Team were Dr Barbara Clyne (project lead), Michelle O'Neill, Karen Jordan, Dr Sinéad O' Neill, Paul Carty, Barrie Tyner, Professor Susan Smith and Dr Máirín Ryan.

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List of abbreviations

AUROC	area under the receiver operating characteristic
AVPU	alert, voice, pain, unresponsive
BP	blood pressure
BPM	beats per min
CCT	controlled clinical trial
CDC	Centers for Disease Control and Prevention
CEMACH MEOWS	Confidential Enquiries into Maternal and Child Health Modified Early Obstetric Warning System
CI	confidence interval
CUA	cost utility analysis
EPOC	Cochrane Effective Practice and Organisation of Care
EWS	Early Warning Score
FiO_2	Fraction of inspired oxygen
GAIN	Guidelines and Audit Implementation Network
GDG	Guideline Development Group
HDU	high dependency ward
HIQA	Health Information and Quality Authority
HRB-CICER	Health Research Board-Collaboration in Ireland for Clinical Effectiveness Reviews
HSE	Health Service Executive
HTA	health technology assessment
OR	odds ratio
HR	heart rate
ICER	incremental cost-effectiveness ratio
ICU	intensive care unit
ICNARC-OEWS	Intensive Care National Audit and Research Centre Obstetric Early Warning Score
IMEWS	Irish Maternity Early Warning System
ISBAR	identify, situation, background, assessment and recommendation
ITS	interrupted time series
IV	intravenous
MEOWS	maternal early obstetric warning system
MEWS	maternity early warning systems
MEWT	Maternal Early Warning Trigger
MOEWS	modified obstetric early warning scoring systems
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NCEC	National Clinical Effectiveness Committee
NEWS	National Early Warning Score
NPV	negative predictive value
ObsEWS	obstetric early warning charts
PET	pre-eclamptic toxaemia

PEWSS	Physiological Early Warning Scoring System
PICO	population, intervention, comparison, outcome
POSW	postoperative support ward
PPH	postpartum haemorrhage
PPV	positive predictive value
PRISMA	Preferred Reporting in Systematic Reviews and Meta-Analysis
QUADAS	Quality Assessment of Diagnostic Accuracy Studies
QALY	quality-adjusted life year
RCSI	Royal College of Surgeons in Ireland
RCT	randomised-controlled trial
ROC	receiver operating characteristics
RR	respiratory rate
SAST	Sepsis Assessment Tool
SaO2	oxygen saturation
SpO2	peripheral capillary oxygen saturation
SD	standard deviation
TTS	track and trigger systems
UK	United Kingdom
US	United States

Executive summary

Background and objectives

Maternity early warning systems are bedside tools that are used for monitoring the condition of hospitalised pregnant and postnatal women to facilitate early detection and management of clinical deterioration. In 2013, the Irish Maternity Early Warning System (IMEWS) was introduced into Irish hospitals. IMEWS was updated in 2014 during the development of National Clinical Guideline No. 4.

The IMEWS chart is completed at the bedside. Vital signs (respiration rate, oxygen saturation, temperature, heart rate, blood pressure, urine and neurological response) are recorded on charts and colour coded according to their value using predefined thresholds for abnormalities. If a patient breaks or triggers these thresholds, an escalation of care should be initiated.

National Clinical Guideline No. 4 was based on a systematic review of the underpinning clinical effectiveness and cost-effectiveness literature up to April 2014. The purpose of this systematic literature review was to update the available clinical effectiveness and cost-effectiveness literature so that changes in the evidence on early warning systems for use in maternity care can inform the updating of this National Clinical Guideline. This involved two systematic reviews:

1. an update of the previous systematic review of clinical effectiveness and cost effectiveness conducted to support the development of the IMEWS guideline
2. a new systematic review to identify clinical audits of early warning systems.

Methods

The systematic review of the literature to support the update of the IMEWS guideline was carried out in the following ways:

- Comprehensive searches of PubMed, EMBASE, CINAHL, the Cochrane Library, MIDIRS, ASSI, HMIC and Global Index Medicus and a comprehensive grey literature search were conducted for the period April 2014 to October 2017 using combinations of keywords and medical subject headings (MeSH) terms.

- Studies were assessed against inclusion and exclusion criteria, and the following categories of studies and reports conducted in obstetric care settings were included: guidelines, effectiveness studies, development and validation studies and health economic studies.
- Two review authors independently assessed studies for inclusion, conducted data extraction, assessed risk of bias and checked for accuracy.
- The quality of the evidence was assessed using the Cochrane GRADE approach.
- A narrative summary of included studies was conducted.

The review of clinical audits of early warning systems (not just maternity early warning systems) in a hospital care setting, including obstetric, paediatrics, general inpatients and emergency departments, was carried out as follows:

- Comprehensive searches of PubMed, EMBASE, CINAHL, the Cochrane Library, MIDIRS, ASSI, HMIC and Global Index Medicus and a comprehensive grey literature search were conducted up to October 2017 using combinations of keywords and medical subject headings (MeSH) terms.
- Studies were assessed against inclusion and exclusion criteria.
- Two review authors independently assessed studies for inclusion, conducted data extraction, assessed study quality and checked for accuracy.
- A narrative summary of included studies was conducted.

Results: Review update

From 293 studies assessed for eligibility, one effectiveness study, eight development and or validation studies and one health economics study were identified. Two references to the current IMEWS guideline were also identified and were not included in the analysis.

One controlled before and after study found severe maternal morbidity was significantly reduced after the introduction of a clinical pathway-specific maternal early warning trigger; however, this was only one study of low methodological quality (that is, high risk of bias).

Eight studies on the development/validation of maternity early warning systems were identified. The majority of studies were conducted in high-risk populations and reported mortality or severe morbidity outcomes; however, there was generally a high risk of bias in these studies. There was variation reported in parameters depending on the maternal early

warning system used, with only respiratory rate and blood pressure being common to all systems.

Only one conference abstract that provided cost-effectiveness data (based on the identified controlled before and after study) was identified. This study found that the use of a maternal early warning trigger tool reduced severe maternal morbidity, which resulted in significant cost savings.

Results: Clinical audits

From 2,363 studies assessed for eligibility, 61 clinical audit studies were identified. Eighteen of these were specifically related to obstetric patients, ten to paediatric patients, 28 to general patient populations, three to emergency department populations and two studies evaluated a number of different early warning scores across patient populations. The 18 obstetric clinical audits included in this review highlight that compliance rates with early warning scores and with documentation and escalation policies is often poor. Education and training, routine audit, implementation of software systems and having clear escalation protocols were suggested as ways of increasing compliance and accuracy. The remaining clinical audits in paediatric, general and emergency department populations reported similar rates of poor compliance and also suggested education and training and routine audit as mechanisms to increase compliance.

Conclusions

A number of maternal early warning systems have been developed. Studies have examined both the performance of these systems and their effectiveness in terms of patient outcomes. However, the conduct and reporting of these studies is generally poor with a high risk of bias. Furthermore, clinical audits tend to be poorly described. Overall, the results of this systematic review demonstrate the literature in this area has not evolved substantially from the last review conducted to support the development of the IMEWS

guideline, and there is limited new evidence to inform changes to the previous recommendations.

Future research should focus on improving reporting, development and validation studies and conducting high-quality effectiveness studies and health economic studies that allow for the conduct of more robust analysis to inform decision making.

Summary of findings tables

Clinical effectiveness of early warning or track and trigger systems on pregnancy, labour and birth, postpartum (up to 42 days) and neonatal outcomes

Patient or population: Pregnant and postpartum women (up to 42 days)
Setting: In-hospital
Intervention: Early warning or track and trigger systems
Comparison: Care as usual, no intervention

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)
	Risk with [comparison]	Risk with [intervention]			
Maternal morbidity	24 per 1,000	0 per 1,000 (0 to 0)	Not estimable	63,252 (1 observational study)	⨁◯◯◯ VERY LOW [a,b,c]
Maternal death				(0 studies)	Not reported
ICU admission				(0 studies)	Not reported
Length of hospital stay				(0 studies)	Not reported

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval

GRADE Working Group grades of evidence
High certainty: We are very confident that the true effect lies close to that of the estimate of the effect
Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

Explanations

a. High or unclear risk of bias for allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data and other biases

b. No confidence intervals presented

c. One study with design limitations

Performance of early warning scores for the prediction of maternal outcomes

Outcomes	Sensitivity % (95% CI)	Specificity % (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)
Maternal morbidity	40–100* (not estimable)	3.6–96.9* (not estimable)	1,598 (6 observational studies)	⨁◯◯◯ VERY LOW [a,b,c,d]
Maternal death	97 (not estimable)	87 (not estimable)	2,274 (2 cohort type accuracy study)	⨁◯◯◯ VERY LOW [a,b,c]
ICU admission	65.0–96.0* (not estimable)	54.0–89.0* (not estimable)	184 (1 case-control type accuracy study)	⨁◯◯◯ VERY LOW [a,b,c,d,e]
Hospital length of stay	Not reported	Not reported	123 (1 cohort type accuracy study)	⨁◯◯◯ VERY LOW [a,e]

*** Range reported across included studies**

CI: Confidence interval

GRADE Working Group grades of evidence
High certainty: We are very confident that the true effect lies close to that of the estimate of the effect
Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

Explanations

a. High or unclear risk of bias application of reference and index tests

b. High or unclear risk in flow and timing

c. High risk population, low applicability

d. Wide range of sensitivity and specificity

e. Single study with small sample

1 Introduction

1.1 Description of the condition

Although most women progress through pregnancy, labour and delivery with few complications, maternal death and severe morbidity remain important public health concerns.[1] The Confidential Maternal Deaths Enquiry published in 2017 confirmed that Ireland continues to have a low maternal mortality ratio (6.5 per 100,000 maternities, 95% confidence interval [CI] 3.5–11.2) by international standards.[2] In comparison with mortality, severe maternal morbidity is more common with figures from the UK indicating that for every maternal death, nine mothers develop severe obstetric complications, including sepsis, massive haemorrhage, hypertensive disorder sequelae and venothrombotic events.[3] In a study of severe maternal morbidity for 2004–2005 in the three Dublin maternity hospitals, the rate of severe maternal morbidity was 3.2 per 1,000 maternities.[4] The most common cause was haemorrhage. Many cases of major maternal morbidity and mortality may be preventable; therefore, early recognition of clinically deteriorating pregnant women remains a priority for improving maternity services.[5]

1.2 Description of the intervention

Maternity early warning systems (MEWS), or physiological track and trigger systems (TTS), are bedside tools that are used for monitoring the condition of hospitalised pregnant and postnatal women to facilitate early detection and management of clinical deterioration.[6]

In April 2013, the Irish Maternity Early Warning System (IMEWS) was introduced into Irish hospitals. The IMEWS chart is completed at the bedside. Vital signs (respiration rate, oxygen saturation, temperature, heart rate, blood pressure, urine and neurological response) are recorded on charts and colour coded according to their value using predefined thresholds for abnormalities.[7]

1.3 The purpose of this review

The IMEWS National Clinical Guideline No. 4 was initially developed to improve the hospital inpatient care of a woman with a confirmed clinical pregnancy and up to 42 days in the postnatal period irrespective of age, location or reason for admission. However, IMEWS has been adopted beyond the inpatient setting, for example, in emergency departments. The purpose of the guideline is, therefore, to improve the management of the care of a woman with a confirmed clinical pregnancy and up to 42 days in the postnatal period through the use of a standard maternity early warning system.[8]

National Clinical Guideline No. 4 was based on a systematic review of the underpinning clinical effectiveness and cost-effectiveness literature up to April 2014.[8] The IMEWS guideline is now being reviewed and updated. The purpose of this systematic literature review was to update the available clinical effectiveness and cost-effectiveness literature, so that any changes in the totality of the evidence on early warning systems for use in maternity care can inform updates to this National Clinical Guideline.[8] This involved:

1. an update of the previous systematic review of clinical effectiveness and cost-effectiveness conducted to support the update of the IMEWS guideline[8]
2. a new systematic review to identify clinical audits of early warning systems.

The new systematic review of clinical audits of all early warning systems was requested by the Childbirth Guideline Development Group but will also facilitate shared learning in relation to the implementation of such systems across other hospital care settings.

The questions for this review were as follows:

1. What early warning systems or track and trigger systems (including escalation protocols and communication tools such as ISBAR (identify, situation, background, assessment and recommendation)) are currently in use internationally in pregnant women or women who delivered in the previous 42 days for the detection of deterioration/timely identification of deterioration in maternity patients? What is the level of clinical validation of these scoring systems, including escalation protocols, clinical audit and communication tools?

2. What education programmes have been established to train healthcare professionals in the delivery of MEWS? What level of evaluation has been used for these education programmes?
3. What are the findings from the economic literature of cost effectiveness, cost impact and resources involved with early warning or track and trigger systems in the detection of deterioration/timely identification of deterioration in pregnant women or women who delivered in the previous 42 days, including implementation costs?

2 Objectives

This review aimed to determine the clinical effectiveness, cost-effectiveness and resource impact of early warning systems in the detection of deterioration/timely identification of deterioration in pregnant women or women who delivered in the previous 42 days.

To answer the review questions, six discrete, yet complimentary, objectives were defined:

1. to describe the education programmes, including their evaluation, that have been established to train healthcare professionals and other non-professional staff in the delivery of MEWS
2. to identify and quality assess clinical guidelines on the use of early warning or track and trigger systems in pregnant women or women who gave birth in the previous 42 days for the detection of deterioration/timely identification of deterioration
3. to evaluate the clinical effectiveness of early warning or track and trigger systems on pregnancy, labour and birth, postpartum (up to 42 days) and neonatal outcomes
4. to describe the development and validation of such early warning or track and trigger systems
5. to evaluate the cost effectiveness, cost impact and resources involved with such early warning or track and trigger systems
6. to identify and describe clinical audits of any early warning system.

Objectives 1 to 5 and the corresponding review questions were consistent with those set out in the previous search conducted to support the development of the IMEWS guideline.[8] Therefore, the aims of this review were to:

1. identify any new evidence in relation to objectives 1 to 5 listed above that became available since the previous review
2. identify and describe clinical audits of any early warning system (objective 6). This was not specifically addressed in the previous review, and a new search was performed for this objective.

3 Methods

The reporting of this systematic review adhered to the Preferred Reporting in Systematic Reviews and Meta-Analysis (PRISMA) criteria.[9] The methods outlined in this section are consistent with those described in the protocol for this systematic review, which was developed and agreed with the Childbirth Guideline Development Group in October 2017.

3.1 Criteria for including studies within this review

The specific inclusion criteria for studies across each of the six objectives listed in Section 2 are summarised across Table 3.1 to Table 3.6 using PICO (population, intervention, comparison, outcome). For objectives 1 to 5, only studies published since April 2014 were included. For objective 6, databases were searched from inception to October 2017. Only studies available in English were included.

Table 3.1. Specific PICO for objective 1

Objective 1: To describe the education programmes, including their evaluation, that have been established to train healthcare professionals and other non-professional staff in the delivery of MEWS	
Population	Healthcare professionals using early warning systems, track and trigger systems, escalation protocols or communication tools in maternity care settings
Intervention	Education programmes focused on: ▪ early warning systems or track and trigger systems, which rely on periodic observation of selected basic physiological signs with predetermined calling or response criteria for escalating care to facilitate prompt recognition of clinical deterioration ▪ escalation protocols or communication tools used in combination with, or as an adjunct to, early warning systems or track and trigger systems
Comparison	Usual care, alternative intervention
Outcome(s)	Use of/compliance with early warning systems, track and trigger systems and escalation protocols
Study design	Studies with a controlled design, that is, RCTs, non-RCTs, controlled before-and-after studies and interrupted time series designs

Key: RCTs — randomised controlled trials.

Table 3.2. Specific PICO for objective 2

Objective 2: To identify and quality assess clinical guidelines on the use of early warning or track and trigger systems in pregnant women or women who gave birth in the previous 42 days for the detection of deterioration/timely identification of deterioration	
Population	Women who were clinically pregnant or who delivered at any gestation within the previous 42 days
Intervention	Clinical guidelines (regional, national, international)
Outcome(s)	Number and type of clinical guidelines (regional, national, international). Key recommendations of guideline.
Study design	Regional, national and international reports on guidelines on early warning systems, track and trigger systems and escalation protocols or communication tools

Table 3.3. Specific PICO for objective 3

Objective 3: To evaluate the clinical effectiveness of early warning or track and trigger systems on pregnancy, labour and birth, postpartum (up to 42 days) and neonatal outcomes	
Population	Women who were clinically pregnant or who delivered at any gestation within the previous 42 days
Intervention	▪ Early warning systems or track and trigger systems, which rely on periodic observation of selected basic physiological signs with predetermined calling or response criteria for escalating care to facilitate prompt recognition of clinical deterioration ▪ Escalation protocols or communication tools used in combination with, or as an adjunct to, early warning systems or track and trigger systems
Comparison	Non-use of systems or use of alternative systems of physiological monitoring
Outcome(s)	Pregnancy, labour and birth, and postpartum outcomes: ▪ maternal death ▪ maternal critical illness (maternal collapse — cardiac or respiratory arrest, haemorrhage, sepsis, eclampsia, etc.) ▪ ICU admission ▪ length of hospital stay (days)
Study design	Studies with a controlled design, that is, RCTs, non-RCTs, controlled before-and-after studies and interrupted time series designs

Key: ICU — intensive care unit; RCTs — randomised controlled trials.

Table 3.4. Specific PICO for objective 4

Objective 4: To describe the development and validation of such early warning or track and trigger systems	
Population	Women who were clinically pregnant or who delivered at any gestation within the previous 42 days
Intervention	▪ Early warning systems or track and trigger systems, which rely on periodic observation of selected basic physiological signs with predetermined calling or response criteria for escalating care to facilitate prompt recognition of clinical deterioration ▪ Escalation protocols or communication tools used in combination with or as an adjunct to early warning systems or track and trigger systems
Outcome(s)	▪ Sensitivity and specificity of early warning system or track and trigger system for adverse outcome/critical illness criterion ▪ Positive predictive value and negative predictive value of early warning system or track and trigger system for adverse outcome/critical illness criterion
Study design	Development studies: focused on the development of early warning or track and trigger systems. Studies were recorded as 'development' studies if reference ranges, parameters, cut-offs, and or design of scoring systems were identified based on the outcomes of the study sample, for example, through the use of ROC curves. Validation studies: focused on the predictive ability of early warning or track and trigger systems in a new sample of women, that is, a sample that differs from the sample used to develop the system.

Key: ROC — receiver operating characteristics.

Table 3.5. Specific PICO for objective 5

Objective 5: To evaluate the cost effectiveness, cost impact and resources involved with early warning or track and trigger systems	
Population	Women who were clinically pregnant or who delivered at any gestation within the previous 42 days
Intervention	▪ Early warning systems or track and trigger systems, which rely on periodic observation of selected basic physiological signs with predetermined calling or response criteria for escalating care to facilitate prompt recognition of clinical deterioration ▪ Escalation protocols or communication tools used in combination with or as an adjunct to early warning systems or track and trigger systems
Comparison	One or more standard treatments
Outcome(s)	Healthcare resource use and expenditure, including costs associated with direct medical resource use (staff time, education input, additional referrals), indirect costs (associated with lost or reduced productivity) and other non-medical costs (such as patient out of pocket expenses) associated with early warning system or track and trigger system use; cost savings; and cost effectiveness measures, for example, incremental cost-effectiveness ratios (ICERs) or quality-adjusted life years (QALYs)
Study design	Full economic evaluation studies (cost-effectiveness analysis, cost-utility analysis and cost-benefit analysis), cost analysis and comparative resource use studies. These could include RCTs or any study that met the eligibility criteria for the review of intervention effects.

Key: ICERs —Incremental cost-effectiveness ratio; QALYs—quality-adjusted life years; RCTs —randomised controlled trials.

Table 3.6. Specific PICO for objective 6

Objective 6: To identify and describe clinical audits of any early warning system	
Population	Healthcare professionals using early warning systems, track and trigger systems, escalation protocols or communication tools in any hospital care setting, including obstetric, paediatrics, general inpatients and emergency departments
Intervention	Early warning systems or track and trigger systems, which rely on periodic observation of selected basic physiological signs with predetermined calling or response criteria for escalating care to facilitate prompt recognition of clinical deterioration
Outcomes	Use of and compliance with early warning systems, trigger systems and escalation protocols or communication tools nationally and internationally
Study design	Clinical audits: process that aims to improve patient care and outcomes by systematic and structured review and evaluation of clinical care against explicit clinical standards [(10)]

3.2 Search methods for identification of studies

Comprehensive search strategies (see Appendix 1) were used to conduct electronic searches in the following databases* between April 2014 and October 2017 for objectives 1 to 5:

- Medical Literature Analysis and Retrieval System Online (MEDLINE)
- The Cumulative Index to Nursing and Allied Health Literature (CINAHL)
- Exerpta Medica Database (EMBASE)
- Maternity and Infant Care (MIDIRS)
- Applied Social Sciences Index and Abstracts (ASSIA)
- The Health Management Information Consortium (HMIC)
- Cochrane Database of Systematic Reviews (CDSR)
- Cochrane Central Register of Controlled Trials (CENTRAL)
- Database of Abstracts of Reviews of Effects (DARES)
- Health Technology Assessment Database
- NHS Economic Evaluation Database (NHSEED)
- Global Health
- Cochrane Methodology Register
- World Health Organisation Global Health Library (Global Index Medicus).

The search for health economic studies was supplemented with searches of the following website:

- National Coordinating Centre for Health Technology Assessment (NCCHTA).

To identify clinical audits, electronic searches were conducted in the following databases from inception to October 2017:

- MEDLINE
- CINAHL
- EMBASE
- MIDIRS
- HMIC
- Cochrane Library
- OpenGrey System for Information on Grey Literature in Europe
- World Health Organisation Global Health Library (Global Index Medicus).

* In the previous search the Health Economic Evaluation Database (HEED) was also included however it ceased publication at the end of 2014.

Other sources

A comprehensive search for grey literature supplemented the electronic database search in order to find relevant clinical evaluations, health economic studies, validation studies, clinical audits and guidelines. The grey literature search was guided by the handbook produced by the Canadian Agency for Drugs and Technology in Health (CADTH).[11]

Established grey literature databases, including OpenGrey System for Information on Grey Literature in Europe (http://www.opengrey.eu/) and the Open University dedicated grey literature site (http://library.open.ac.uk/resources/reports.html), were searched.

In addition, the following grey literature sources were searched:

- ERIC database
- GrayLit Network (via science.gov)
- Networked Digital Library of Theses.

The following websites were also searched for clinical guidelines on the use of early warning or track and trigger systems in pregnant women or women who gave birth in the previous 42 days:

- The American Congress of Obstetricians and Gynecologists
- Agency for Healthcare Research and Quality
- AETSA (Andalusian Agency for Health Technology Assessment)
- Association of Anaesthetists of Great Britain and Ireland
- Australian National Health and Medical Research Council Clinical Practice Guidelines
- Belgian Health Care Knowledge Centre
- Canadian Medical Association InfoBase of Clinical Practice Guidelines
- eGuidelines (UK)
- Danish Health Authority
- European Society of Intensive Care Medicine
- Finnish Medical Society Duodecim
- Geneva Foundation for Medical Education and Research
- Guidelines International Network
- German Institute of Medical Documentation and Information
- Haute Autorité de santé
- Institute for Healthcare Improvement
- Intensive Care Society
- Intensive Care Society – Ireland

- Intensive Care National Audit & Research Centre
- Japan Council for Quality Health Care
- Journal of Obstetrics and Gynaecology Canada
- Lenus (The Irish health repository)
- National Institute for Health and Clinical Excellence
- National Library for Health Guidelines Finder
- National Library for Health Protocols and Care Pathways database
- National Guideline Clearinghouse
- National Clinical Effectiveness Committee
- New Zealand Guidelines Group
- NHS Evidence database
- NHS Institute for Innovation and Improvement
- Obstetric Anaesthetists Association
- Royal College of Physicians
- Royal College of Surgeons
- Royal College of Anaesthetists
- Royal College of Midwives
- Royal College of Nursing
- Scottish Intensive Care Society
- Scottish Intercollegiate Guidelines Network
- Singapore Ministry of Health
- Socialstyrelsen (Health and Medical Care and Social Services, Sweden)
- Society of Critical Care Medicine
- TRIP Database
- World Health Organization.

Lastly, clinical trial registers were searched (World Health Organization Clinical Trials Search Portal: http://apps.who.int/trialsearch/, which allows for searching multiple databases simultaneously) for completed but unpublished and ongoing clinical trials. Manual searching of the reference list of any included study and forward citation searching for all included studies using Scopus were also carried out.

3.3 Data collection and analysis

3.3.1 Selection of studies

Citations were screened by one reviewer to eliminate clearly irrelevant studies. Two reviewers screened titles and abstracts of the remaining citations as per the inclusion criteria (summarised across Table 3.1 to Table 3.6). During the screening and selection

process, citations were tagged against the relevant objectives, for example as development/validation study, guidelines or health economic study.

3.3.2 Data extraction and management

Data extraction was performed independently by two reviewers using standardised data extraction forms, with any disagreements being resolved by discussion. Data was extracted by study category as described in Table 3.7. It was intended that clinical guidelines would be included; however, the only clinical guideline identified was the IMEWS guideline itself.

Table 3.7. Data extracted by study category

Study category	Data extracted
Effectiveness studies	▪ Study design, for example, RCTs, controlled clinical trial or interrupted time series ▪ Study setting ▪ Participant characteristics and numbers ▪ Intervention, that is, early warning, track and trigger system, escalation protocol or communication tool under evaluation ▪ Comparator, for example, no system or alternative system ▪ Outcomes measures ▪ Effect estimates (the number of specific outcome events divided by the total in intervention and comparator groups)
Development/ validation studies	▪ Study design, for example, prospective or retrospective ▪ Study setting ▪ Participant characteristics and numbers ▪ Outcomes measures ▪ Predictive ability (the data for each outcome measure was extracted and entered into 2 x 2 data extraction tables classified according to the results of the early warning system score and according to the presence or absence of an outcome measure, for example, sepsis, in each individual study)
Health economic studies	▪ Study design, for example, cost-utility analysis, cost-effectiveness analysis or costing study ▪ Study setting ▪ Participant characteristics and numbers ▪ Measures of 'cost' data, including capital and non-capital resources ▪ Outcome measures ▪ Analysis details, for example, model type, perspective, discount rate or time horizon
Clinical audits	▪ Study design and aim ▪ Study setting ▪ Participant characteristics and numbers ▪ Performance being measured ▪ Standard/early warning score ▪ Outcome measures ▪ Analysis details ▪ Results ▪ Key recommendations

Key: CCT —Controlled clinical trial; RCT — Randomised controlled trial; ITS — Interrupted time series.

3.3.3 Assessment of the quality of studies included in the review

Two reviewers independently assessed the quality or risk of bias of full-text articles included in the review using standardised critical appraisal instruments, with any disagreements resolved through discussion. Identified conference abstracts were not assessed as, in general, they lacked sufficient information to inform a judgement. As a result, all conference abstracts were categorised as having an unclear risk of bias.

Identified intervention studies were assessed using the risk of bias criteria from the Cochrane Effective Practice and Organisation of Care (EPOC) group.[12] For development and validation studies, the QUADAS-2 (Quality Assessment of Diagnostic Accuracy Studies) tool was used.[13] This tool assesses risk of bias across four domains (patient selection, index test, reference standard and flow of participants) and applicability across three domains (patient selection, index test and reference standard) guided by prompt questions. Audit-specific critical appraisal tools are limited. Recently, critical appraisal tools for quality improvement interventions have been developed, for example, the Minimum Quality Criteria Set or QI-MQCS[14]; however, these have not been widely used and encompass a wide variety of quality improvement initiatives. The Health Service Executive (HSE) Clinical Audit Checklist[15] was used to assess the quality of full-text clinical audits included in this study. This document describes a five step approach to clinical audit, including planning for audit, standard/criteria selection, measuring performance, making improvements and sustaining improvements. Full-text audits included in this study were assessed against these domains, excluding the planning for the audit steps as these steps were unlikely to be reported in the studies (see Appendix 2).

3.3.4 Assessment of the quality of the evidence using the GRADE approach

The GRADE approach was used to assess the quality of evidence relating to the following outcomes: maternal death, maternal morbidity, ICU admission and length of hospital stay.

GRADEpro software[16] was used to create summary of findings tables. A summary of the intervention effect and a measure of quality for each of the above outcomes was produced.

The GRADE approach uses five considerations (study limitations, consistency of effect, imprecision, indirectness and publication bias) to assess the quality of the body of evidence for each outcome. The evidence can be downgraded by one level for serious limitations (or by two levels for very serious limitations) depending on assessments for risk of bias, indirectness of evidence, serious inconsistency, imprecision of effect estimates or potential publication bias. The summary of findings table in this current report is based on the totality of evidence underlining the IMEWS guideline and as such includes the full-text studies identified in the previous review to support the development of the IMEWS guideline in April 2014.[8]

3.3.5 Data synthesis

Data analysis and synthesis of included studies was conducted by study category as described below.

3.3.5.1 Guidelines

It was intended that a description and comparative summary of individual guidelines would be included in this review; however, as the only guideline identified was the IMEWS guideline itself, no data extraction or analysis was performed.

3.3.5.2 Effectiveness studies

As only one effectiveness study was identified, a meta-analysis could not be conducted. A narrative summary is, therefore, presented.

3.3.5.3 Development and validation studies

The individual papers included did not report sufficient information to allow for calculation of pooled sensitivity or specificity of the identified early warning systems. Therefore, the reported predictive ability of the early warning system or track and trigger system of an event occurring (for example, sepsis or maternal death) is reported and summarised narratively using:

- sensitivity (ability of a test to correctly classify an individual as diseased)
- specificity (ability of a test to correctly classify an individual as disease-free)
- positive predictive value (PPV) (percentage of patients with a positive test who actually have the disease)
- negative predictive value (NPV) (percentage of patients with a negative test who do not have the disease).

3.3.5.4 Health economic studies

A narrative synthesis of the results from identified health economic studies was provided.

3.3.5.5 Clinical audits of early warning systems

A narrative synthesis of the results from the identified clinical audits was provided. Studies were grouped by the following patient populations:

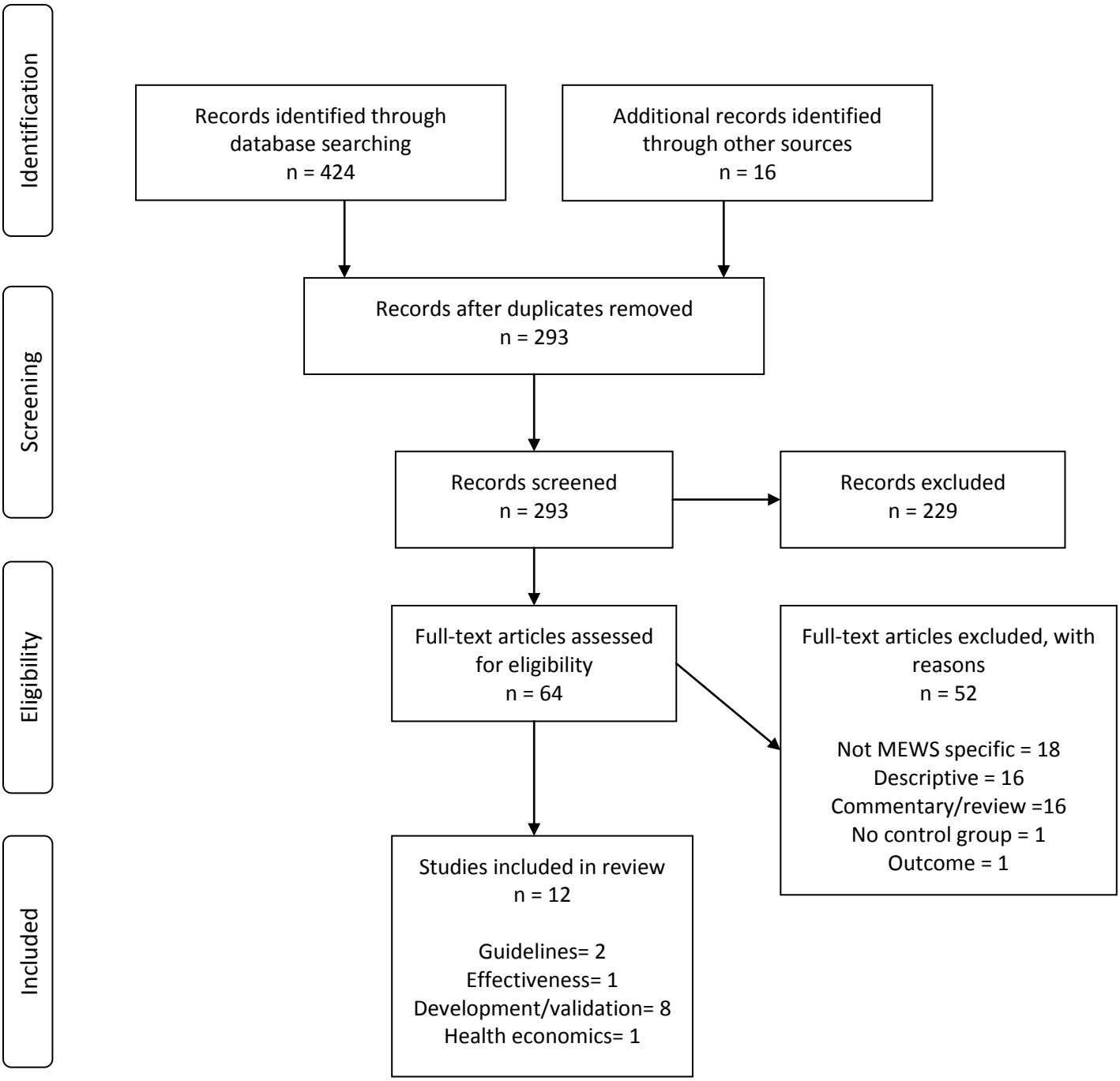
- obstetric patients
- paediatric patients
- emergency department
- general patient populations
- mixed patient populations.

4 Results

4.1 Search results for the update

The search strategy for objectives 1 to 5 (Appendix 1) identified 440 potentially relevant references through searching listed databases and grey literature. After the exclusion of duplicates, 293 records were screened, with a further 229 references excluded based on a review of the titles and abstracts. A total of 64 full-text articles were then assessed for eligibility. Of these, 52 references were excluded according to the inclusion and exclusion criteria. The reasons for exclusion were that the articles were not about MEWS (18), that they were commentary/review papers (16), that they were descriptive studies (16), that there was no control group for effectiveness studies (1), and the outcome was not relevant to this review (1). Further details on excluded studies are summarised in Appendix 3. This resulted in 12 studies being included in the review update. Figure 4.1 shows the objectives 1 to 5 study flowchart, which follows PRISMA guidelines.

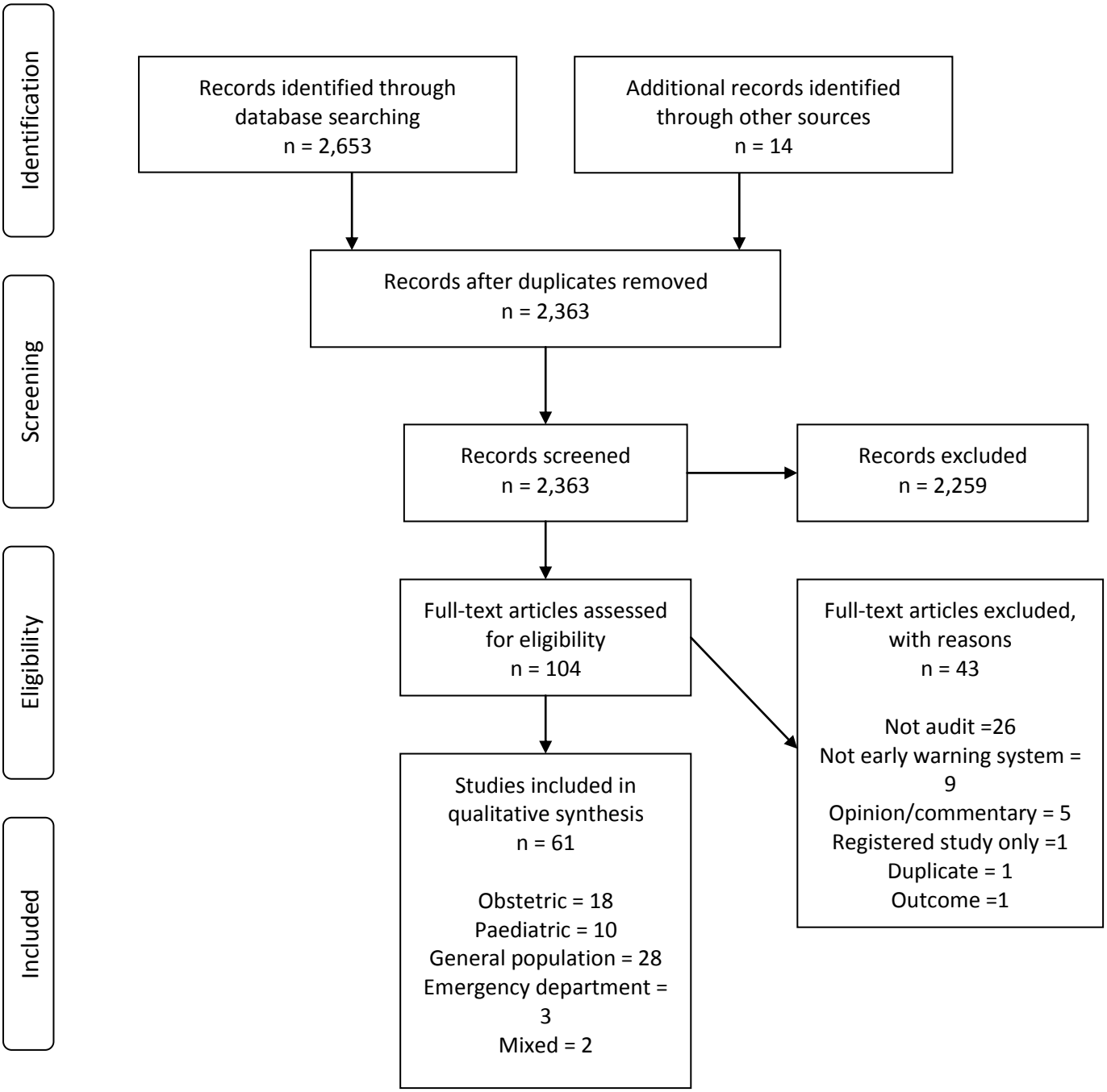
Figure 4.1. PRISMA flow diagram for objectives 1 to 5



4.2 Search results for clinical audits

The search strategy for objective 6 (Appendix 1) identified 2,667 potentially relevant references through searching listed databases and grey literature. After the exclusion of duplicates, 2,363 records were screened. A further 2,259 references were excluded based on a review of titles and abstracts. A total of 104 full-text articles were then assessed for eligibility. Of these, 43 references were excluded according to the inclusion and exclusion criteria. The reasons for exclusion were that they were not an audit (26), that they were not related to early warning systems (9), that they were opinion/commentary (5), that it was a registered study only (1), that it was a duplicate (1), and that the outcome was not relevant (1). Further details on excluded studies are summarised in Appendix 3. This resulted in 61 studies being included in the narrative summary. Figure 4.2 shows the objective 6 study flowchart, which follows the PRISMA guidelines.

Figure 4.2. PRISMA flow diagram for objective 6



4.3 Included studies

Of the 73 studies included in the review, one was categorised as an effectiveness study; eight were development and or validation studies; one was a health economics study; and 61 were clinical audits. Two references to the current IMEWS guideline were also identified and were not included in the results section.[8, 17]

4.4 Findings by study category

4.4.1 Effectiveness studies

One study provided effectiveness data, and the characteristics of the study are shown in Table 4.1. The study was a controlled before and after study conducted in 29 maternity centres in the US in patients admitted to intensive care units (ICU) (high risk population).[18] Maternal morbidity outcomes were compared before and after the introduction of a clinical pathway-specific maternal early warning trigger (MEWT) tool in six intervention hospitals. Outcomes from the six intervention hospitals were also compared to outcomes in 23 control hospitals in the after phase. The tool addressed four areas of maternal morbidity: sepsis, cardiopulmonary dysfunction, preeclampsia-hypertension and haemorrhage. To activate a response, triggers needed to be sustained for more than 20 minutes and were defined as severe or nonsevere. For triggers to be defined as severe they required a single abnormal value of, specifically, maternal heart rate (HR) >130 beats/min (bpm), respiratory rate (RR) >30/min, mean arterial pressure <55 mmHg, oxygen saturation <90%, or nurse concern. A nonsevere trigger required two of the following abnormal values: temperature >38 or <36°C, blood pressure (BP) >160/110 or <85/45 mmHg, HR >110 or <50 bpm, RR >24 or <10/min, oxygen saturation <93%, fetal HR >160 bpm, altered mental status, or disproportionate pain. Recommended management or assessment was also provided for both severe and nonsevere triggers.

The reported results indicate that severe maternal morbidity (using the Centers for Disease Control and Prevention (CDC) definition) was significantly reduced (-18.4%, P=0.01) when comparing before and after implementation rates. A comparison of the six intervention

hospitals to the 23 control hospitals (after implementation only) also found that the control hospitals had a significantly lower maternal morbidity rate ($P< 0.01$).

Table 4.1. Characteristics of included effectiveness studies

Authors Year Country	Study setting and population	Aim of study	Study design	Participants	Intervention	Control	Outcome measures	Results
Shields (2016)[18] US	Setting 29 maternity centres Before data: Jan 2012 - Dec 2013 After data: Oct 2014 - Oct 2015 Population High risk: Maternity patients admitted to ICU	To prospectively evaluate the use of a pathway specific MEWT tool and determine if its use was associated with a reduction in maternal morbidity	Controlled before-and-after study	*Intervention:* 6 hospitals, 24,221 deliveries before, 12,611 after *Control:* 23 hospitals, 95,718 deliveries before, 50,641 after	Pathway-specific MEWT to address sepsis, cardiovascular dysfunction, severe preeclampsia-hypertension, and severe haemorrhage Positive triggers: Sustained for >20 minutes and were defined as 1. Severe (single abnormal value): maternal HR >130 bpm, RR >30/min, mean arterial pressure <55 mmHg, oxygen saturation <90%, or nurse concern; 2. Nonsevere (required 2 abnormal values):	Care as usual	*Primary:* * Severe maternal morbidity (Centers for Disease Control and Prevention (CDC) defined) * Composite maternal morbidity (CDC criteria plus hemorrhage, dilation & curettage, or ICU admission) *Secondary:* i) Screening rate	*Primary:* * CDC-defined severe maternal morbidity: 1. Before MEWT compared to after MEWT — significant reduction (-18.4%, P =0.01) 2. Before control compared to after control — no change 3. 6 MEWT intervention sites compared to 23 control sites (after only) – significant reduction (P < .01) * Composite maternal morbidity 1. Before MEWT compared to after MEWT — significant reduction (-13.6%, P =0.01) 2. Before control compared to after control — no change 3. 6 MEWT intervention sites compared to 23 control (after only) – significant reduction (P < 0.01) *Secondary:* i) Screening rate: 93.4%

					temperature >38 or <36^{0}C, BP >160/110 or <85/45 mmHg, HR >110 or <50 bpm, RR >24 or <10/min, oxygen saturation <93%, fetal HR >160 bpm, altered mental status, or disproportionate pain		ii) Screen positive alert rate iii) Following of clinical pathway iv) Provider response timeline v) Rates of maternal sepsis, eclampsia, hemorrhage, hysterectomy, dilation & curettage	ii) Screen positive alert rate: 2.3% iii) Following of clinical pathway: 83.1% iv) Physician intervention time: <30 mins 71.9% and <60 min 83.1% v) Rates of: Maternal sepsis: 38% Cardiopulmonary dysfunction: 6% Hypertension: 15% Hemorrhage: 31% Other: 6%

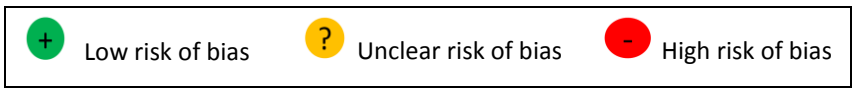
Key: BP — blood pressure; bpm — beats/min; CDC — Centers for Disease Control and Prevention; HR — heart rate; ICU — intensive care unit; MEWTs — maternal early warning triggers; RR — respiratory rate.

4.4.1.1 Methodological quality

The methodological quality of this effectiveness study is presented in Figure 4.3. The study has a high risk of selection bias due to its study design (non-randomised controlled before and after study). Participants and personnel were not blinded in this study, resulting in a high risk of performance bias. In relation to how missing study data were handled, the risk of bias was unclear because adequate information was not reported.

Figure 4.3. Quality appraisal of included effectiveness studies

Domain	Shields (2016)
Was the allocation sequence adequately generated?	-
Was the allocation adequately concealed?	-
Were baseline outcome measurements similar?	+
Were baseline characteristics similar?	?
Were incomplete outcome data adequately addressed?	?
Was knowledge of the allocated interventions adequately prevented during the study?	-
Was the study adequately protected against contamination?	+
Was the study free from selective outcome reporting?	+
Was the study free from other risks of bias?	?



4.4.1.2 Quality of the evidence: GRADE

The evidence was downgraded to very low-quality for the study outcome (maternal morbidity) due to study limitations (allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data and other biases) and limited data (one small study, few events for the outcomes and no confidence intervals). The previous review conducted to support the development of the IMEWS guideline identified one effectiveness study; however, as it was a conference abstract, it was not appraised or included in the summary of findings table.

4.4.2 Development and validation studies

We identified eight development and validation studies that evaluated the predictive ability of MEWS for a range of outcomes. As summarised in Table 4.2, six of these were available in full-text format[19-24] and one was in abstract form.[25] The final one was a study protocol for an on-going prospective cohort study in the UK,[26] and this publication is summarised in Table 4.3 and Section 4.4.2.5.

Three studies were conducted in the US,[19, 20, 24] and one each was carried out in the UK,[25] Canada,[22] Columbia,[21] and India.[23] Three of the studies were retrospective cohort designs,[19, 21, 24] two were retrospective case-control designs,[20, 22] one was a retrospective case note review,[25] and one was a prospective cohort design.[23] The majority of studies included high-risk populations, including two studies on women admitted to ICU,[21, 22] one study in women started on a sepsis-6 bundle (local care bundle for assessment and treatment of parturients[†] suspected of sepsis),[25] one study in women with chorioamnionitis,[19] one study in women with acute pyelonephritis,[24] and one study in women with symptoms requiring evaluation in obstetric triage.[20] Only one study included all pregnant women regardless of co-morbidities.[23]

[†] Women who are in labour, about to give birth or have recently given birth.

The predictive ability of MEWS was examined for a variety of outcome measures, including maternal morbidity,[19, 20, 23-25] maternal death,[21] ICU admission,[22] and length of stay.[24] Six studies specified the parameters included in the MEWS.[19-24] Two studies specified using the Confidential Enquiries into Maternal and Child Health Modified Early Obstetric Warning System (CEMACH MEOWS),[22, 23] while one study specified using the Intensive Care National Audit and Research Centre Obstetric Early Warning Score (ICNARC-OEWS).[21] Edwards et al. compared the predictive ability of six published modified obstetric early warning scoring systems (MOEWS).[19] RR, BP were common to all scoring systems, while five of the six systems included oxygen saturation[19, 20, 22-24] and temperature. [19-22, 24]

4.4.2.1 Morbidity

Three studies looked at maternal morbidity in general,[20, 23, 24] while two studies focused specifically on sepsis.[19, 25]

Using a retrospective case-control design, Hedriana et al. investigated maternal early warning triggers (MEWTs) to predict an escalating state of morbidity.[20] Cases were those admitted to ICU (*n*=50) and controls were patients admitted to maternity units with normal delivery (*n*=50). The authors assessed six MEWTS (HR>110 bpm or <50 bpm; mean arterial pressure <65 mmHg; altered mental state; temperature ≥38°C or ≤36°C; RR including >24 or <10 breaths per minute; peripheral capillary oxygen saturation (SpO2) <94%). Results indicated that the presence of two or more persistent triggers (defined as lasting 30 minutes or more) gave a sensitivity of 72% (95% CI 57–83), a specificity of 96% (95% CI 85–99), a positive predictive value (PPV) of 95% (95% CI 81–99) and a negative predictive value (NPV) of 77% (95% CI 65–87).

Singh et al., in the only prospective study included, evaluated the predictive ability of a maternal early obstetric warning system (MEOWS) for predicting obstetric morbidity in women admitted in labour beyond 28 weeks' gestation and up to 6 weeks postpartum (*n*=1,065).[23] The MEOWS contained the following parameters: RR, oxygen saturation, HR,

systolic BP, diastolic BP, lochia, proteinuria, colour of liquor, neurological response and general condition. The ability of MEOWS in predicting obstetric morbidity was 86.4% sensitivity, 85.2% specificity, a PPV of 53.9% and a NPV of 96.9%.

Valent et al. evaluated in a retrospective cohort, the ability of the MOEWS in pregnant women with pyelonephritis, to predict maternal morbidity.[24] MOEWS parameters included systolic BP, diastolic BP, RR, HR, oxygen saturation, temperature and level of consciousness. The MOEWS, which had a cut-off[‡] of 7, had 50% sensitivity and 79% specificity for the prediction of progressive maternal morbidity.

Edwards et al. compared the predictive ability of six published modified obstetric early warning scoring systems (MOEWS) for the development of severe sepsis in a retrospective cohort of women with chorioamnionitis (*n*=364).[19] There was wide variation in the design and pathophysiological thresholds used in the six included MOEWS, and the majority had not been validated. The reported sensitivities of the MOEWS in predicting severe sepsis ranged from 40% to 100% and the specificities ranged from 4% to 97%. The authors concluded that the MOEWS generally performed poorly in predicting severe sepsis in obstetric patients — in general, severe sepsis was over detected.

In an abstract of a retrospective case note review, Seeley et al. compared an undefined MOEWS with a new Sepsis Assessment Tool (SAST) score to predict which patients who are suspected to have sepsis go on to develop sepsis.[25] Included patients were in labour or committed to delivery and had been started on the sepsis-6 bundle (*n*=46). The SAST score includes all the physiological variables of the MOEWS score as well as white cell count, C-reactive protein, lactate and evidence of source of infection. Neither SAST nor MOEWS showed a statistically significant association in predicting sepsis.

[‡] Value above or below which the test is positive

4.4.2.2 Maternal death

In a retrospective cohort study, Paternina-Caicedo et al. validated the performance of the ICNARC-OEWS in predicting death among pregnant women who required admission to ICU (*n*=702).[21] The ICNARC-OEWS contains seven parameters (systolic BP, diastolic BP, RR, HR, fraction of inspired oxygen (FiO2), temperature and level of consciousness). The area under the ROC curve (AUROC) was 0.84 (95% CI 0.75–0.92) indicating that ICNARC-OEWS would be considered good at predicting mortality.

4.4.2.3 ICU admission

Using a retrospective case-control design, Ryan et al. validated the performance of the CEMACH MEOWS to predict maternal ICU admission.[22] In this study, cases were those admitted to ICU (*n*=46) and controls were patients who did not receive critical care (*n*=138). The parameters listed by the authors were RR, temperature, HR, systolic BP, diastolic BP, oxygen saturation, pain score, neurologic response, looks unwell, amniotic fluid, lochia, passed urine (yes/no) and dipstick proteinuria. The CEMACH MEOWS components of either ≥1 red or ≥2 amber scores had a sensitivity of 0.96 (95% CI 0.84–0.99) and a specificity of 0.54 (95% CI 0.46–0.6) for identifying women at risk of ICU admission for 24 hours or longer. When considered separately, ≥1 red trigger had a sensitivity of 0.91 (95% CI 0.78-0.97) and specificity 0.72 (95% CI 0.63-0.79); and ≥2 red triggers lowered sensitivity (0.65, 95% CI 0.50–0.78) and increased specificity (0.89, 95% CI 0.82–0.94). As a secondary analysis, the authors explored modifications to the CEMACH MEOWS and developed a four variable model, where the variables were temperature, HR, systolic blood pressure and RR. The AUROC for the four-variable model was 0.91 (95% CI 0.83–0.95), with activation of ≥1 red or ≥2 amber triggers providing sensitivity of 0.87 (95% CI 0.73–0.95) and specificity of 0.84 (95% CI 0.77–0.90). Sensitivity with ≥1 red trigger was 0.78 (95% CI 0.63–0.89) and specificity was 0.88 (95% CI 0.82–0.93).

4.4.2.4 Length of stay

Valent et al. evaluated in a retrospective cohort the ability of the MOEWS to predict prolonged hospitalisation (>4 days) in pregnant women with pyelonephritis.[24] MOEWS parameters were systolic BP, diastolic BP, RR, HR, oxygen saturation, temperature and level of consciousness. The MOEWS had a modest ability to discriminate prolonged hospitalisation, with an AUROC of 0.67 (95% CI 0.54–0.80).

4.4.2.5 On-going studies

One on-going study was identified in the search and summarised in Table 4.3. The prospective cohort study aims to recruit 1,000 women aged 16 or above in the UK with a singleton pregnancy of less than 20 weeks' gestation. The data collected will be used to define reference ranges of vital signs across normal pregnancy, labour and the immediate postnatal period to inform the design of a centile-based early warning scoring system for pregnancy, labour and the postpartum period.[26]

Table 4.2. Characteristics of included development and validation studies

Authors Year Country	Study setting and population	Aim of study	Study design	Participants	Tool evaluated	Outcomes	Results
Maternal morbidity							
Edwards (2015)[19] US	Setting Single maternity hospital (June 2006 — November 2007) Population High risk: Women with chorioamnionitis	To compare the predictive power of 6 modified obstetric early warning scoring systems (MOEWS) for the development of severe sepsis in women with chorioamnionitis	Retrospective cohort	Confirmed cases of chorioamnionitis (n=913) Mean age: 29.7 (±5.8) Complete vital sign data were available for 364 patients	**Colour coded trigger systems (red/amber alert):** 1. MOEWS A (Trigger Score ≥2 Ambers or ≥1 Red) 2. MOEWS B (Trigger Score ≥2 Ambers or ≥1 Red) 3. MOEWS C (Trigger Score ≥2 Ambers or ≥1 Red) All have 7 parameters with varying physiological thresholds: - pulse rate - systolic BP - diastolic BP - RR - temperature - O_2 saturation - mental state. **Aggregate score MOEWS:** 4. MOEWS D 6 parameters: - pulse rate - systolic BP	Severe sepsis Definition: American College Chest Physicians/Society of Critical Care Medicine 2001 consensus	**MOEWS A % (95% CI)** Sensitivity: 100 (47.8–100) Specificity: 29 (24.3–34) PPV: 1.92 (0.63–4.43) NPV: 100 (96.5–100) AUROC: 0.65 (0.62–0.67) **MOEWS B % (95% CI)** Sensitivity: 100 (47.8–100) Specificity: 3.9 (2.15–6.46) PPV: 1.43 (0.47–3.3) NPV: 100 (76.8–100) AUROC: 0.52 (0.51–0.53) **MOEWS C % (95% CI)** Sensitivity: 100 (47.8–100) Specificity: 3.6 (1.94–6.11) PPV: 1.42 (0.46–3.29) NPV: 100 (75.3–100) AUROC: 0.52 (0.51–0.53) **MOEWS D % (95% CI)** Sensitivity: 60 (14.7–94.7) Specificity: 84.4 (80.2–88) PPV: 5.08 (1.06–14.1) NPV: 99.3 (97.7–99.9) AUROC: 0.72 (0.48–0.96) **MOEWS E % (95% CI)**

Authors Year Country	Study setting and population	Aim of study	Study design	Participants	Tool evaluated	Outcomes	Results
					- RR - temperature - O_2 saturation - mental state. Medium risk: Score 4–5 High risk: Score ≥6 5. MOEWS E Medium risk: Score 4–5 High risk: Score ≥6 6. MOEWS F Medium risk: Score ≥4 or single parameter = 3 High risk: Score ≥6 E and F, 7 parameters with varying physiological thresholds: - pulse rate - systolic BP - diastolic BP - RR - temperature - O_2 saturation - mental state.		Sensitivity: 40 (5.27–85.3) Specificity: 96.9 (94.6–98.5) PPV: 15.4 (1.92–45.4) NPV: 99.1 (97.5–99.8) AUROC: 0.68 (0.44–0.92) **MOEWS F % (95% CI)** Sensitivity: 40 (5.27–85.3) Specificity: 90.8 (87.3–93.6) PPV: 5.71 (0.70–19.2) NPV: 99.1 (97.4–99.8) AUROC: 0.65 (0.41–0.89)
Hedriana (2016)[20] US	Setting 7 hospitals (July 2012 – May 2013)	To investigate whether predetermined maternal early warning triggers (MEWTs) can be	Retrospective case–control	50 Cases 50 Controls Mean age: Cases 29.1 (±6.17)	**Model development:** 6 parameters - HR including tachycardia (>110 BPM) or bradycardia (<50 BPM)	Morbidity (not defined)	**≥2 MEWTs % (95% CI)** Sensitivity: 72 (57–83) Specificity: 80 (66–90) PPV: 78 (63–89) NPV: 74 (60–85)

Authors Year Country	Study setting and population	Aim of study	Study design	Participants	Tool evaluated	Outcomes	Results
	Population High risk **Cases***:* term or preterm patients with vaginal bleeding, hypertension, abdominal pain, labor, ruptured membranes, fever, gastrointestinal symptoms, and other symptoms requiring evaluation in obstetric triage **Controls:** patients admitted to the maternity units after triage with normal delivery outcome	used to predict an escalating state of morbidity		Controls 29.7 (±7.35)	- mean arterial pressure >65 mmHg - RR including tachypnea (>24 breaths per minute) or bradypnea (<10 breaths per minute) - low oxygen saturation (SpO2 <94%) - abnormal temperature (oral or aural), including high (≥38°C) or low(<36°C) - altered mental state, defined as confusion, agitation, persistent intensifying pain, and or non-responsiveness. **Final scoring system** The frequency and intervals of observation of MEWTs in the cases and controls were compared and ORs and 95% CIs were generated. Presence of 2 or more persistent MEWTS (≥30 minutes) was chosen.		**≥2 persistent MEWTs % (95% CI)** Sensitivity: 72 (57–83) Specificity: 96 (85–99) PPV: 95 (81–99) NPV: 77 (65–87)

Authors Year Country	Study setting and population	Aim of study	Study design	Participants	Tool evaluated	Outcomes	Results
Seeley (2017)[25] UK	Setting Unspecified Population High risk: Consecutive patients in labour or committed to delivery and had been started on sepsis-6	To compare MOEWS with a newly proposed SAST score in the prediction of sepsis	Retrospective case note review 6 months	46 patients	**MOEWS score** Not defined **SAST score** MOEWS physiological variables plus - white cell count - C-reactive protein - lactate - evidence of source of infection.	Sepsis 24h following delivery	28 (61%) sepsis 18 (39%) no sepsis Neither SAST nor MOEWS showed a statistically significant association in predicting sepsis. **MOEWS** OR 1.09 (95% CI 0.62, 1.94, P=0.76) **SAST** OR 1.29 (95% CI 0.95, 1.76, P=0.08)
Singh (2016)[23] India	Setting 1 hospital (Oct 2012 – Apr 2014) Population Pregnant women in labour beyond 28 weeks gestation and up to 6 weeks postpartum	To evaluate MEOWS chart as a bedside screening tool in prediction of maternal morbidity	Prospective cohort	1,065 Age: approximately 90% aged 20–30 years Lower or middle socio-economic status	**CEMACH MEOWS** Parameters: - RR - oxygen saturation - HR - systolic BP - diastolic BP - lochia - proteinuria - colour of liquor - neurological response - general condition. Trigger: a single markedly abnormal observation (red) or combination of 2 simultaneously mildly abnormal observations (2 yellow).	Obstetric morbidity: - hypertensive disorder of pregnancy - eclampsia - obstetric haemorrhage - suspected infection - pulmonary oedema - shock - gestational diabetes - diabetic ketoacidosis - intracranial bleed - acute asthma - status epilepticus.	173 had obstetric morbidity **MEOWS for prediction of obstetric morbidity** Sensitivity: 86.4% Specificity: 85.2% PPV: 53.9% NPV: 96.9%

Authors Year Country	Study setting and population	Aim of study	Study design	Participants	Tool evaluated	Outcomes	Results
Maternal death							
Paternina-Caicedo (2017)[21] Columbia	Setting 1 hospital (Jan 2006 – Dec 2011) Population High risk: Pregnant and postpartum (up to 42 days) women who required admission to ICU	To validate the performance of the ICNARC-OEWS for the prediction of maternal death in peripartum women admitted to a critical care unit in a developing country	Retrospective cohort	724 patients admitted to ICU Complete data on 702	**ICNARC-OEWS:** 7 parameters: - systolic BP - diastolic BP - RR - HR - fraction of inspired oxygen (FiO2) - temperature - level of consciousness **Score** 0: routine care 1–3: low-grade response 4–5 in the aggregate score or 3 in 1 abnormal vital: medium response ≥6: high response	Maternal death defined as death during pregnancy or within 42 days postpartum	29 deaths Case fatality rate: 4.1% The AUROC of the ability of OEWS to discriminate mortality: 0.84 (95% CI 0.75–0.92)
ICU Admission							
Ryan (2017)[22] Canada	Setting 2 tertiary obstetric units (Jan 2000 – Dec 2011) Population High risk: **Cases***:* pregnant or recently	To externally validate the CEMACH MEOWS Secondary: to explore modifications to the CEMACH MEOWS model	Retrospective case-control	46 Cases 138 Controls	**CEMACH MEOWS** Parameters - RR - temperature - HR - systolic BP - diastolic BP - oxygen saturation - pain score - neurologic response	Maternal ICU admission >24 hours	**CEMACH MEOWS** ≥ 1 Red/≥ 2 amber (95% CI) Sensitivity: 0.96 (0.84–0.99) Specificity: 0.54 (0.46–0.6) PPV: 0.41 (0.32–0.51) NPV: 0.97 (0.90–0.995) ≥1 red trigger (95% CI) Sensitivity: 0.91 (0.78–0.97) Specificity: 0.72 (0.63–0.79)

Authors Year Country	Study setting and population	Aim of study	Study design	Participants	Tool evaluated	Outcomes	Results
	pregnant (<6 weeks postpartum, irrespective of gestational age at the end of the pregnancy) admitted women who subsequently required admission to the ICU for >24 hours **Controls:** first 3 women identified from hospital databases who were either pregnant or recently pregnant and admitted to the hospital for >24 hours during study period who did not receive critical care				- looks unwell - amniotic fluid - lochia - passed urine - dipstick proteinuria. **New four variable model** Stepwise logistic regression of significant variables identified 4 parameters: - maximum temperature - HR - systolic BP - RR		PPV: 0.52 (0.41–0.63) NPV: 0.96 (0.90–0.99) ≥2 red triggers (95% CI) Sensitivity: 0.65 (0.50–0.78) Specificity: 0.89 (0.82–0.94) PPV: 0.67 (0.51–0.80) NPV: 0.89 (0.82–0.93) **New four variable model** AUROC 0.91 (95% CI 0.83–0.95) ≥ 1 Red/≥ 2 amber (95% CI) Sensitivity: 0.87 (0.73–0.95) Specificity: 0.84 (0.77–0.90) PPV: 0.65 (0.51–0.76) NPV: 0.95 (0.89–0.98) ≥1 red trigger (95% CI) Sensitivity: 0.78 (0.63–0.89) Specificity: 0.88 (0.82–0.93) PPV: 0.69 (0.55–0.81) NPV: 0.92 (0.86–0.96)
Length of stay							
Valent (2017)[24] US	<u>Setting</u> 5 teaching hospitals <u>Population</u>	Usefulness of MOEWS to differentiate women with pyelonephritis	Retrospective cohort	123 with a diagnosis of acute pyelonephritis	**MOEWS** Parameters: - systolic BP - diastolic BP - RR	Prolonged hospitalization (>4 days) Composite	25 had prolonged hospitalization <u>MOEWS for prediction of Prolonged Hospitalization</u>

Authors Year Country	Study setting and population	Aim of study	Study design	Participants	Tool evaluated	Outcomes	Results
	Women with a diagnosis of acute pyelonephritis (Jan 2012 – Dec 2013)	who develop maternal morbidity and require prolonged hospitalisation			- HR - oxygen saturation - temperature - level of consciousness.	maternal morbidity: one of the following: - pulmonary injury - ICU admission - blood transfusion - sepsis.	Sensitivity: 48% Specificity: 84% AUROC 0.67 (95% CI: 0.54–0.80) <u>MOEWS for prediction of progressive maternal morbidity</u> <u>(cut-off 7)</u> Sensitivity: 50% Specificity: 79% AUROC 0.71 (95% CI: 0.56–0.85)

Key: AUROC — area under the receiver operating characteristic; BP — blood pressure; bpm — beats per min; CEMACH MEOWS — Child Health Modified Early Obstetric Warning System; CI — confidence interval; HR — heart rate; ICNARC-OEWS — Intensive Care National Audit and Research Centre Obstetric Early Warning Score; ICU — intensive care unit; MEOWS — maternal early obstetric warning system; MOEWS — modified obstetric early warning scoring systems; OR — odds ratio; NPV — negative predictive value; PPV — positive predictive value; and SAST — Sepsis Assessment Tool.

Table 4.3. Characteristics of on-going studies

Authors Year Country	Study setting and population	Aim of study	Study design	Participants	Tool evaluated	Outcomes	Results
Kumar (2017)[26] UK	Setting 3 university teaching hospitals (August 2012 – estimated date of completion September 2017)	To develop a database of vital sign measurements from pregnancy, labour and the postpartum period to inform the development of a centile-based obstetric early warning score system for pregnancy, labour and the postpartum period	Prospective cohort	Aim to recruit 1,000 women	Obstetric early warning score No data available yet	No data available yet	No data available yet

4.4.2.6 Methodological quality

The overall methodological quality of the six eligible studies is shown in Figure 4.4. One study was a conference abstract (Seeley et al.) and was excluded from this assessment, [25] as was the one identified on-going study.[26] The overall quality of the studies included was moderate. In the area of patient selection, four studies[19, 21, 23, 24] (66.6%) were judged as having a low risk of bias and two were judged to have a high risk of bias due to the case-control design.[20, 22] Two studies[20, 22] were deemed as having a high risk of bias in the conduct of the index test, while four[19, 21, 23, 24] studies had an unclear risk as they failed to record whether the index test was interpreted with or with knowledge of the reference standard. Three studies[19, 21, 22] had a high risk of bias and two studies[20, 23] had an unclear risk in patient timing and flow due to inadequately describing loss to follow-up in the cohort or methods used to account for missing data.

In relation to concerns about applicability of each individual study to the current systematic review questions, three were rated as high risk due to study populations.[20-22] A low level of risk was noted in five[19, 21-24] studies in relation to the applicability of the index test and reference test.

4.4.2.7 Quality of the evidence: GRADE

The evidence was downgraded to very low-quality for all study outcomes for the following reasons:

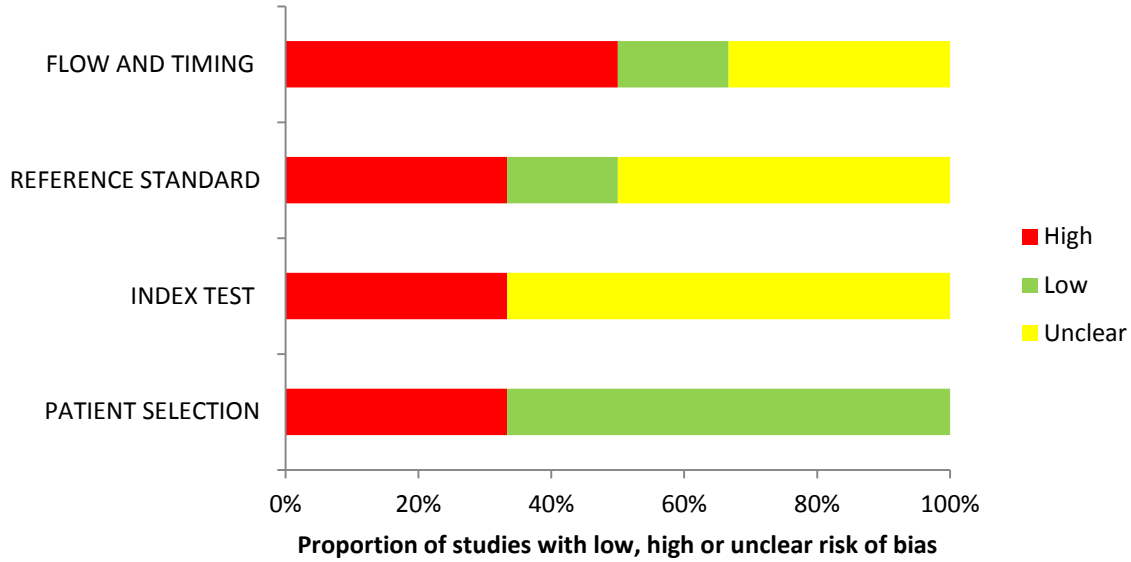
- maternal morbidity
    - study limitations (high or unclear risk of bias in application of reference and index tests, flow and timing), applicability (high risk population) and data limitations (wide range of sensitivity and specificity values)
- maternal death
    - study limitations (high or unclear risk of bias in application of reference and index tests, flow and timing), applicability (high risk population) and data limitations (one small study, wide range of sensitivity and specificity values)
- ICU admission
    - study limitations (high or unclear risk of bias in application of reference and

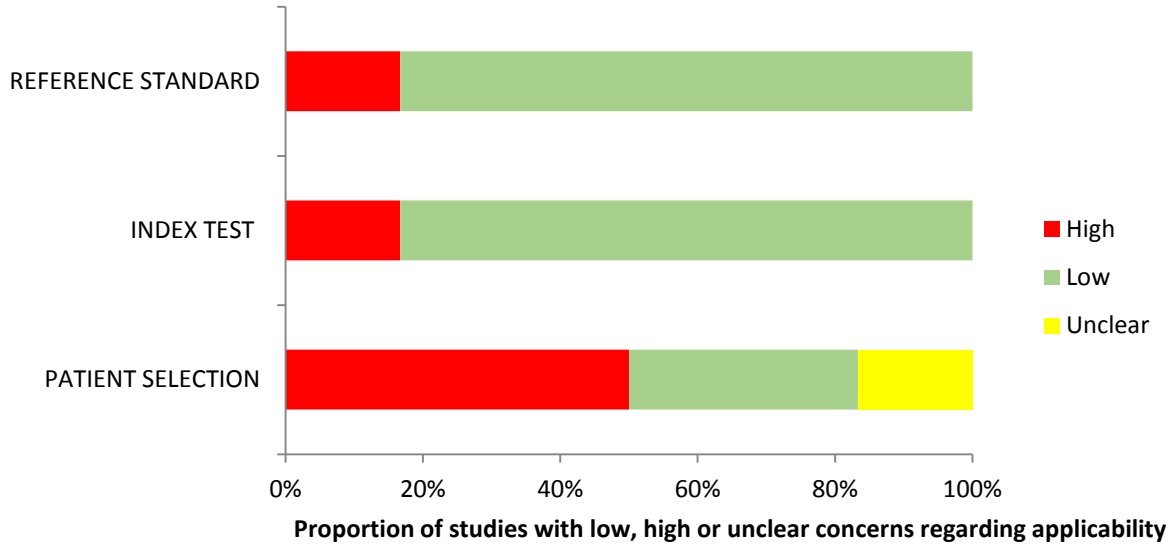
index tests, flow and timing), applicability (high risk population) and data limitations (one small study, wide range of sensitivity and specificity values)

- length of stay
    - study limitations (high or unclear risk of bias in application of reference), and data limitations (one small study).

The summary of findings tables is based on the totality of evidence underlining the guideline and as such includes the full-text studies identified in the previous review to support the development of the IMEWS guideline conducted in April 2014.

Figure 4.4. Quality appraisal of included development and validation studies





4.4.3 Health economic studies

One included study provided cost-effectiveness data.[27] This study was available in abstract form only and is described in more detail in Table 4.4. The authors confirmed that this study was based on data from the clinical effectiveness study described in Section 4.4.1. The study assessed the cost-effectiveness of the MEWT in the reduction of severe maternal morbidity and maternal mortality during delivery hospitalizations using a decision-analytic model. In a theoretical cohort of 4 million women, the MEWT tool led to a 14.6% reduction in maternal mortality, a 20% reduction in overall rates of severe maternal morbidity, a 33% reduction in hysterectomy and an 80% reduction in eclampsia. Improvement in these outcomes translated to an additional 40,000 maternal quality-adjusted life years (QALYs) and cost savings of nearly US$330 million for the cohort of 4 million women.

As this study was available in abstract form only, its quality cannot be assessed.

Table 4.4. Characteristics of included health economic studies

Authors Year Country	Study setting and population	Study design	Participants	Analysis details	Measures of cost data	Intervention and comparators	Clinical and QALY outcome measures	Results
Hess (2017)[27] US	**Risk category:** Maternal death and severe maternal morbidity - acute renal failure, cardiac arrest or ventricular fibrillation, heart failure during procedure or surgery, adult respiratory distress syndrome, eclampsia, and hysterectomy	Cost-utility analysis	Theoretical cohort of 4 million women	**Model type** A decision-analytic model **Perspective:** Unspecified **Discount rate:** Unspecified **Time horizon:** Unspecified	Costs during delivery Hospitalizations before and after implementation of MEWT tool — cost breakdown unavailable MEWT tool cost was $20 per person based on 2016 pricing	Before and after implementation of MEWT	MEWT tool led to: - 14.6% reduction in maternal mortality - 20% reduction in overall rates of severe maternal morbidity - 33% reduction in hysterectomy - 80% reduction in eclampsia.	Improvement in these outcomes translated to an additional 40,000 maternal QALYs and cost savings of nearly $330 million Sensitivity analysis revealed that the MEWT tool was a dominant strategy (lower costs, better outcomes) up to $111 per person and cost-effective up to $1,217 per person

Key: CUA — cost utility analysis; MEWTs — maternal early warning triggers; and QALY — quality-adjusted life year.

4.4.4 Clinical audits of early warning systems

A total of 61 clinical audit studies were identified, 31 of which were available in full-text format and 30 in abstract form only. Of these, 18 studies were specifically related to obstetric patients, 10 were related to paediatric patients, 28 were related to general patient populations, three were related to emergency department populations and two studies evaluated a number of different early warning systems across patient populations.

4.4.4.1 Obstetric population

Of the 18 studies identified in obstetric populations, four were available in full text and 14 were abstract only (as summarised in Table 4.5). The majority of studies (*n*=14) were conducted in the UK [28-41] and the remaining four were conducted in Ireland.[42-45] For those studies that provided explicit patient inclusion criteria, one included antenatal patients,[44] three included intrapartum women,[37-39] five included postnatal patients,[28, 29, 31, 32, 40] and two included both antenatal and postnatal patients.[33, 42] Eleven studies included women from high risk populations, including four studies in post-operative recovery,[29, 31, 32, 34] four studies on women in high dependency units (HDU),[28, 37, 38, 44] two studies on women with maternal bacteraemia,[43, 45] and one study on women in ICU.[40] Of the two studies that specifically stated the early warning score parameters, RR, HR, oxygen saturation, BP and temperature were common to both.[34, 43] Alert, voice, pain, unresponsive (AVPU) was also recorded in one study.[43]

A national clinical audit of compliance with the IMEWS Clinical Practice Guideline in selected Irish maternity hospitals/units, found that six out of seven hospitals sampled were using the IMEWS at the time of the audit (May – November 2014).[42] Within the six hospitals using IMEWS, the clinical audit concluded that compliance with vital signs recording was good and the majority of hospitals demonstrated a high level of compliance in relation to escalating the necessary clinical care in cases of red and multiple yellow triggers. However, compliance in relation to the consistent completion of accurate scores when taking sets of observations needed improvement.

Four studies were before and after designs.[29, 34, 35, 43] Eakin et al. found that, following midwife training with a consultant anaesthetist, compliance with recording observations one hour postoperatively increased from 15% to 63% while recording observations two hours postoperatively increased from 42% to 60%.[29] The remaining studies looked at the effect of introducing early warning scores on physiological observations and patient outcomes. As the early warning score was not in use during the before period, only the after period results are presented in this analysis. Maguire et al. found that, after the introduction of the IMEWS, recording of vital signs was above 90% across temperature (100%), HR (95%) and BP (95%); however, the recording of RR was low (35%).[43] A second study found similar rates after the introduction of a MOEWS for temperature (82%) and HR (93%), but higher rates for RR (74%).[34] Using the minutes of clinical risk meetings, Treadgold et al. investigated the impact of a MEOWS on late recognition of maternal illness.[35] They found that after the introduction of the MEOWS late detection was a factor in 3 (10.3%) out of 29 cases.

Smith et al. reviewed the use of obstetric early warning systems (ObsEWS) across the UK.[41] The authors found considerable variation in the charts, warning systems and escalation protocols. Of the 120 maternity units surveyed, 69% used a colour-coded escalation system while 34% required staff to calculate a score from an aggregate weighted system. Of the 120 charts assessed, 102 (85%) included all seven vital signs that appear on the CEMACH chart (HR, RR, systolic BP, diastolic BP, oxygen saturation and AVPU). The majority of charts (90.8%) provided instructions about who to contact following triggering, but only 41.7% gave instructions about subsequent observation frequency.

Compliance rates with early warning scores varied across the remaining audit studies. Where charts were in operation, use ranged from lows of 21% [33, 39] to 33%[37] to highs of 100% compliance.[28, 32, 38, 40] However, where reported, completed charts were often inaccurate, with charts being completed in accordance with guidelines from 6% to 92% of the time.[28, 33] In relation to adherence to escalation of care protocols, Fitzpatrick et al.[30] reported that 80% of patients were seen within 30 minutes, while other studies reported no

action was taken after a trigger in 16–69% of patients. [28, 31-33] One study reported no documentation of any action taken in 17% of red triggers and 77% of yellow triggers.[28]

Where recommendations were specifically made, authors suggested education and training for midwifery and obstetric staff as a way of increasing compliance and accuracy.[28-32, 34, 35, 37, 38, 42] Other recommendations included routine audit,[33-35] implementation of software systems[38] and having clear escalation protocols in place.[33]

Table 4.5. Characteristics of included clinical audits in obstetric populations

Authors Year Country	Study setting and population	Aim of study	Study design	Participants	Performance measurement	Reference standard	Outcomes	Results	Authors key recommendations
Allman (2010)[28] Wales	Setting 1 hospital Population Postoperative support ward (POSW) and obstetric HDU	To audit compliance with modified early obstetric warning system	Conference abstract Audit 2 month period A 24 hour time period for each chart was audited (or up to discharge home if <24 hours)	50 patients: 43 POSW and 7 HDU	Not reported	Modified early obstetric warning system Parameters - RR - SpO_2 - temperature - HR - BP - neuro - pain - lochia - looks well.	Use of modified early obstetric warning system chart Frequency of observation Triggering episodes and action taken	Use of modified early obstetric warning system chart 100% Charts filled in according to guidelines: 3 (6%) Frequency of observation No observations recorded for a number of consecutive hours: 64% (for 2hrs) to 2% (for 7hrs) Triggering episodes and action taken Red: 12 (24%) No documentation of action taken: 2/12 (16.6%) Yellow: 13 (26%) No documentation of action taken: 10/13 (77%)	Recording of all the required observations needs to be improved. Changes implemented included incorporating an anaesthetic-led teaching session on midwifery study days and displaying teaching resources in the delivery suite.

Authors Year Country	Study setting and population	Aim of study	Study design	Participants	Performance measurement	Reference standard	Outcomes	Results	Authors key recommendations
Bapir (2013)[38] UK	Setting Unspecified Population All admissions to delivery suite HDU and general HDU	To compare local standards of care in maternity critical care against national standards	Conference abstract Retrospective audit October 2011 – October 2012	28 patients: delivery suite HDU 19 and general HDU 9	National guidelines (unspecified)	MEWS Parameters Unspecified	Compliance with MEWS score	MEWS score Total compliance: 100% Delivery suite HDU compliance: 100% General HDU compliance: 100%	Improving documentation by introducing HDU software into the delivery suite for documentation in HDU care. Introduction of standard forms in both delivery suite and general HDU for admission, discharge and transfer. Investing in staff training would help to improve documentation and clinical care.
Eakin (2011)[29] Northern Ireland	Setting 1 Hospital Population Post-operative obstetric patients	To establish if appropriate care is being provided	Conference abstract Before and after	20 midwives and 20 consecutive caesarean section patients	The standards employed in this audit are those set out by the Association of Anaesthetists of Great Britain and Ireland	Early warning scoring Parameters Unspecified	Recording of observations and frequency of observations	Proportion of observations recorded meeting standards for frequency **1hr post-operatively** Before: 15% After: 63% **2hrs post-operatively** Before: 42% After: 60%	Training needs to continue on a regular basis, with 100% attendance by all midwives.

Authors Year Country	Study setting and population	Aim of study	Study design	Participants	Performance measurement	Reference standard	Outcomes	Results	Authors key recommendations
Fitzpatrick (2010)[30] England	Setting High risk obstetric ward Population Obstetric patients	To determine compliance following introduction of modified early warning score	Conference abstract Audit: one day per month	694 patients	Not reported	Modified early warning score Parameters Unspecified Modified taking into account the physiological changes of pregnancy	Compliance with modified early warning score	Compliance Recording at appropriate intervals increased from 40% to 100% Recording three times daily until discharge increased from 23% to 86% compliance for parameters **Before:** RR — 73% Urine output — 32% Oxygen saturation — 74% Conscious level — 11% **After:** 100% (for all) Response time 80% who required escalation were reviewed within 30mins	Full compliance with recording and charting basic observations and the modified early warning score can be achieved by using a bedside teaching approach and audit. More work is needed to see whether using the modified early warning score in addition to basic observations improves outcomes.

Authors Year Country	Study setting and population	Aim of study	Study design	Participants	Performance measurement	Reference standard	Outcomes	Results	Authors key recommendations
Health Service Executive (2014)[42] Ireland	Setting 7 maternity hospitals/units Population Pre and post natal admissions	To determine compliance with IMEWS Clinical Practice Guideline To test if IMEWS triggered an escalation of care in cases of detected maternal septicaemia (DMS)	National clinical audit May – November 2014	Not reported	National Clinical Guideline No. 4 (NCG) for the IMEWS	IMEWS Parameters Specified: - temperature, - pulse, respiration - BP.	Use of IMEWS Appropriate recording of vital signs Appropriate escalation of care	Use of IMEWS Operational in 6/7 hospitals Areas of good compliance: — vital signs Areas of poor compliance: - initialling and scoring of observations - completion of repeat observations within the recommended timeframes following a trigger Appropriate escalation of care Areas of good compliance: escalating necessary clinical care in cases of red and multiple yellow triggers	1. Local training and education programmes must incorporate the importance of accurately recording the scores of all presenting triggers in the IMEWS observation chart and a corresponding entry must be recorded in the nursing notes of the healthcare record in the format of 'IMEWS=2Y' in conjunction with recording any relevant actions. 2. All observations must be initialled and dated in all entries in the IMEWS. 3. All nursing/midwifery staff must complete a full set of observations in the required timeframe when a trigger occurs, i.e. >30, <60, =30, =15 or continuous. 4. The implementation of the use of midwifery metrics must be

Authors Year Country	Study setting and population	Aim of study	Study design	Participants	Performance measurement	Reference standard	Outcomes	Results	Authors key recommendations
									considered locally in order to promote improvements in the delivery of safe, effective and person-centred care. A ward based self-assessment audit programme for IMEWS must be introduced in all hospitals with results and findings made available to nursing/midwifery staff.
Helme (2012)[31] England	<u>Setting</u> 1 hospital <u>Population</u> Obstetric patients who had a procedure in theatre under regional or general anaesthetic	To see if the routine monitoring of a sub-group of high-risk obstetric patients, was being carried out appropriately as described by maternity unit policy for recovery care	Conference abstract	36 patients	100% compliance with local policy guidelines	Modified obstetric early warning score <u>Parameters</u> Unspecified	Level of compliance with post-operative observations: Perfect — 100% compliance Sub-optimal — observations were taken at correct time but some data was missing Poor – entire sets of	<u>Level of compliance with post-operative observations</u> 1st hour Perfect: 17% Suboptimal: 72% Poor: 11% 2nd hour Perfect: 23% Suboptimal: 50% Poor: 27% 3rd to 24th hour Perfect: 9% Suboptimal: 3% Poor: 91% <u>Trigger response</u>	Improved education for the midwife and obstetric staff in the modified obstetric early warning score chart is the main learning point. In response to this, anaesthetic-led study sessions have been started.

Authors Year Country	Study setting and population	Aim of study	Study design	Participants	Performance measurement	Reference standard	Outcomes	Results	Authors key recommendations
							observations missed Triggers and response	Doctor contacted: 24% Senior midwife contacted: 7% Nothing done: 69%	
Hayes Ryan (2012)[44] Ireland	Setting 1 hospital HDU Population Admissions with severe pre-eclampic toxaemia (PET)	To examine standards of care of women with severe PET To identify areas of potential improvement and to implement change to facilitate this improvement	Conference abstract Retrospective audit 8 month period	22 patients	16 standards of care based on published guidelines	Early warning scoring system Parameters Unspecified	Not reported	Narrative results: Significant improvement in the monitoring and appropriate response to severe hypertension and in appropriate fluid restriction in cases of severe PET	
Hunjan (2013)[39] England	Setting 1 Hospital Population Cases of primary postpartum haemorrhage (PPH) (blood loss >500 mL for vaginal and >1000 mL for caesarean delivery)	To assess if healthcare professionals are following hospital Trust guidelines for the management of PPH	Conference abstract Retrospective audit January 2011 – January 2012	52 patients	Trust guideline, including communication, resuscitation, monitoring/investigation and arresting the bleeding	Obstetric early warning score Parameters Unspecified	Recording of vital signs every 15 min on an appropriate obstetric early warning score or HDU chart	Recording of vital signs every 15 min on appropriate chart 11/52 (21%)	Urgently revision of guideline to differentiate the management of minor and major PPH should increase compliance. A checklist has been designed for incorporation at the front of the guideline to ensure no crucial steps are omitted.

Authors Year Country	Study setting and population	Aim of study	Study design	Participants	Performance measurement	Reference standard	Outcomes	Results	Authors key recommendations
Jeffrey (2011)[32] UK	Setting 1 hospital Population Consecutive women from theatre (caesarean section, forceps and manual removal of placenta) with blood loss > 1000 mls and sepsis or possible sepsis	Not reported	Conference abstract	50 patients	100% of patients have a chart which has all observations made and an accurate score. For those whose scores reach trigger levels, then appropriate action should have been taken.	Maternity surgical early warning scoring Parameters Unspecified	Use of Chart Accuracy of scoring Triggers and response	Use of Chart 100% Accuracy of scoring 60% accurate Triggers and response 2 triggered scores 1 appropriate action taken	Education offered to midwifery and recovery staff.
Mackintosh (2014, unpublished data)[33] UK	Setting 1 hospital Population Ante-natal and postnatal ward	To explore implementation of the modified obstetric early warning score in practice	Audit 5 day period	127 patients 26 ante-natal and 81 postnatal	Not reported	Modified obstetric early warning score Parameters Unspecified	Use of charts Accuracy and frequency of observations charted Triggering and escalation	Use of charts 27/127 (21%) Accuracy 25/27 (92%) completed correctly 25/27 (92%) correctly calculated Frequency Mean frequency of observations: 4 hourly Triggering and escalation	1. Maternity services should ensure that observations for all obstetric admissions are recorded on a MEOWS chart. 2. Maternity services should develop a clear escalation protocol for women who 'trigger' as requiring urgent intervention. 3. Maternity risk group should review the results of this audit and develop an action plan to ensure that

Authors Year Country	Study setting and population	Aim of study	Study design	Participants	Performance measurement	Reference standard	Outcomes	Results	Authors key recommendations
								1 trigger with no evidence of escalation	improvements in practice are achieved. 4. Routine re-audit should continue to be undertaken to ensure that standards are improved and maintained.
Maguire (2014)[45] Ireland	<u>Setting</u> 1 hospital <u>Population</u> Women with maternal bacteremia	To examine whether the use of the IMEWS would have been beneficial in cases of proven maternal bacteraemia	Conference abstract Retrospective audit (2009–12)	56 women Mean age: 29.8 years (standard deviation ± 6.1)	Not reported	IMEWS <u>Parameters</u> 4 specified: - BP - HR - RR - temperature.	Location of observation recording Frequency of recording Retrospective trigger rate	<u>Location of observation recording:</u> Clinical notes (narrative) 46/56 (82%) Observation charts 24/56 (43%) Partograms 23/56 (41%) Hospital modified early obstetric warning system 9/56 (16%) <u>Frequency</u> Not standardised <u>Most frequent trigger cause</u> pyrexia (n = 49) pyrexia ≥38.0 °C trigger time to intravenous antibiotic: 81	Not reported

Authors Year Country	Study setting and population	Aim of study	Study design	Participants	Performance measurement	Reference standard	Outcomes	Results	Authors key recommendations
								minutes Other parameters triggers time to intravenous antibiotic: 282 minutes	
Maguire (2015)[43] Ireland	<u>Setting:</u> 1 university maternity hospital <u>Population:</u> Women with maternal bacteremia	To assess whether introduction of the IMEWS improved the recording of vital signs	Before and after (after only reported) Before: Jan 2009 to April 2013 After: April 2013 to March 2014	81 bacteremia cases 61 patients before 20 after Mean age: 30.0 ±6	Not reported	IMEWS <u>Parameters</u> - RR - SpO2 - temperature - HR - systolic BP - diastolic BP - AVPU	Recording of vital signs Interval from IMEWS trigger to antibiotic administration	<u>Recording of vital signs</u> **After** Temperature 20/20 (100%) HR 19/20 (95%) BP 19/20 (95%) RR 7/20 (35%) <u>Interval from IMEWS trigger to antibiotic administration</u> **After**: 98 minutes	Not reported
O'Connor (2010)[34] Scotland	<u>Setting:</u> 1 hospital <u>Population:</u> Patients with elective or emergency caesarean section	To assess and compare monitoring standards on maternity wards before and after introduction of MEOWS charts	Conference abstract (after only reported) Before and after 8 weeks	149 patients 76 before 73 after	Four-hourly recordings of BP, HR, RR, temperature and SaO2	Modified early obstetric warning score <u>Parameters</u> - BP - HR - RR - SaO2	Patients with four hourly recordings	<u>Four hourly recordings</u> **After** BP 68/73 (93%) HR 68/73 (93%) RR 54/73 (74%) SaO2 28/73 (38%) Temperature 60/73 (82%)	Post implementation audit, evaluation and continuing education will aid refinement of the system and improve monitoring standards further.

Authors Year Country	Study setting and population	Aim of study	Study design	Participants	Performance measurement	Reference standard	Outcomes	Results	Authors key recommendations
						- temperature.			
Ram-Mohan (2013)[40] England	Setting 1 hospital Population Patients admitted to the critical care unit	To review a series of critically ill obstetric patients admitted to a critical care unit and to formulate a guideline for the care of these women	Conference abstract Retrospective audit 01 January 2006 – 31 December 2011	55 patients	Not reported	MEWS Parameters Unspecified	Compliance with MEWS chart	Compliance with MEWS chart: 100%	Documentation of patient and family debrief needs to be improved. All these women should be seen in gynaecology follow-up clinic for debriefing. Guidelines for critically ill pregnant or recently pregnant women and sepsis in pregnancy and puerperium should be formulated.
Smith (2017)[41] UK	Setting Maternity units in the UK and Channel Islands. Population Maternity unit admissions	To compare: (i) vital sign values used to define physiological normality; (ii) symptoms and signs used to escalate care; (iii) type of chart used; (iv) presence of explicit instructions for	Audit (survey)	120 charts from: England (88) Scotland (15) Wales (11) Northern Ireland (5) Channel Islands (1)	Not reported	ObsEWS Parameters Unspecified	Chart colour-coding Who to call on ObsEWS triggering Frequency of vital signs monitoring expected after activation Items used as triggers for	Chart colour coding: 107/120 (89.2%) Colour-coded escalation system: 83/120 (69.2%) ObsEWS calculated using an aggregate weighted system: 41/120 (34.2%) Instructions on who to call once the ObsEWS had	Determination of a set of 'normal' vital signs ranges for pregnancy would facilitate development of a single validated ObsEWS for the UK and Channel Islands, although a particular challenge will be identification of suitable clinical outcomes against which ObsEWS can be validated.

Authors Year Country	Study setting and population	Aim of study	Study design	Participants	Performance measurement	Reference standard	Outcomes	Results	Authors key recommendations
		escalating care.					escalation Values used to determine physiological normality for each vital sign Other observations, criteria or abnormality used as triggers	triggered: 109/120 (90.8%) Instructions about changes in the vital sign measurement frequency after activation: 50/120 (41.7%) The most commonly chosen 'normal' range for HR, RR, systolic BP and SpO2 was used in only approximately 50% of units Use of 'normal' ranges described in the CEMACH report: 16/120 (13.3%) Inclusion of all 7 vital signs that appear on the CEMACH chart: 102/120 (85%) 75 discrete combinations of 'normal' ranges in use for these 7 vital sign sets	Identify whether it is necessary or feasible to introduce a different ObsEWS for each phase of pregnancy. With regard to aggregate weighted scoring systems, issues that require resolution are: (i) agreement on the range of weightings (i.e. 0–2 or 0–3), and (ii) the aggregate EWS at which care escalation occurs.

Authors Year Country	Study setting and population	Aim of study	Study design	Participants	Performance measurement	Reference standard	Outcomes	Results	Authors key recommendations
								Use of a different ObsEWS for different stages of pregnancy or in the postpartum period: 0/120 (0%) Other clinical observations or measurements used as a component of Triggering system: Maternal pain score 76 (63.3%) Characteristics of lochia 68 (56.7%) Proteinuria 65 (54.2%) Mother looks unwell 63 (52.5%) Characteristics of amniotic fluid 47 (39.2%) Presence of nausea 13 (10.8%) Drains/blood loss 12 (10.0%)	

Authors Year Country	Study setting and population	Aim of study	Study design	Participants	Performance measurement	Reference standard	Outcomes	Results	Authors key recommendations
								Uterine tone 11 (9.2%) Sedation level 3 (2.5%) Briskness of neuroreflexes 3 (2.5%) Level of epidural-related motor block 3 (2.5%) Level of epidural-related sensory block 2 (1.7%) Maternal blood glucose level 2 (1.7%)	
Treadgold (2010)[35] Wales	<u>Setting:</u> 1 tertiary centre (>6,000 deliveries) <u>Population:</u> Anonymised minutes of clinical risk review meetings — delivery suite	To investigate if a modified early obstetric warning score chart reduced late recognition of maternal illness	Conference abstract Before and after (after only reported) 34 months: 20 months before 14 months after	60 patients 31 before 29 after	Not reported	Modified early obstetric warning score chart <u>Parameters</u> Unspecified	Late detection of illness Late presentation of obstetric haemorrhage	<u>Late detection of illness</u> **After** 3/29 (10.3%) <u>Late presentation of obstetric haemorrhage</u> **After** 4.8%	Training in the use of the modified early obstetric warning score chart now occurs in all areas for all staff. The authors recommend its use, especially for early detection of haemorrhage and hypertensive disease, and intend to continue this audit on an annual basis as a marker of

Authors Year Country	Study setting and population	Aim of study	Study design	Participants	Performance measurement	Reference standard	Outcomes	Results	Authors key recommendations
									quality assurance.
Tufail (2009)[36] Wales	Setting 1 obstetric unit Population Clinical risk meetings where a poor outcome and substandard care were considered contributory	To review cases that had an adverse outcome to identify if an early warning system might have altered patient care	Conference abstract Retrospective audit	9 case reports	Two yellow or one red score constituted a trigger	CEMACH obstetric early warning chart Parameters Unspecified	Timing of red flags Time to first senior review, first recognition of the sick mother and time of a definitive plan	Time to trigger (min): Mean 225 (range 0–1,440) Time to senior review (min) Mean 1,005 (range 0–3,360) Time to definitive action (min) Mean 2,387.4 (range 90–11,370)	Documentation on a universal chart might have improved clarity and this audit indicates that early warning systems could aid the recognition of acute illness in the parturient.
Waldron (2011)[37] England	Setting 1 hospital Population HDU patients	To assess the quality of HDU care within delivery suite	Conference abstract January – July 2009 Retrospective case note review	27 patients PET patients: 21 Major haemorrhage patients: 6	Trust's monitoring standards: 90% compliance with observation chart documentation	Modified obstetric early warning score Parameters Unspecified	Vital signs documented adequately Modified obstetric early warning score documented adequately	Vital sign documentation PET patients: 47% Haemorrhage patients: 50% Modified obstetric early warning score documentation PET patients: 33% Haemorrhage patients: 33%	Regular multi-disciplinary staff training now targets the documentation issues highlighted by this audit. The HDU chart has been reformatted and guidelines outlining indications for obstetric HDU care have been written by the audit authors.

Key: AVPU — alert, voice, pain, unresponsive; BP — blood pressure; bpm – beats per minute; CEMACH — The Confidential Enquiry into Maternal and Child Health; HR — heart rate; HDU — high dependency ward; ICU — intensive care unit; IMEWS — Irish Maternity Early Warning System; IV — intravenous; ObsEWS — obstetric early warning charts; PET — pre-eclamptic toxaemia; POSW — postoperative support ward; PPH — postpartum haemorrhage; RR — respiratory rate; SaO2 — oxygen saturation; SD – standard deviation.

4.4.4.2 Paediatric populations

Of the ten studies identified in paediatric populations, seven were abstract only, as summarised in Table 4.6. Six studies were conducted in the UK,[46-51] two in Ireland,[52, 53] and one each in Uganda[54] and the US.[55] The majority of studies that provided patient inclusion criteria were conducted in general inpatients, with one study being conducted in patients with cardiac arrest[51] and one in paediatric oncology.[54]

Two studies specifically stated the parameters included. In an Irish study, Ennis utilised the National Health System (NHS) paediatric early warning score chart, including respiratory rate, respiratory distress, oxygen use, stridor or apnoea, heart rate, consciousness and level of concern of nurse/doctor/parent.[52] The HSE national clinical audit utilised the Irish Paediatric Early Warning System (PEWS), which has the core parameters of RR and respiratory effort, oxygen therapy, HR, conscious level and clinician/family concern and five additional parameters (determined on a case-by-case basis), namely, oxygen saturations, central capillary refill time, BP (systolic), skin colour and temperature.[53]

The HSE national clinical audit of compliance with the Irish Paediatric Early Warning System (NCEC National Clinical Guideline No. 12) in four acute Irish hospitals found that correct PEWS recording rates varied across hospitals (0–83%). Additional parameters were recorded correctly 100% of the time in three sites, while one site had a lower percentage of compliance (67–100%).[53] In patients requiring escalation of care (that is, PEWS ≥3), there was evidence of a documented nursing response in 54% of cases and a documented medical response to requested action in 63% of cases. PEWS training occurred in three out of four hospitals and audits were routine in one hospital.

Three studies were before and after designs.[50, 54, 55] Watson et al. found delays in documentation of early warning scores by registered nurses (RNs) and inconsistencies between the early warning scores and vital signs collected and documented by non-RN personnel (for example, patient care technicians).[55] An educational campaign increased consistency of RN charting of the early warning scores with the most recently charted vital sign for HR but not RR. The other two studies looked at the effect of introducing early

warning scores on physiological observations and patient outcomes. As the early warning score was not in use during the before period, only the after period results are presented in this analysis. Collord et al. found that after the introduction of a paediatric observation chart with a modified paediatric early warning score, 90% of children had bedside observations charted and vital signs were recorded once per day on average in a resource-limited setting.[54] Theilen et al. found that after the introduction of an early warning system with weekly team training, the average time from breach of early warning criteria to first response was 1.1 hours, while the time from breach to paediatric intensive care unit (PICU) admission was 10 hours.[50] Furthermore, the proportion of deteriorating patients seen by a consultant was 82%, PICU length of stay had a mean value of five days and the number of deaths was four.

Across the remaining audit studies, compliance rates varied from 87% to 100%.[48, 49] Where reported, completed charts were accurate in over 80% of cases.[47, 48] Where individual parameters were reported, temperature was the most poorly recorded.[47] Reported rates of appropriate escalation of care and actions taken also varied. Escalation to the right person occurred in between 29% and 97% of cases,[47, 52] and within the recommended time frame for between 92% and 100% of cases.[52] The actions taken were considered appropriate 54% to 88% of the time.[48, 49]

Where recommendations were specifically made, authors suggested education and training.[50, 53] Other recommendations included electronic implementation[46, 55] and more research into why high scores do not always trigger a response.[47] Ennis highlighted the need for a nationally co-ordinated approach to developing and implementing PEWS systems in Irish hospitals.[52] Subsequent to this paper, the Irish PEWS (NCEC National Clinical Guideline No. 12) was published.[56]

Table 4.6. Characteristics of included clinical audits in paediatric populations

Authors Year Country	Study setting and population	Aim of study	Study design	Participants	Performance measurement	Reference standard	Outcomes	Results	Authors key recommendations
Collord (2014) [54] Uganda	Setting: Tertiary paediatric oncology centre Population: Unspecified	To improve inpatient supportive care	Conference abstract Audit Before and after (after only reported) (April 2012 – July 2013)	Not reported	Implementation of bedside charts and compliance with guidelines	Modified paediatric early warning score Parameters Unspecified	Bedside observations charted Vital sign recording	Bedside observations charted After: 90% Vital sign recording average recording once per day Pulse, oxygen saturation and BP were documented at least once per day in 75-95% of instances, RR was documented <20% of the time.	Not reported
Ennis (2014)[52] Ireland	Setting 30 bed acute children's ward Population: Inpatient admissions	To evaluate the clinical utility and effectiveness of a paediatric early warning score (PEWS) system when incorporated in routine nursing observation and multidisciplinary team communication	Prospective cohort 4 month period	72 children, of which 35 had PEWS ≥3 Age range: 0–12 years	Full concordance with the use of PEWS tools Response time PEWS 3–4: review by relevant senior house officer in a maximum response time of 30 minutes PEW≥5: should be	NHS paediatric early warning score chart Parameters - RR - respiratory distress - oxygen use - stridor or apnoea - HR - Conscious	Adherence to escalation protocol	Response time Score 3–4 (*n*=64) Review by relevant SHO: 97% Reviews undertaken within 15 minutes: 92% Score ≥5 (*n*=8) Reviews undertaken within 15 minutes: 100% Responses to alerts	The experience of, and response to, this local initiative highlighted the need for a nationally co-ordinated approach to developing and implementing PEWS systems in children's services in Irish hospitals. A number of other acute children's services have since expressed interest in implementing this system.

Authors Year Country	Study setting and population	Aim of study	Study design	Participants	Performance measurement	Reference standard	Outcomes	Results	Authors key recommendations
		processes			reviewed by the registrar within 15 minutes	- level of concern of nurse/doctor/ parent.		59/72 (82%) specific intervention or change to treatment 13/72 (18%) continue to monitor	
Health Service Executive (2017)[53] Ireland	<u>Setting:</u> 4 acute hospitals <u>Population:</u> Unspecified	Audit of compliance with National Clinical Guideline (NCG) No. 12 for the Irish Paediatric Early Warning System (PEWS)	National clinical audit	80 cases (20 per site)	NCG No. 12 for the Irish PEWS Completion, by nursing staff of a paediatric observation chart for each patient PEWS score ≥3: escalation guide setting out the clinical response for the patient that should be followed	PEWS <u>Parameters</u> Core: - RR - respiratory effort - oxygen therapy - HR - conscious level - clinician/family concern. Additional parameters (determined on a case-by-case basis): - oxygen saturation - central capillary	Appropriate documented PEWS chart, including scoring of core physiological parameters and additional parameters Adherence to escalation guideline PEWS training undertaken at site level PEWS audits undertaken at site level	<u>PEWS recorded correctly:</u> Site 1: 70% Site 2: 0% Site 3: 79% Site 4: 83% <u>Additional parameters recorded correctly:</u> Site 1: 100% Site 2: 67–100% Site 3: 100% Site 4: 100% <u>Adherence to the escalation guideline</u> 35/80 charts had PEWS ≥3 Evidence of a documented nursing response to PEWS: 19/35 (54.3%)	The National Director of Acute Hospitals must: 1. ensure that an evaluation of the effectiveness of PEWS training is undertaken in all relevant acute hospitals 2. liaise with the PEWS Steering Group to ensure a review of the education on and the positioning of the 'frequency of observations' and 'reassess within' variables on the PEWS chart, given the low percentage compliance with completing these variables where they were clinically required 3. communicate to all hospitals the following recommendations common to the 4 sites and the need

Authors Year Country	Study setting and population	Aim of study	Study design	Participants	Performance measurement	Reference standard	Outcomes	Results	Authors key recommendations
						refill time - BP (systolic) - skin colour - temperature.		Evidence of a documented medical response to requested action: 12/19 (63.1%) Signature of doctor present in the medical notes: 11/12 (91.67%) <u>PEWS training</u> 3/4 sites had training in place <u>PEWS audits</u> 1/4 sites had robust culture of audit	for all hospitals to ensure their compliance with same: • PEWS charts must be documented in line with the national guidelines as follows: o All relevant staff must document all core parameter scores on the PEWS chart and ensure that the overall score is correct. o Nursing staff must complete the 'frequency of observations' and 'reassess within' sections as clinically appropriate on the PEWS charts. o Nursing staff must complete a full set of observations in the required timeframe (minimum observation frequency specified for PEWS Scores) as per each hospital's paediatric observation chart escalation. o The correct PEWS chart for the appropriate age is used at all times. • All relevant staff must adhere to the local PEWS escalation guide; in

Authors Year Country	Study setting and population	Aim of study	Study design	Participants	Performance measurement	Reference standard	Outcomes	Results	Authors key recommendations
									particular, all staff must document within a child's record the rationale for the decision not to escalate scores of ≥3. • All relevant staff must document within a child's healthcare record any responses to PEWS scores ≥3. • Medical staff must date, time and sign all entries in the healthcare records (as per the HSE Standards and Recommended Practices for Healthcare Records Management 2011). • Medical and nursing staff must include a reference to PEWS scores (when relevant) in the documented management plans • Medical staff must document medical escalation suspensions and parameter amendments in medical management plans as per the standards detailed within the NCG and relevant PEWS user manuals. • An audit programme must be developed and

Authors Year Country	Study setting and population	Aim of study	Study design	Participants	Performance measurement	Reference standard	Outcomes	Results	Authors key recommendations
									adhered to in line with the NCG to include patient outcome such as PEWS alert calls audits.
Joshi (2011)[46] England	Setting 1 hospital Population Unspecified	To evaluate use of Royal Manchester Children's Hospital early warning score (ManChEWS) since its introduction in order to allow continued improvement and development.	Conference abstract	Not reported	Not reported	ManChEWS Parameters 6 Unspecified	3 audits 1. Evaluate ManChEWS in emergency admissions to the PICU/PHDU (2006 to 2007). 2. Prospective audit of children who trigger early warning score on the ward but do not require admission to the PHDU/PICU (2009). 3. To evaluate the use of ManChEWS in children that died between 2005 and 2008 following	Narrative results ManChEWS correctly identified clinically deteriorating children on the ward. ManChEWS over-triggered, leading to staff becoming immune to triggers, due to the high frequency of underlying illness in admitted children. Medical staff not redefining parameters for children with abnormal baseline parameters. ManChEWS not universally used. 25% of deaths were	Development of an early warning system steering group. Daily review of patients triggering ManChEWS by development of an outreach team. Electronic implementation across the Trust. Patients with underlying illness may have individualised parameters set by senior medical staff.

Authors Year Country	Study setting and population	Aim of study	Study design	Participants	Performance measurement	Reference standard	Outcomes	Results	Authors key recommendations
							an acute deterioration on the wards.	attributable in part to 'the failure to recognise a sick child'.	
Lloyd-Hughes (2011)[47] UK	<u>Setting</u> 1 children's hospital <u>Population</u> Inpatients	To determine whether documentation of PEWS charts is complete and if clinical responses are appropriate.	Conference abstract	58 patients	Not reported	PEWS <u>Parameters</u> Unspecified	Age-appropriateness Correct documentation of time, date, patient details, physiological parameters and PEWS score.	<u>Age-appropriateness</u> 97% (56/58) of charts were appropriate <u>Complete documentation</u> Patient details: 60% (35/58) Date: 62% (36/58) Time: 100% (58/58) <u>Physiological parameters:</u> HR, RR: 100% (58/58) Oxygen saturations, oxygen therapy, respiratory distress, capillary refill time: 98% (57/58) BP:83% (48/58) AVPU: 69% (40/58) Temperature: 64%(37/58)	A PEWS score of 9 is not always triggering a response. Further research could evaluate this threshold and identify barriers to calling for assistance.

Authors Year Country	Study setting and population	Aim of study	Study design	Participants	Performance measurement	Reference standard	Outcomes	Results	Authors key recommendations
								PEWS score accurate 88% (51/58) Score and medical review PEWS 5–8: 19 Medical review: 4/14 (29%) PEWS >8: 5 Medical review: 2/3 (67%)	
McDonald (2017)[48] UK	Setting 5 hospital trusts — all paediatric departments Population Unspecified	To create a standardised regional paediatric early warning score chart.	Conference abstract	Not reported	Not reported	4 standardised age-based PEWS charts 15 Parameters Unspecified	Chart use and completion Appropriate escalation	Chart use and completion 100% All parameters completed for each time point 87.1% Actions appropriate for scores 88.6%	The long-term aim is that 100% compliance would be achieved in each parameter.
Sundaram (2014)[49] England	Setting 1 hospital Population Medical and surgical patients	To establish prevalence of false positive and false negative alerts generated by a paediatric early	Conference abstract 3 days	248 patients	Score 1–4: discuss with charge nurse Score 5–8: inform nurse in charge or own team	Paediatric early warning score Parameters Unspecified	Observations in paediatric early warning score chart Scores and response	Observations in chart 87% Scores ≥9: 2% 5–8: 13%	Clinicians override the recommendations of the PEWS. It should be determined if this due to poor calibration of the score or clinician disbelief.

Authors Year Country	Study setting and population	Aim of study	Study design	Participants	Performance measurement	Reference standard	Outcomes	Results	Authors key recommendations
		warning score.			Score ≥9: call patients own medical team or the PICU immediately			1–4: 85% Inappropriate response taken Score ≥9: 46% Score 4–8: 57%	
Theilen (2010)[50] Scotland	Setting Paediatric teaching hospital Population Unspecified	To evaluate the impact of an early warning system and paediatric emergency team training on unplanned admissions to PICU.	Conference abstract Before and after (after only reported)	Not reported	Not reported	Early warning system (EWS) Parameters Unspecified	Unplanned admissions Resuscitation team calls: Time to first response after breaching EWS Proportion of deteriorating patients seen by consultant Time to admission to PICU PICU LOS (mean days) Deaths	Unplanned admissions After: 115 Resuscitation team calls: After: 36 Time to first response after breaching EWS After: 1.1 h Proportion of deteriorating patient seen by consultant After: 82% Time to admission to PICU After: 10 h PICU LOS (mean days) After: 5.0 Deaths	Study suggests that weekly team training, a local innovation to support early warning implementation, influences the judgement of key decision makers in the care of deteriorating patients.

Authors Year Country	Study setting and population	Aim of study	Study design	Participants	Performance measurement	Reference standard	Outcomes	Results	Authors key recommendations
								After: 4	
Watson (2014)[55] US	Setting 1 paediatric hospital Population 7 non-ICU inpatients units	To assess degree to which registered nurses (RNs) are able to document early warning scores in real time.	Before and after	196 beds	Not reported	PEWS Parameters Unspecified	Differences in PEWS documentation between RNs and non-RNs Consistency of PEWS documentation with elevated vital sign before and after educational campaign	Early warning scores available 85% Number of VS documented **RNs**: 675/2583 (27%) **Non-RNs**: 1,878/2,583 (73%) Mean delay in charting of vital signs **RNs:** 36.5 minutes (median = 3, IQR = 0–50) **Non-RNs:** 20 minutes (median = 0, IQR = 0–26) Consistency of PEWS with most recently charted VS HR >20 above normal Before: 6/71 (8%) After: 22/62 (35%)	Significant differences pre- and post educational campaign were reported: an increase in the delay in the charting of the early warning score and more consistent documentation between the cardiovascular subscore and HR. Additional system-based improvement initiatives to improve the functionality of early warning scores could include changes to the physical environment or improved technology interfaces that are more supportive of real time data entry.

Authors Year Country	Study setting and population	Aim of study	Study design	Participants	Performance measurement	Reference standard	Outcomes	Results	Authors key recommendations
								P<0.001 HR >30 above normal Before: 0/24 (0%) After: 25/66 (29) P<0.001 RR >10 above normal Before: 21/70 (30%) After: 44/106 (41%) P = 0.12 RR >20 above normal Before: 2/18 (11%) After: 7/28 (25%) P = 0.25	
Wright (2011)[51] England	Setting 1 paediatric hospital Population In-patients with cardiac arrest	To assess whether routine use of observation charts incorporating a paediatric early warning tool (PEWT) are effective for screening inpatients and predicting those at risk of acute	Conference abstract Retrospective case note audit May – December 2009	55 arrest	PEWT 'triggered' defined as when documented on the observation chart, a medical review is requested within the PEWT time targets and the PEWT logged onto the hospital computerised patient information	PEWT Parameters Unspecified	Patients triggering PEWT in preceding 24h Prediction of cardiac arrest	Patients triggering PEWT in preceding 24h 10/55 (18%) 6 of these had an arrest call within 30 min of triggering Patients not triggering PEWT in preceding 24h 45/55 (82%)	The use of observation charts incorporating a PEWT was only 49% sensitive at predicting cardiac arrest calls inpatients in a tertiary paediatric hospital. This sensitivity is being reduced further by incorrect implementation of the PEW process when the tool is 'triggered'.

Authors Year Country	Study setting and population	Aim of study	Study design	Participants	Performance measurement	Reference standard	Outcomes	Results	Authors key recommendations
		deterioration.			system.			17/45 (38%) patients should have triggered 10/17 (59%) had request for review by the medical team <u>Prediction</u> 27/55 (49%) of cardiac arrest calls could have been predicted by either observation charts or PEWT	

Key: AVPU — alert, voice, pain, unresponsive; BP — blood pressure; EWS — early warning system; ManChEWS — Manchester Children's Hospital early warning score; NCG — National Clinical Guideline; PEWS — paediatric early warning system; PEWT — paediatric early warning tool; PHDU — paediatric high dependency unit; PICU — paediatric intensive care unit; RN — registered nurse; RR — respiratory rate.

4.4.4.3 General adult population

Of the 28 studies identified in general adult populations, eight were conference abstracts only, as summarised in Table 4.7. Twenty-one studies were conducted in the UK,[57-77] three in Ireland,[78-80] and one each in Afghanistan,[81] the US,[82] Denmark,[83] and Australia.[84] The majority of studies that provided patient inclusion criteria were conducted in general adult inpatients. Two studies were conducted in patients admitted to ICU,[57, 77] and three studies included patients with high early warning scores — one study in patients admitted under an infectious disease service with scores ≥4,[80] one with scores ≥6[68] and one with scores ≥7.[79] One study was conducted in adults admitted to a children's hospital,[82] one in a military field hospital,[81] one in a step down unit (SDU),[59] one in patients with potential epidural complications[60] and one in a private hospital.[84]

Fifteen studies specifically stated the parameters included in the early warning scores.[59-63, 69, 71, 73, 76, 78, 79, 81-84] One score was an early warning chart to identify epidural complications (parameters: motor block, sensory block, epidural site, epidural duration and other factors).[60] Among the remaining 14[59, 61-63, 69, 71, 73, 76, 78, 79, 81-84] studies, three parameters were common to all: RR, HR and temperature. Twelve studies included oxygen saturation,[61-63, 69, 71, 76, 78, 79, 81-84] and four studies included blood pressure[59, 69, 76, 83] while systolic blood pressure was specified in ten studies.[61-63, 71, 73, 78, 79, 81, 82, 84] Seven studies included urine output.[59, 61, 63, 73, 76, 81, 84] and ten included consciousness level,[61, 62, 69, 71, 73, 76, 78, 79, 82, 84] with five studies specifying AVPU.[61, 62, 73, 79, 84] Central nervous system function was specified in four studies.[59, 63, 85] Additional parameters included pain,[76, 81] Glasgow coma scale changes,[81, 83]chest pain,[84] nurse concern,[81] biochemistry changes (for example, creatinine and urea),[81] receiving supplemental oxygen therapy,[62] oxygen route[78] and oxygen supplement.[79]

A national clinical audit of compliance with the National Early Warning Score (NEWS) (NCEC National Clinical Guideline No. 1) in three acute hospitals in Ireland found reasonably good compliance with the selected criteria in one hospital and limited compliance in the other two.[78] Areas of poor compliance identified included incorrect totals, poor documentation

of escalation and poor attendance at NEWS update training. A national clinical audit of the NEWS in nine acute hospitals across Ireland is currently underway and expected to be completed in 2018.

Patterson et al. reviewed the use of track and trigger systems in all hospitals admitting acute medical patients in Scotland and London in 2010, finding 11 different systems in use in London and five in Scotland.[72] The parameters of HR, RR and systolic BP were common to all systems. The majority of hospitals included level of consciousness, oxygen saturation, temperature and urine output. A minority of hospitals included additional parameters such as requirement for supplemental oxygen and subjective clinical concern. Forty percent of London hospitals and 70% of Scottish hospitals incorporated the minimum data set recommended by the National Institute for Health and Care Excellence (NICE).[86] The authors highlight that there is marked variation in the nature of early warning scores used across Scotland and London.

Eight studies were before and after designs.[63, 64, 66, 67, 71, 74, 75, 81] Five before and after studies looked at increasing compliance with and the accuracy of completion of early warning scores. All studies reported an increase in compliance (from lows of 39–52% to rates of over 80% in most cases) following staff training.[63, 64, 74, 75, 81] The remaining three studies looked at the effect of introducing early warning scores on physiological observations and patient outcomes.[66, 71] As the early warning score was not in use during the before period, only the after period results are presented in this analysis. McBride et al. found that following the introduction of a modified early warning score which incorporated RR, the percentage of occupied beds where at least one RR recording had been made in a single 24 hour period was 91%.[66] Paterson et al. found that following the introduction of a standardised early warning scoring system (SEWS), documentation of physiological parameters was conducted 76% of the time.[71] The parameter with the poorest recording was RR (87%). McCormick et al. found the frequency of four-hourly observations was 50% of total observations after the introduction of a physiological observation chart with an integrated early warning score.[67]

Across the remaining clinical audit studies, compliance rates varied. Evidence of a documented early warning score was reported in 68–98% of patients.[61, 65, 69, 70, 73, 77, 82-84] Where a score was available, it was accurate and complete in 22–95% of charts.[57, 61, 68, 70, 77] Where reported, parameters were incomplete in 25–64% of cases.[58, 61] Where individual parameters were reported, RR was most frequently missing (33–51%).[61] Adherence to expected monitoring schedules was found to be lower at night time than during the day.[62]

Appropriate escalation of care and actions taken also varied. Patients were seen within the recommended timeframe in 30–62% of the time.[76] Appropriate actions were reported in one study as 38%.[83] Documentation of actions taken were reported in 21–66% of cases.[58]

One Irish study examined patients with a NEWS score ≥7.[79] The study found that the score did not result in a change in clinical management in 65% of cases and 94% of patients with no change in clinical management were subsequently discharged home. The authors concluded that the respiratory variables of the NEWS score are poor discriminators of patients who are clinically deteriorating. Better tools (such as the chronic respiratory early warning score (CREWS) score) are required to distinguish acutely ill from chronically ill patients with respiratory disease.

Where recommendations were specifically made, a number of authors suggested education and training.[57-59, 61, 63, 64, 76, 83] Other recommendations included routine audit[61, 65] and the establishment of predetermined hours to undertake 'observation rounds', taking into account other important patient and clinical activities, staffing levels and monitoring equipment availability.[62]

Table 4.7. Characteristics of included clinical audits in general adult populations

Authors Year Country	Study setting and population	Aim of study	Study design	Participants	Performance measurement	Reference standard	Outcomes	Results	Authors key recommendations
Appleton (2009)[57] Scotland	Setting 1 hospital Population Patients admitted to district general ICU	To audit documentation of a MEWS	Conference abstract Prospective audit 10 week study period	64 ICU admissions 56 meeting inclusion criteria	Not reported	MEWS Parameters Unspecified	Charts appropriately completed	Charts appropriately completed: 22%	Further investigation is required to clarify factors contributing to incomplete MEWS recording. Focus on education and training of MEWS recording and application recommended.
Carter (2013)[81] Afghanistan	Setting UK Role 3 field hospital Population Adult patients	To audit recording of the Defence Medical Services (DMS) Early Warning Scoring (EWS) tool	Full audit cycle Before and after	80 charts	Not reported	DMS EWS Parameters 3 domains: 1. New symptoms (nurse concerned, chest pain, abdominal aortic aneurysm pain, shortness of breath) 2. Physiology (pulse, core temperature, RR, SpO2, Systolic BP OR Glasgow	DMS EWS calculated DMS EWS calculated correctly Recording of physiological observations	DMS EWS calculated Before: 21/40 (52.5%) After: 32/40 (80%) DMS EWS calculated correctly Before 7 (33%) After: 19 (59%) Physiological observations Before: RR, SpO2, oxygen concentration, pulse, BP,	With the launch of NEWS tool across the UK and its subsequent generic e-learning pack for all clinical staff, the DMS must consider reviewing the current EWS and decide if NEWS would be appropriate in the deployed clinical environment.

Authors Year Country	Study setting and population	Aim of study	Study design	Participants	Performance measurement	Reference standard	Outcomes	Results	Authors key recommendations
						comma score changes, urine output) 3. Biochemistry (K+, Na+, pH, pCO2, SBE, pO2, creatinine, Hb, urea)		temperature, all ≥ 90% Level of consciousness 75% Urine output 2.5% After: RR, SpO2, oxygen concentration, pulse, BP, temperature, all ≥ 95% Level of consciousness 97.5% Urine output 77.5%	
Connelly (2015)[58] England	Setting 1 hospital Population Unspecified	To evaluate adherence to a colour-coded EWS adult observation chart	Conference abstract	194 patients	A single amber, double amber or red observation should trigger a specified action (to be documented in the clinical notes) and increased frequency of	Colour coded EWS Parameters Unspecified	Completion of observation Escalation	Incomplete observation parameters 25% Single amber observations: 21% had any subsequent action recorded, and 67% had frequency of	The current chart does not appear to be as effective or utilised in the way that it was designed. To re-establish effective use of the current chart will require a massive trust wide education programme. The proposed Royal College Royal College of Physicians

Authors Year Country	Study setting and population	Aim of study	Study design	Participants	Performance measurement	Reference standard	Outcomes	Results	Authors key recommendations
					observations.			observations increased. Double amber observations: 33% had any subsequent action recorded, and 83% had frequency of observation increased. Red observations: 11, 3 with actions documented	(RCP) NEWS system has been tested and demonstrated to be an effective system for identifying at risk patients. It may make more sense to concentrate education efforts on the introduction of the RCP NEWS system rather than re-launching the old one.
Conway-Habes (2017)[82] US	Setting 1 academic children's hospital 1 26-bed medical/ surgical ward Population Patients ≥21 years admitted to a children's hospital	To implement and standardize NEWS	Prospective audit 7 month study period	56 patients (84 admissions) Average age: 26.6	NEWS assessments performed and documented with routine nursing assessments 80% of the time	NEWS Parameters - level of alertness - HR - RR - oxygen saturation - temperature - systolic BP.	Primary Percentage of NEWS documented with every 4-hour nursing assessment	NEWS scores documented at 17 weeks 77%	A key insight during implementation was the importance of oversight and sponsorship from the unit charge nurse.

Authors Year Country	Study setting and population	Aim of study	Study design	Participants	Performance measurement	Reference standard	Outcomes	Results	Authors key recommendations
Day (2003)[59] England	Setting 1 acute general hospital 1 step down unit (SDU) Population Unspecified	To determine doctor response time to calls for assistance after trigger	Audit 2 month study period	45 calls	If a score is ≥4, advice should be sought immediately from a senior house officer or registrar. The doctor must review patients within 30 minutes.	Derby Modified Early Warning System (DMEWS) Parameters - HR - RR - temperature - BP - urine output - central nervous system.	Doctor response time Disparity between response times to calls instigated by SDU and outreach staff	Source of calls 30 SDU staff 15 critical care outreach team Average response time SDU calls 46.1 min (range 7–112) Average DMEWS score requiring action: 4.6 Outreach team calls 11 min (range 5–21) Average DMEWS score requiring action: 6.3	Extend training to all student nurses and doctors. Allow alteration of trigger scores for individual patients based on doctor instructions after first review. Training on how to give concise verbal reports on patient condition. Critical care skills training.
Day (2012)[60] England	Setting Not stated Population Before: patients with potential epidural complications After: patients who had	To test the validity of an early warning chart to identify epidural complications	Conference abstract Retrospective and prospective audit	109 Retrospective: 34 patients prospective : 75 patients	Not reported	Early warning chart to identify epidural complications Parameters - motor block - sensory block - epidural	Sensitivity in identifying epidural complications	Retrospective Sensitivity: 100% 2/34 EWS picked up abnormalities one day earlier than actually happened Prospective 8/75 (11%) triggered	The chart is sensitive to identify early signs of concern in patients with epidurals. It is easy to use and does not require any extra monitoring than is routinely performed postoperatively by ward nursing staff. The numbers of patients 'triggering' the system does not appear to overwhelm the resources

Authors Year Country	Study setting and population	Aim of study	Study design	Participants	Performance measurement	Reference standard	Outcomes	Results	Authors key recommendations
	received thoracic epidural analgesia					site - epidural duration - other factors.			available; however, the specificity needs to be such that potential devastating complications are recognised.
Gordon (2011)[61] Scotland	<u>Setting</u> 1 teaching hospital 1 ward, 1 combined assessment unit (CAU) <u>Population</u> Patients causing overnight clinical concern necessitating medical review	To quantify proportion of unwell patients who did not have SEWS correctly calculated or recorded, and which parameters were omitted	Audit 2 week period	181 patients Ward: 156 CAU: 25	A score ≥4 should trigger medical review within 20 minutes	SEWS <u>Parameters</u> - Systolic BP - HR, - oxygen saturation - temperature - RR, - urine output - consciou s level (AVPU).	Accurate completion of SEWS	<u>No SEWS chart</u> Ward: 3/156 (2%) CAU: 0 (0%) <u>SEWS chart calculated incorrectly</u> Ward: 121/156 (78%) CAU: 8/25 (32%) <u>Types of errors in incorrect chart</u> i) Total missing Ward: 67/121 (55%) CAU: 4/8(50%) ii) Observation in wrong box Ward: 18/121 (15%) CAU: 2/8 (25%) iii) Total score incorrect	Implementation of a comprehensive educational programme with training at ward level in the function and use of SEWS, with a view to auditing the effectiveness of such an intervention.

Authors Year Country	Study setting and population	Aim of study	Study design	Participants	Performance measurement	Reference standard	Outcomes	Results	Authors key recommendations
								Ward: 26/121 (21%) CAU: 2/8 (25%) iv) Observations missing Ward: 77/121 (64%) CAU: 3/8 (38%) <u>Frequency of missing observations</u> i)temperature Ward: 35/77 (45%) CAU: 1/3 (33%) ii) pulse Ward: 2/77 (3%) CAU: 0/3 (0%) iii) BP Ward: 2/77 (3%) CAU: 0/3 (0%) iv)oxygen saturation Ward: 3/77 (4%) CAU: 0/3 (0%)	

Authors Year Country	Study setting and population	Aim of study	Study design	Participants	Performance measurement	Reference standard	Outcomes	Results	Authors key recommendations
								v) RR Ward: 39/77 (51%) CAU: 1/3 (33%) vi)Neurological status Ward: 25/77 (32%) CAU: 1/3 (33%)	
Hands (2013)[62] England	Setting 1 district general hospital Population Adult hospital inpatients (May 2010 – April 2011)	To study the pattern of recording of vital signs observation throughout the day and examine its relationship with monitoring frequency component of the clinical escalation protocol	Audit	950,043 complete observation sets	Hospital's clinical protocol for the interval between observation sets VitalPAC Early Warning Score (ViEWS) 0–1: 6 or 12 hourly ViEWS 2: 6 hourly ViEWS 3–6: 4 hourly ViEWS 7–8: 1 hourly ViEWS ≥9: 30 min	ViEWS Parameters - pulse rate - breathing rate, - systolic BP - oxygen saturation - temperature - consciousness level (AVPU). Additional points: receiving supplemental oxygen	Number of vital signs sets collected each hour expressed as a percentage of the total number of vital signs collected in a day. Number of vital signs sets collected in each vital sign group each hour, expressed as a percentage of the total number in that VIEWS group for 24 hrs. Adherence to expected day/night monitoring	Percentage of vital sign sets collected each hour 23:00–05:59 Range: 0.93–2.87% 10:00–17:59 Range: 3.35–6.08% 06:00–06:59: 13.58% 21:00–21:59: 8.58% Percentage of vital sign sets collected by VIEWS group ViEWS 0–1: 0.5–15.6%	Substantial hourly differences in observation frequency were found. The authors suggest staff may locally establish predetermined hours to undertake 'observation rounds', taking into account other important patient and clinical activities, staffing levels and monitoring equipment availability. Future research should focus on the evidence regarding optimal frequency for vital sign measurement.

Authors Year Country	Study setting and population	Aim of study	Study design	Participants	Performance measurement	Reference standard	Outcomes	Results	Authors key recommendations
						therapy	schedule.	ViEWS 2: 0.99–13.7% ViEWS 3–6: 1.5–10.7% ViEWS 7–8: 2.2–6.7% ViEWS ≥9: 2.9–5.7% <u>Adherence to expected day/night monitoring schedule (proportion with subsequent vital sign dataset within next 6 hrs)</u> 08:00–11:59: 73.1% 20:00–23:59: 25.3%	
Health Service Executive (2015)[78] Ireland	<u>Setting</u> 3 acute hospitals <u>Population</u> Medical and surgical inpatients	To establish compliance with selected criteria from the NEWS national clinical guideline	National clinical audit	30 (10 per site)	NCG No. 1 for the National Early Warning Score (NEWS)	NEWS <u>Parameters</u> - HR - RR - Systolic BP - levels of	Compliance with completion Escalation protocol Formal communication protocol in use	<u>Completion</u> 3/3 sites — patient demographics and vital signs recorded 1/3 sites — incorrect totals	The National Director, Acute Care Division must engage with senior management in all acute hospitals with regard to the following recommendations: 1. Agree an organisational

Authors Year Country	Study setting and population	Aim of study	Study design	Participants	Performance measurement	Reference standard	Outcomes	Results	Authors key recommendations
						consciousness - oxygen saturation - oxygen route - temperature.	(ISBAR) Education programme Emergency response system	Vital sign adjustments made: 17/30 (57%) Time of adjustment recorded: 12/17 (70%) <u>Escalation</u> Documentation of nurse in charge being informed of NEWS ≥ 3: 0% Frequency of observations within recommended time frame: 15/30 (50%) Documentation of nurse contacting senior house officer or registrar: 21/27 (78%) Record of time senior house officer or registrat	response to the management of adjustments to physiological parameters for patients. 2. Reinforce the processes in relation to the utilisation and accurate completion of the National Adult Patient Observation Chart as per the NCG. 3. Reinforce the requirement to date and time all entries/ observations on the National Adult Patient Observation Chart. 4. Reinforce the stages of the protocol for escalation of care to include an agreed structured communication.

Authors Year Country	Study setting and population	Aim of study	Study design	Participants	Performance measurement	Reference standard	Outcomes	Results	Authors key recommendations
								reviewed patient: 12/21 (59%) Completion of ISBAR tool 17/27 (63%) Education Attendance at NEWS update training during 2014 ranged between 48–67% Emergency response system All sites used the cardiac response system	
Higgins (2008)[63] England	Setting 1 hospital trust Population Unspecified	Unclear	Full audit cycle Before and after	1,140 observations	All inpatients have a minimum of at least 1 full set of observations in a 24 hr period Target: Q1: 60% Q2: 75%	Modified early warning score Parameters - HR - RR - Temperature - central	Full set of observations	Full set of observations Q1: 695/1140 (61%) Q4: 1117/1140 (98%)	The standard was included in all clinical education programmes run by the trust. Early warning scores have been included in the nursing undergraduate curriculum in a partner university.

Authors Year Country	Study setting and population	Aim of study	Study design	Participants	Performance measurement	Reference standard	Outcomes	Results	Authors key recommendations
					Q3: 90% Q4: 100%	nervous system - urine - systolic BP - oxygen saturation.			Continuous audit has created an atmosphere where improvements made have been sustained.
Leech (2014)[64] England	<u>Setting</u> 1 university teaching hospital <u>Population</u> Adults, excluding: emergency medicine, coronary care, burns, perioperative and intensive care, end-of-life care	Not reported	Conference abstract Before and after	619 patients Before: 303 After: 316	Not reported	EWS <u>Parameters</u> Unspecified	Compliance with EWS	<u>Compliance</u> Before: 39% (range 12–94%) After: 75.6% (range 61–96%) p<0.0001.	A targeted approach to training in the use of and rationale for MEWS charts significantly improved chart completion and compliance of chart completion, potentially increasing the ability of staff to recognise at-risk adult patients.
Lobo (2015)[79] Ireland	<u>Setting</u> 1 acute hospital <u>Population</u> Medical admissions (acute or elective) that	To determine the clinical relevance in medical patients who presented with or subsequently reached a NEWS score of ≥7 by determining if	Cross-sectional audit Retrospective (April 2012 – June 2012)	79 patients	NEWS score of ≥7 warrants immediate review by the team registrar or registrar on call. It recommends continuous	NEWS <u>Parameters</u> - RR - oxygen saturation - oxygen supplem	Change in clinical management CREWS score (applied to patients with chronic hypoxaemia)	<u>Change in clinical management</u> 51/79 (64.6%) had no change in clinical management for their first episode	NEWS has a lack of sensitivity in specific subgroups of patients such as patients with chronic hypoxaemia. Patients with respiratory conditions often have oxygen saturations below normal even when their condition is stable.

Authors Year Country	Study setting and population	Aim of study	Study design	Participants	Performance measurement	Reference standard	Outcomes	Results	Authors key recommendations
	had at least one NEWS score of ≥7 at any point during hospitalisation	there was any change in clinical management of these patients			patient monitoring, activating the emergency response system and planning transfer to a higher level of care.	ent - systolic BP - pulse rate - AVPU - temperature Chronic respiratory early warning score (CREWS) <u>Parameters</u> Unspecified		48/51 (94.1%) discharged home 39/51 (76.5%) NEWS score was determined to be acceptable based on clinical assessment of the patient by the medical team 12/51 (23.5%) doctor was not informed about the NEWS score of ≥7 23/51 patients had a repeat NEWS score ≥7 17/23 (73.9 %) had no further change in treatment <u>CREWS score</u> When the	Application of CREWS scoring could reduce the triggers.

Authors Year Country	Study setting and population	Aim of study	Study design	Participants	Performance measurement	Reference standard	Outcomes	Results	Authors key recommendations
								CREWS score was applied, the number of patients with early warning score ≥7 was reduced to 11 (70.3% reduction)	
Marler-Hausen (2011)[65] England	Setting 1 hospital Population Bone marrow transplant patients	To determine effective implementation of Physiological Observation Track and Trigger score (POTTS) To determine whether it is effective predictor to identify patients who deteriorate	Conference abstract Retrospective audit 3 month period	35	Not reported	POTTS Parameters Unspecified	Compliance rates	Compliance rates 5,259 observations completed 98.2% had POTTS score	A nurse-led morbidity and mortality meeting is being developed to help focus on the associated nursing issues and interventions. A simple audit tool will be developed to evaluate practice and identify trends for the future.
McBride (2005)[66] England	Setting 1 hospital Population 6 wards: 2 orthopaedic, 2 surgical, 2 medical	To determine the short- and long-term effects of introducing the modified early warning score on the prevalence of respiratory rate recording	Before and after (after only reported) Audit period before: 17 weeks After: 4 weeks	1,851 After: 600	Not reported	Modified early warning score Parameters Unspecified	Percentage of occupied beds in which at least one RR recording had been made in the prior 24 hrs	Percentage of occupied beds in which at least one RR recording had been made in the prior 24 h After: 91.2 ± 5.6	This study confirms the beneficial effect of introducing the modified EWS system.

Authors Year Country	Study setting and population	Aim of study	Study design	Participants	Performance measurement	Reference standard	Outcomes	Results	Authors key recommendations
McCormick (2005)[67] Northern Ireland	Setting 1 hospital Population 3 acute surgical wards	To develop and implement an observation chart with integrated early warning score	Before and after (after only reported)	Not reported	Not reported	Early warning score Parameters Unspecified Traffic light system	Frequency of observations Most frequent abnormal parameters	Frequency of four-hourly observations After: 50% Most frequent abnormal parameters scores >1: Temperature, BP and HR. Urine output did not appear to be useful in this sample.	
Mukhal (2013)[68] England	Setting Unspecified Population patients with NEWS ≥6	To determine if the NEWS system was being used effectively to identify patients	Conference abstract	Not reported	Not reported	NEWS Parameters Unspecified	Accuracy of documentation Actions taken and agreement with locally agreed protocol	NEWS scores documented correctly 24% Actions taken Majority of escalated cases were to the wrong member of the team, namely, the junior doctor The outcome of medical reviews failed to produce clear	The results of the initial audit indicated that not only was the NEWS poorly used but also escalation of these patients did not meet the gold standard. The findings were presented at a local clinical governance meeting and actions agreed before re-auditing.

Authors Year Country	Study setting and population	Aim of study	Study design	Participants	Performance measurement	Reference standard	Outcomes	Results	Authors key recommendations
								management plans	
Niegsch (2013)[83] Denmark	Setting 1 acute teaching hospital Population 12 wards, 269 beds	To assess degree to which guidelines were being followed	Cross-sectional audit Prospective 7 days	132 patients	All patients to have EWS recorded at least 3 times daily during the first 24 hours of admission unless a doctor decides otherwise EWS = 0 during the first 24 hours, EWS recording frequency can be reduced to once a day	Early Warning System Parameters - RR - BP - breath rate - temperature - Glasgow Coma Scale - oxygen saturation.	Proportion of patients who were observed and managed in accordance with chart guidelines Proportion of patients who had each EWS element recorded Proportion of patients with EWS calculated Proportion of patients with abnormal EWS (>0) recorded with documentation of appropriate action taken Proportion of patients with abnormal EWS recorded by investigator with staff aware that	Proportion of patients who were observed and managed in accordance with chart guidelines 77/132 (58%) Each EWS element recorded 101/132 (77%) Proportion of patients with EWS calculated at least once within 24 hours prior to audit 101/132 (77%) Proportion of patients with abnormal EWS (>0) 50/132 Appropriate action taken 19/50 (38%)	Authors suggest a redesign of current training programmes to educate staff in recognising and caring for critically ill patients.

Authors Year Country	Study setting and population	Aim of study	Study design	Participants	Performance measurement	Reference standard	Outcomes	Results	Authors key recommendations
							the patient had abnormal EWS Interobserver agreement (Cohen's Kappa) between staff and investigator regarding abnormal EWS	<u>Patients with abnormal EWS recorded by investigator</u> 73 44/73 (60%) staff was aware that the patient had abnormal EWS <u>Cohen's Kappa</u> Not reported	
Nwulu (2012)[69] England	<u>Setting</u> 2 teaching hospitals <u>Population</u> 6 inpatient wards	To describe the adoption of an electronic observation charting function	Audit April – July 2010	149 beds	Not reported	SEWS <u>Parameters</u> - temperature, - BP - oxygen saturation - RR - pulse - consciousness level.	Percentage of complete SEWS	<u>Percentage of complete SEWS</u> 80.5% <u>Charts with missing vital signs (VS) (that is, no SEWS)</u> 5 VS only: 12.4% (AVPU most often missing) 4 VS only : 2.9% 3 VS only: 0.8% 2 VS only: 0.9% 1 VS only: 2.6%	
Oakey (2006)[70]	<u>Setting</u> 1 general hospital	To improve the recording and accuracy of EWS	Audit 5 weeks	264 beds	Not reported	POTTS score <u>Parameters</u>	Charts completed and correct	<u>Completed charts</u> 255/264 (97%)	

Authors Year Country	Study setting and population	Aim of study	Study design	Participants	Performance measurement	Reference standard	Outcomes	Results	Authors key recommendations
England	<u>Population</u>	calculation				Unspecified		<u>Charts completed and correct</u> 246/264 (90%)	
Page (2008)[84] Australia	<u>Setting</u> Acute private hospital <u>Population</u> 2 wards: 1 neurovascular, 1 orthopaedic	To pilot a nursing tool, comprising a colour-coded observation chart and response algorithm, to support ward nurses in the early identification of and rapid response to deteriorating patients on two general wards	Pilot study audit 8 weeks	71 beds	Not reported	Mater Private Modified Early Warning System <u>Parameters</u> - temperature - systolic BP - HR - Breaths - oxygen saturation - conscious level (AVPU) - urine output - chest pain.	Compliance rate Average medical emergency team calls called per month	<u>Compliance rate</u> Ward 1: 89.8% Ward 2: 92.3% <u>Average medical emergency team calls calls(per month)</u> Ward 1 Before pilot: 2.75 After pilot: 1.5 Ward 2 Before pilot: 2.08 After pilot: 1.5	Further research is needed to evaluate the success of the EWS in order to modify it further.

Authors Year Country	Study setting and population	Aim of study	Study design	Participants	Performance measurement	Reference standard	Outcomes	Results	Authors key recommendations
Paterson (2006)[71] Scotland	Setting 1 hospital Population Unselected emergency medical and surgical admissions	To assess the impact of the introduction of a SEWS on physiological observations and patient outcomes	Before and after (after only reported)	848 patients 413 pre-SEWS 435 post-SEWS Median age pre-SEWS: 67 post-SEWS: 69	Not reported	SEWS Parameters - RR - oxygen saturation - temperature - systolic BP - HR - consciou s level.	Completeness of documentation of physiological parameters	Documentation of all physiological parameters Post-SEWS: 328/435 (75.6%) Documentation of physiological parameters Post-SEWS: RR: 376 (86.6%) SaO2: 416 (95.9%) Temperature: 416 (95.9%) BP: 433 (99.8%) HR: 430 (99.1%) AVPU: 402 (92.6%)	A system such as SEWS should be standard practice in the acute setting.
Patterson (2011)[72] England and Scotland	Setting All hospitals in London and Scotland with acute medical units Population Acute medical admission	To review the use of track and trigger systems in all hospitals admitting acute medical patients, and to compare current practice with national guidelines	Audit	48 hospitals London: 25 Scotland: 23	Compliance with audit standards for early warning score	Early warning scoring systems	Systems in use Type of system Parameters used Use of triggers additional to NICE recommendations Adherence to optimal scoring	Number of different systems in place London: 11 Scotland: 5 Type of system **Single parameter** London: 10 (40%) Scotland: 0	Results show widespread adoption of NEWS and may be enhanced by the provision of a single structured scoring system with associated documentation and a strategy for training, audit, and review.

Authors Year Country	Study setting and population	Aim of study	Study design	Participants	Performance measurement	Reference standard	Outcomes	Results	Authors key recommendations
								Multiple parameter London: 1(4%) Scotland: 1 (4%) **Aggregate-weighted scoring systems** London: 14 (56%) Scotland: 22 (96%) <u>Parameters included</u> **HR** Scotland: 23(100%) London: 25(100%) **RR** Scotland: 23 (100%) London: 25(100%) **Systolic BP** Scotland: 23 (100%) London: 25(100%) **Level of**	

Authors Year Country	Study setting and population	Aim of study	Study design	Participants	Performance measurement	Reference standard	Outcomes	Results	Authors key recommendations
								consciousness Scotland: 23 (100%) London: 18 (72%) **Oxygen saturation** Scotland: 16 (70%) London: 15 (60%) **Temperature** Scotland: 23 (100%) London: 20 (80%) **All of the above** Scotland: 16 (70%) London: 10 (40%) Phi coefficient = 0.30 **All of the above plus urine output** Scotland: 13(57) London: 6(24) Phi coefficient = 0.29	

Authors Year Country	Study setting and population	Aim of study	Study design	Participants	Performance measurement	Reference standard	Outcomes	Results	Authors key recommendations
								Hospitals using additional triggers London: 17/25 (68%) Scotland: 21/23 (91%) Additional physiological parameters triggers to minimum NICE recommendations: **Age >70 years** Scotland: 1 (4%) London: 0 **Pain** Scotland: 0 London: 1 (4%) **Peripheral hypoperfusion** Scotland: 1 (4%) London: 0 **Subjective clinical concern** Scotland: 0 London: 2 (8%)	

Authors Year Country	Study setting and population	Aim of study	Study design	Participants	Performance measurement	Reference standard	Outcomes	Results	Authors key recommendations
								Supplemental oxygen Scotland: 1 (4%) London: 6 (24%) **Sweating** Scotland: 1 (4%) London: 0 **Urine output** Scotland: 20 (87%) London: 17 (68%) **White cell count** Scotland: 1 (4%) London: 0 <u>Adherence to optimal scoring</u> London: 6/25 (24%) Scotland: 14/23 (61%)	
Quarterman (2005)[73] England	<u>Setting</u> 1 university teaching hospital <u>Population</u> Medical and surgical wards	To audit and support the introduction of a modified early warning scoring system	Audit June 2002 – May 2003	365 patients 619 triggers 63% male	Not reported	Modified early warning scoring <u>Parameters</u> - RR - systolic BP	Calculable charts Timing of trigger scores Number patients with scores and patient	68% of charts were calculable <u>Timing of recording</u> 06:00hrs –14:00 hrs: 43% 14:00hrs –	

Authors Year Country	Study setting and population	Aim of study	Study design	Participants	Performance measurement	Reference standard	Outcomes	Results	Authors key recommendations
						- HR - APVU - temperature, - urine output.	outcome	22:00: 49% 22:00hrs – 06:00hrs: 8% <u>Score 3–4:</u> *n* = 236 Died: 41/236 (17.4%) <u>Score ≥ 5:</u> *n* = 105 Died 35/105 (33.3%)	
Smith (2011)[74] England	<u>Setting</u> 1 hospital trust <u>Population</u> Unspecified	Preventing harm and reducing in-hospital cardiac arrest and mortality through earlier recognition and treatment of deteriorating patients.	Before and after	120 patient	Not reported	EWS <u>Parameters</u> Unspecified	Most recent EWS recorded Most recent and all EWS recorded Correct action taken Action documented Observations recorded at appropriate frequency Observations prescribed for alternative	<u>Most recent EWS recorded</u> Before: 86% After: 93% <u>Most recent and all EWS recorded</u> Before: 63% After: 78% <u>Correct action taken</u> Before: 71% After: 88% <u>Action documented</u> Before: 63% After: 86%	

Authors Year Country	Study setting and population	Aim of study	Study design	Participants	Performance measurement	Reference standard	Outcomes	Results	Authors key recommendations
							frequency	Observations recorded at appropriate frequency Before: 62% After: 91% Observations prescribed for alternative frequency Before: 58% After: 92%	
Staveacre (2014)[75] England	Setting 1 acute hospital Population 3 acute medical wards	Not reported	Conference abstract Before and after 12 month period	Not reported	Not reported	NEWS Parameters Unspecified	Referral to outreach Cardiac arrests	Referral to outreach (mean per month) Before:36.6 After:182 397% increase Cardiac arrests Before:13 After:5	A multi-layered implementation of NEWS, including structured response systems and communication tools, results in wide spread acceptance and uptake.
Sterling (2002)[76] UK	Setting 1 hospital Population 5 acute, general adult medical and surgical wards 2 month period	To establish the sensitivity of Lewisham patient-at-risk trigger scoring system (PAR-T) for identifying patients at risk of developing critical illness, and to measure	Prospective audit	70 patients	Not reported	PAR-T Parameters - HR - BP - RR - SpO2 - Temperature - level of	Time patient was seen after trigger Grade of doctor attending patients who trigger Patient outcome after trigger	Time patient was seen in within 30 mins: 62% ≥1 hr: 8% Grade of doctor Registrar: 45% House officer: 24% Not seen: 15%	More training is required. Chronic patients triggered more so the thresholds were reviewed for these patients. Due to workload, the protocol was amended to escalate to middle grade clinicians as opposed to

Authors Year Country	Study setting and population	Aim of study	Study design	Participants	Performance measurement	Reference standard	Outcomes	Results	Authors key recommendations
		outcomes of patients who triggered and evaluate the protocol for managing them				consciousness - urine output - pain.		Consultant: 5% Senior house officer: 4% Night nurse practitioner: 3% Unknown: 4% <u>Patient overall outcome at end of audit</u> Died: 51% In hospital: 21% Home: 11% Transferred: 3% Unknown: 14%	senior clinicians.
Strange (2009)[77] Northern Ireland	<u>Setting</u> 1 hospital <u>Population</u> Consecutive emergency ICU admissions	To assess the calculation of EWS, the scores of patients admitted to ICU and the compliance with guidelines regarding further intervention for patients who were admitted to ICU	Conference abstract 24 hr period	25 patients	Not reported	EWS <u>Parameters</u> Unspecified	Not reported	<u>EWS charts completed</u> 96% of emergency ICU admissions 88% calculated correctly <u>Complete EWS parameters</u> 32% <u>EWS score and ICU mortality rate</u> EWS 3–7: 10.5% EWS 8–10: 80%	Following audit, the following were introduced: a critical care outreach team educational programme for staff with emphasis both on the complete and accurate recording of EWS scores and the necessity for appropriate action to be taken on the basis of these scores.

Authors Year Country	Study setting and population	Aim of study	Study design	Participants	Performance measurement	Reference standard	Outcomes	Results	Authors key recommendations
Teoha (2017, unpublished data)[80] Ireland	Setting Tertiary referral centre Population 1 medical, 1 surgical ward, all patients admitted under the Infectious Disease Service	To measure the receiver operating characteristics, sensitivity, specificity, positive-predictive value and negative-predictive-value of the EWS for early identification of sepsis	Prospective Audit	86 patients EWS ≥ 4	Not reported	EWS Parameters Unspecified	Patients EWS score National Sepsis form completion rate Average time for review from trigger Sepsis-6 completion rate Average time to completion of sepsis-6 Median time to first antibiotic from trigger	EWS score 4–6: 55 ≥7: 31 National Sepsis form completion rate: 11/86 (12.8%) Average time for review from trigger: 49 minutes Sepsis-6 completion rate: 53/63 (84.13%) Average time to completion of sepsis-6: 86.7 minutes Median time to first antibiotic: 59 minutes	

Key: AVPU — alert, voice, pain, unresponsive; BP — blood pressure; CAU — combined assessment unit; CPR — Ccardiopulmonary resuscitation; CREWS — chronic respiratory early warning score; DMEWS — Derby Modified Early Warning System; DMSEWS—- Defence Medical Services Early Warning Score; EWS — early warning score; ICU — intensive care unit; ISBAR — identify, situation, background, assessment and recommendation; NCG — National Clinical Guideline; NEWS — National Early Warning Score; PAR-T — patient-at-risk trigger scoring system; POTTS — Physiological Observation Track and Trigger Score; RCP — Royal College Of Physicians; RR — respiratory rate; SDU — step down unit; SEWS — standardised early warning scoring system; SHO — senior house officer; ViEWS — VitalPAC Early Warning Score; VS — vital sign

4.4.4.4 Emergency department

Of the three studies identified in emergency department populations, one was a conference abstract. All studies were conducted in the UK, as summarised in Table 4.8. Two studies were conducted in medical assessment units (MAU)[87, 88] and one in an emergency department.[85]

Of the two studies that specifically stated the early warning score parameters, RR, HR, BP and temperature were common to both.[85, 88] Additional parameters included oxygen saturation and neurological status[88] and central nervous system function and urine output.[85]

Two studies assessed compliance rates. Patients had a documented score between 70%[87] and 84% of the time.[85] One study highlighted that scores were accurate and complete in 95% of charts.[85] Documentation of actions taken were reported in 66% of cases.[85] Where patients required review, 31% were reviewed within one hour.[87]

In a before and after study, Morris et al. reported an increase in compliance and the accuracy of completion of early warning scores following staff training.[88] Overall, they found an increase in the frequency of observations being recorded and an increase in the frequency of recording in all parameters, particularly with RR (from 58% to 88%) and neurological status (from 41% to 100%).

Many of the authors highlighted the importance of education and training[87, 88] and audit.[88]

Table 4.8. Characteristics of included clinical audits in emergency department populations

Authors Year Country	Study setting and population	Aim of study	Study design	Participants	Performance measurement	Reference standard	Outcomes	Results	Authors key recommendations
Altemimi (2010)[87] England	Setting 1 district general hospital (500 beds) Population MAU	To measure key performance indicators in the MAU and identify specific areas for improvement	Conference abstract Retrospective audit 1 week study period	149 patients Age range: 16–94	Not reported	EWS Parameters Unspecified	Documentation of EWS Decision to escalate treatment for patients with high EWS	Documentation of EWS on admission 70% Decision to escalate EWS>3: 13 (9%) Reviewed within 1 hour: 4/13 (30.7%)	The Critical Care Outreach team have prominent role in education to identify abnormal physiology early and take action as appropriate.
Morris (2010)[88] England	Setting 1 MAU Population Unspecified	Audit of EWS chart completeness and frequency of observation before and after implementation of training	Before and after	20 patients Before: 12 After: 8	Not reported	EWS Parameters - RR - oxygen saturation - temperature - HR - BP - Neurological.	Frequency of observations Frequency of observations by parameter	Frequency of observations **Before** Patients admitted < 18 hours: 7, no observations Patients admitted 18–48 hrs: 3, 2 sets of observations Patients admitted > 48 hrs: 2, 8 sets of observations Frequency of observations	The initial stages of the change process appear to have been successful, with minimal resistance and good compliance. Education within the medical unit is a long-term project, requiring the full commitment of senior staff. The responsibility for stabilization and monitoring practice remains with the unit manager and her deputy.

Authors Year Country	Study setting and population	Aim of study	Study design	Participants	Performance measurement	Reference standard	Outcomes	Results	Authors key recommendations
								After Patients admitted < 2 hrs: 4, no observations Patients admitted 4 hrs: 1, 3 sets of observations Patients admitted 5 hrs: 2, 3 sets of observations Patients admitted 12 hrs: 1, 11 sets of observations <u>Frequency of observations by parameter</u> i) RR **Before:** 7/12 (58%) **After:** 7/8 (88%) ii) O2 saturation **Before:** 11/12 (98%) **After:** 8/8 (100%)	Audit will be repeated in 3 months to identify whether current standards are maintained and to identify areas for further educational input.

Authors Year Country	Study setting and population	Aim of study	Study design	Participants	Performance measurement	Reference standard	Outcomes	Results	Authors key recommendations
								iii) Temperature **Before:** 9/12 (75%) **After:** 6/8 (75%) iv) HR **Before:** 12/12 (100%) **After:** 8/8 (100%) v)BP **Before:** 11/12 (91%) **After:** 8/8 (100%) vi) Neurological **Before:** 5/12 (41%) **After:** 8/8 (100%)	
Windle (2009)[85] England	<u>Setting</u> 1 emergency department (ED) <u>Population</u> GP lodgers (patients referred by their GPs to ED when there are no beds	To audit the use of modified Patient At Risk (mPAR) early warning scores for GP lodgers To assess how well ED staff could use them with little training	Audit review 11 weeks	165	Not reported	mPAR <u>Parameters</u> - BP - HR - RR - Temperature - central nervous system function	Not reported	<u>mPAR scores calculated on arrival</u> 84% (139/165) <u>Scores correctly calculated</u> 95% (132/139) <u>Scores calculated on arrival</u> 87%	Using mPAR will be continued for all adult GP lodgers, even though doing so has little additional benefit for patients in the emergency department.

Authors Year Country	Study setting and population	Aim of study	Study design	Participants	Performance measurement	Reference standard	Outcomes	Results	Authors key recommendations
	available)	and to compare how patient need is prioritised using mPAR				- urine output.		Time to complete mPAR scores (mean minutes) 8.1 Documentation of action taken 66%	

Key: BP — blood pressure; EWS — early warning score; MAU — medical assessment unit; mPAR — modified Patient At Risk; RR — respiratory rate

4.4.4.5 Mixed population

Two studies evaluated the use of early warning systems across mixed populations (that is, adults and paediatrics), as summarised in Table 4.9. Both studies were conducted in the UK.[89, 90] One related to acute care[90] while the other related to patients admitted to ICU or HDU.[89]

The Guidelines and Audit Implementation Network (GAIN) study assessed the compliance of hospitals in Northern Ireland with existing regional and local guidance and with an internationally recognized model of good practice in dealing with the acutely ill and or deteriorating patients.[89] The study assesses 21 indicators, as presented in Appendix 4. With regards to documentation, a chart was complete on average in 91% of patients. However, all parameters were completed within each set of observations in only 34% of patients and a total score for each set of observations was calculated correctly in 31%. In relation to escalation, overall compliance with hospital trust guidance on whom to contact when a threshold was breached was relatively high, at around 90%. However, there was poor compliance with guidance that all charts/clinical notes should contain an indication of the required frequency of observations for that patient at 19.5% overall. A full list of the recommendations is presented in Appendix 4.

In a before and after study, Wood et al. aimed to increase compliance with completion of both an adult and a paediatric early warning score in one hospital in England.[90] The service improvement strategy consisted of multi-faceted, inter-professional high impact interventions, including ward-delivered education, human factors training and clinician feedback, combined with regular performance audits. The approach increased the performance of four-hourly observations (from 65% to 96%), correct scoring (from 88% to 93%), correct nursing escalation (from 22% to 57%) and correct medical escalation (from 31% to 37%).

Table 4.9. Characteristics of included clinical audits in multiple patient populations

Authors Year Country	Study setting and population	Aim of study	Study design	Participants	Performance measurement	Reference standard	Outcomes	Results	Authors key recommendations
GAIN (2011)[89] Northern Ireland	Setting 5 hospital trusts Population Medical/ surgical inpatients ≥ 14 years admitted to ICU/ HDU	To assess compliance of Northern Ireland hospital physiological early warning scoring system (PEWSS) practice with existing regional and local guidance and with an internationally recognized model of good practice in dealing with the acutely ill and or deteriorating patient	Retrospective case note audit November 2007 to October 2008	413 patients	21 audit indicators, which are summarised in Appendix 4 PEWSS chart complete: 100% Required frequency of observation: 100% All parameters were completed within each set of observations: 100% Correct Score: 100%	All physiological Early Warning Scoring System (PEWSS) in use in Northern Ireland trusts	PEWSS chart complete Required frequency of observations Percent of parameters completed within each set Correct score	PEWSS chart complete: 375/413 (90.8%) Chart contains indication of required frequency of observations 19.5% Percent of parameters completed within each set 34.1% Correct score: 31.4% Compliance with Trust guidance on whom to contact when a threshold is breached 90%	See Appendix 4
Wood (2015)[90] England	Setting 1 acute teaching hospital Population	To increase compliance with completion of an adult early EWS and	Audit Before and after	Not reported	1. At least 75% patients should have 4 hourly observations 2. EWS correctly	EWS paediatric EWS	4 hourly observations EWS correctly scored and	4 hourly observations Before: 65% After: 96% Correct score	In embedding an EWS tool in any trust, the first step must be ascertaining compliance and defining the culture.

	6 wards: 1 short and 1 long stay acute medical admission, 1 surgical admission, 1 respiratory assessment, 1 specialist receiving unit and 1 paediatric acute admissions	paediatric EWS tool (PEWS)			scored and added up ≥95% patients 3. Where frequency of observations should have been increased, this should be done correctly in at least 35% 4. Mandated nursing escalation interventions should be carried out in at least 35% of patients 5. Mandated medical escalation should be carried out in at least 35% of patients, that is, reviewing patient within a set timeframe, involvement of senior medical staff if no immediate improvement and documentation of a management plan		added up Observations increased appropriately Correct nursing escalation Correct medical escalation	Before: 88% After: 93% <u>Observations increased appropriately</u> Before: 36% After: 50% <u>Correct nursing escalation</u> Before: 22% After: 57% <u>Correct medical escalation</u> Before: 31% After: 37%	

Key: EWS — early warning score; ICU — intensive care unit; HDU — high dependency unit; PEWSS — physiological early warning scoring system

4.4.4.6 Quality of studies

All 31 full-text clinical audit studies (four in obstetric populations and 27 in all other populations) were assessed in according to the HSE Clinical Audit Checklist[15] in terms of reporting the standard/criteria selection, measuring performance, making improvements and sustaining improvements. The full assessment is presented in Table 4.10.

Reporting in relation to identifying the standards and audit criteria against which the audit was conducted was poor in the included clinical audit studies. In particular, details on the early warning score used were unclear or not specified in 50% (2/4) of obstetric audits and 51% of all other studies (14/27). A defined level or degree of expected compliance with audit criteria (performance levels) was unclear or not specified in 50% (2/4) of obstetric audits and 59% of all other studies (16/27).

Performance measurement was generally well reported in all included audits. Seventy-five percent of obstetric audits (3/4) while 63% (17/27) of all other studies specified the data collection tools utilised. Appropriate descriptive statistics were reported in 75% (3/4) of obstetric audits, and 89% (24/27) of all other studies. Half (2/4) of obstetric audits and 85% (23/27) of all other studies reported the results in full.

Making improvements and sustaining change was only considered applicable to studies that were before and after design or full audit cycles. Cross-sectional type audits of compliance were not considered in this domain. There were 14 full-text studies meeting this criterion, two in obstetric populations and 12 in all other populations. Of these, 50% (1/2) of obstetric audits and 75% (9/12) of all other studies identified areas for improvement where the required standards were not being met. Furthermore, none of the obstetric audits and 67% (8/12) of the other studies developed quality improvement plans. However, only 50% (6/12) of the other studies identified the person responsible, reasonable timescales or progress measurements, and, in 92% (11/12) of these cases, how changes were supported was unclear or not specified.

Table 4.10. Reporting quality of included clinical audits

Author	Component													
	Audit topic clearly stated	Objective clearly stated	Standard identified and evidence based	Identified audit criteria	Set targets/ performance levels	Appropriate inclusion/ exclusion criteria	Appropriate data collection tools	Appropriate statistical techniques	Presented results in full	Reviewed areas for improvement and agreed priorities for action	Identified appropriate interventions	Developed quality improvement plan	Identified: persons responsible, reasonable timescale, progress measurement	Ensured that change was supported
Carter 2013[81]	Yes	Yes	Unsure	Yes	No	Yes	Unsure	Yes	Yes	Yes	Yes	Yes	No	No
Conway-Habes 2017[82]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Day 2003[59]	Yes	Yes	Unsure	Yes	Yes	Yes	Yes	Yes	Yes	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Ennis 2014[52]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Unsure
Gordon 2011[61]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
GAIN 2011[89]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Hands 2013[62]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Unsure	Yes	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
HSE 2014[42]	Yes	Yes	Yes	Yes	No	Yes	Unsure	Unsure	No	Yes	Yes	No	No	No
HSE 2015[78]	Yes	Yes	Yes	Yes	Yes	Yes	Unsure	Yes	Yes	Yes	Yes	No	No	No
HSE 2017[53]	Yes	Yes	Yes	Yes	Yes	Unsure	Yes	Yes	Yes	Yes	No	Yes	Yes	No
Higgins 2008[63]	Yes	Unsure	Yes	Yes	Yes	Unsure	Unsure	Unsure	Yes	Yes	Yes	Yes	Unsure	Unsure
Lobo 2015[79]	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Mackintosh 2014[33]	Yes	Yes	No	No	No	Yes	Yes	Yes	Unsure	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Maguire 2015[43]	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	No	No	No	No	No
McBride 2005[66]	Yes	Yes	Yes	Yes	No	Unsure	Unsure	Yes	Yes	No	No	No	No	No
McCormick 2005[67]	Yes	Yes	Unsure	Yes	No	Unsure	Unsure	Yes	Yes	No	No	No	No	No
Morris 2010[88]	Yes	Yes	Yes	Yes	No	Unsure	Unsure	Yes	Yes	Yes	Yes	Yes	Yes	Unsure
Niegsch 2013[83]	Yes	Yes	Unsure	Yes	Yes	Yes	Yes	Yes	No	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Nwulu 2012[69]	Yes	Yes	Unsure	Yes	No	Yes	Yes	Yes	Yes	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Oakey 2006[70]	Yes	No	Yes	Yes	No	Yes	Unsure	Yes	Yes	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Page 2008[84]	Yes	Yes	Unsure	Yes	No	Unsure	Unsure	Yes	Yes	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Paterson 2006[71]	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	No	No	No	No	No
Patterson 2011[72]	Yes	Yes	Unsure	Yes	Unsure	Yes	Yes	Yes	Yes	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Quarterman 2005[73]	Yes	Yes	Unsure	Yes	No	Yes	Yes	Yes	Yes	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Smith 2011[74]	Yes	Yes	Unsure	Yes	No	Unsure	Unsure	Yes	Unsure	Yes	Yes	Yes	Yes	Unsure
Smith 2017[41]	Yes	Yes	Unsure	No	No	Yes	Yes	Yes	Yes	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Sterling 2002[76]	Yes	Yes	Unsure	Yes	No	Yes	Yes	Yes	Yes	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Teoha 2017[80]	Yes	Yes	Unsure	Yes	No	Yes	Yes	Unsure	No	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Watson 2014[55]	Yes	Yes	Unsure	Yes	No	Yes	Yes	Yes	Yes	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Windle 2009[85]	Yes	Yes	Unsure	No	No	Yes	Unsure	Yes	Unsure	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Wood 2015[90]	Yes	Yes	Unsure	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

5 Conclusion

5.1 Summary of findings

This systematic review involved an update of the previous systematic review of clinical effectiveness and cost-effectiveness conducted to support the development of the IMEWS guideline[8] and a new systematic review to identify clinical audits of early warning systems. For the update, one effectiveness study, eight development and or validation studies, one health economics study and two references to the current IMEWS guideline were identified. For the new systematic review 61 audits were identified, eighteen of which were conducted in obstetric populations.

5.2 Context of previous review and implications for guideline recommendations

The previous review to support the development of the IMEWS guideline was conducted in April 2014.[8] This review identified one effectiveness study, a before and after study that found that the implementation of a physiological observation track and trigger system (POTTS) in a maternity unit was associated with improved observation documentation and a higher level of medical involvement.[8] However, this evidence is from a conference abstract of a before and after study. While this study demonstrates improved observation documentation, it does not provide any evidence on improving maternal outcomes. For the current update, we identified one further controlled before and after study, which found severe maternal morbidity was significantly reduced after the introduction of a clinical pathway-specific maternal early warning trigger. This additional study was of poor methodological quality and only marginally improves the evidence base in this area.

The previous review identified six studies (reported across nine citations) on the development/validation of maternity early warning systems.[8] The review concluded that there was relatively little high-quality evidence on developing and testing the predictive ability of MEWS and the majority of work has been performed with selected high-risk

populations using mortality or severe morbidity outcomes. The studies included reported wide variation in predictive components depending on the MEWS used. This limited the applicability of the evidence to inform decisions on implementation of MEWS routinely on an unselected maternity population. The eight studies included in this current update do not strengthen the evidence base in this area. The additional studies are also of poor methodological quality, and the majority of work continues to be performed in high risk populations.

The previous review did not identify any economic analysis of MEWS.[8] This update identified one conference abstract that provided cost-effectiveness data. The study found that the use of a maternal early warning trigger tool reduced severe maternal morbidity, which translated into significant cost savings. As this study was available in abstract form only, there is relatively little evidence to inform decisions on the economic impact of MEWS.

For this current review, a new question was added to identify and describe clinical audits of any early warning system in obstetrics and other hospital settings. The findings from this review highlight that the majority of clinical audits in this area are conducted in relation to general early warning systems with fewer clinical audits focused specifically on maternity early warning scores. The descriptive studies included in the previous review highlighted that compliance rates were generally low.[8] The clinical audits identified in this review highlight that compliance with documentation and escalation policies remains an issue.

The previous review found that education and training appeared to assist in improving compliance rates with maternal early warning systems, and that compliance diminished over time.[8] This current review did not identify any evaluations of education programmes in the delivery of early warning scores. Consequently, what form this education should take, how often it should be conducted and who should deliver and attend is not clear from the literature. Interestingly, one of the few studies to explore compliance from a temporal perspective highlighted that adherence to expected monitoring schedules was lower at night time than during the day. The authors suggested that staff adhered to the protocol when possible but not when important patient and clinical activities, staffing levels and

monitoring equipment availability impinged on it. This suggests that poor compliance may be due to other important factors other than simply a lack of knowledge.

This current review did not identify any evaluations of communication tools in the delivery of early warning scores. However, National Clinical Guideline (No 5) Communication (Clinical Handover) in Maternity Services recommends that the ISBAR communication tool should be used when communicating information in relation to deteriorating and or critically ill patients. Where a situation is deemed to be critical, this must be clearly stated at the outset of the conversation.[91]

Overall, the results of this systematic review demonstrate the literature in this area has not evolved substantially from the last review and there is little new evidence to inform substantial changes to the previous recommendations.

5.3 Implications for research

5.3.1 Effectiveness studies

There is a dearth of studies on the effectiveness of introducing an early warning or track and trigger system on processes of care and patient outcomes in obstetric population. No high quality effectiveness studies were identified in this area. While the traditional RCT may not be appropriate in this area, alternative designs such as the stepped wedge cluster randomised trial (increasingly being used in the evaluation of service delivery type interventions)[92] could be considered in the future.

5.3.2 Development and validation studies

The majority of identified development and validation studies in this area have focused on high-risk populations, using mortality or severe morbidity as outcomes. Increased focus needs to be placed on developing predictive models that are appropriate to the general maternal population.

An increased emphasis on improving the conduct and reporting of development and validation studies is also necessary. Adherence to the standardised reporting guidelines such as the Transparent Reporting of a Multivariable Prediction Model for Individual Prognosis or Diagnosis (TRIPOD) statement[93] would improve reporting, potentially allowing for the conduct of more robust diagnostic/prognostic accuracy meta-analysis to inform decision making.

5.3.3 Health economics

There is a lack of robust economic evaluation to establish the cost-effectiveness and resource implications related to implementation. This may reflect that economic evaluation literature tends to be published after the initial clinical literature, and, as this review has highlighted, few effectiveness studies have been published. Future planned effectiveness studies should incorporate economic evaluations and the potential for using economic modelling in future studies should be explored.

5.4 Strengths and limitations

The main strengths of this review are the systematic search of multiple databases, the use of broad inclusion criteria and the use of validated tools to assess methodological quality. However, the findings of this systematic review need to be interpreted in the context of the limitations of the original studies. The small number of studies identified in each category (with the exception of the clinical audits), study heterogeneity, and lack of available data in some meant that a meta-analysis was not possible. A limitation of this review is that only studies available in English were included, in keeping with the previous systematic review of clinical effectiveness and cost-effectiveness conducted to support the IMEWS guideline.[8] Clinical audits and quality improvement studies are often not published in peer reviewed journals, and, despite an extensive grey literature search, there is the potential that some clinical audits may have been missed in this search.

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Appendix 1 — Sample search strategies

Sample search strategies are presented below; however, full search strategies are available on request.

Sample search strategy for objectives 1 to 5

	MEDLINE (via Ovid) 05.10.17	N=72
1.	exp Pregnancy/	878,141
2.	exp Pregnancy Complications/	416,452
3.	exp Obstetric Surgical Procedures/	129,948
4.	exp Prenatal Care/	25,032
5.	exp Postpartum Period/	60,591
6.	Hospitals, Maternity/	2,897
7.	exp Maternal Health Services/	44,455
8.	Nurse Midwives/ or Midwifery/	41,780
9.	exp Obstetrics/	22,437
10.	(antenatal or prenatal or perinatal or puerperal or puerperium or postnatal or postpartum or peripartum or post-natal or post-partum or ante-natal or ante-partum or obstetric*).tw.	342,808
11.	or/1-10	1,105,254
12.	(mews or meows or moews or IMEWS).tw.	151
13.	(early adj warnin g).mp.	3,901
14.	(warning adj systems).mp.	655
15.	(warning adj system).mp.	1,230
16.	(warning adj score*).mp.	436
17.	(track adj2 trigger).tw.	73
18.	(trigger* adj4 score*).tw.	107
19.	(escalation adj protocol*).mp	128
20.	(escalation adj policy).mp.	7
21.	(escalation adj policies).mp.	4
22.	POTTS.ti,ab.	1,453
23.	or/12-22	6,212
24.	11 and 23	196
25.	Limit 24 to yr=2014-2017	72

Sample search strategy for objective 6

	Medline (ovid) **10.10.17**	**N=363**
1.	Audit.af	41,468
2.	exp Clinical audit/	21,895
3.	Exp medical audit/	17,200
4.	exp Quality Assurance, Health Care/	311,257
5.	exp Quality Improvement/	17,030
6.	exp quality control/	47,539
7.	(Quality adj administration).mp.	22
8.	Key performance indicat*.tw.	388
9.	(performance adj indicat*).tw.	3,119
10.	KPI*.tw.	463
11.	OR/1-10	386,361
12.	(clinical adj deteriorat*).ab,ti.	3675
13.	(detect* adj deteriorat*).ab,ti.	115
14.	(risk adj assessment).tw	42,442
15.	(early adj warning).mp.	3,901
16.	(warning adj system*).mp.	655
17.	(warning adj score*).mp.	1,770
18.	(track adj2 trigger).tw.	73
19.	(trigger* adj4 score*).tw.	107
20.	(escalation adj protocol*).mp	128
21.	(escalation adj polic*).mp.	11
22.	emergency response system.tw.	99
23.	Patient at Risk score.ab,ti.	3
24.	"Physiological Scoring System*".ab,ti.	28
25.	Vital Sign Score.ab,ti.	8
26.	(Manchester Protocol or Manchester system or Manchester Triage).ti,ab.	156
27.	BioSign.ab,ti.	10
28.	VitalPAC.ab,ti.	17
29.	Between the flags.ab,ti.	12
30.	Worthing.ab,ti.	44
31.	(Pediatric Early Warning Score or neonatal Early Warning Score).ab,ti.	23
32.	(mews or meows or IMEWS or PEWS).ab,ti.	198
33.	sbar.mp.	148
34.	OR/12-33	8830
35.	11 AND 34	363

Appendix 2 — Clinical audit checklist*

Stage 1 : Plan for audit		**Yes, No, Not applicable, unclear**
Step 1	Was the audit topic clearly stated	
Step 2	Was the objective of the audit clearly stated	
Stage 2 : Select standard/criteria		**Yes, No, Not applicable, unclear**
Step 1	Was the standard identified evidence based and described in full with appropriate references	
Step 2	Identified audit criteria - measurable statements of what should be happening (or what is currently happening if known?)	
Step 3	Set targets/expected performance levels	
Step 4	Were appropriate inclusion/exclusion criteria used	
Stage 3 : Measure performance		**Yes, No, Not applicable, unclear**
Step 1	Collected data using appropriate data collection tools	
Step 2	Analysed data using appropriate statistical techniques	
Step 3	Presented results in full	
Stage 4 : Make improvements		**Yes, No, Not applicable, unclear**
Step 1	Reviewed areas for improvement and agreed priorities for action	
Step 2	Identified appropriate interventions	
Step 3	Developed quality improvement plan (if required)	
Step 4	Identified: - persons responsible for each task / action - reasonable timescale for completion - how and when progress will be measured	
Step 5	Ensured that change was supported by those with the necessary authority to effect such change	
Stage 5 : Sustain improvements		**Yes, No, Not applicable, unclear**
Step 1	Monitored implementation of changes	
Step 2	Re-audited to ensure changes have improved practice and decide if further audit procedures are required	

* Adapted from The HSE Quality and Patient Safety Division 'A Practical Guide to Clinical Audit' has a clinical audit checklist

Appendix 3 — Excluded studies

Excluded studies: objectives 1 to 5

Reason for exclusion	Study references
Commentary/opinion/review	Anbazhagan 2015,[94] Cheng 2014,[95] Cole 2014,[96] D'Alton 2014,[97] Friedman 2015,[98] Maguire 2015,[99] Maguire 2015,[99] Maguire 2014,[100] Kacmar 2017,[101] Mhyre 2014,[102] Padilla 2017,[103] Parfitt 2017,[104] Pollard 2017,[105] Quinn 2016,[106] Witcher 2015,[107] Zuckerwise 2017[108]
Descriptive study	Behling 2005,[109] Bick 2014,[110] Cook 2014,[111] Dennis 2016,[112] Eppes 2017,[113] King 2014,[114] Lavigne 2017,[115] Maguire 2015,[43] Maguire 2016,[7] Mangion 2015,[116] Murove 2014,[117] Nasir 2015,[118] Preshaw 2016,[119] Richards 2017,[120] Sandall 2012,[121] Smith 2017[122]
Focus not maternal early warning system	Austin 2014,[123] Burger 2017,[124] Connell 2016,[125] Crofts 2015,[126] Eppes 2016,[127] Esegbona 2015,[128] Gratton 2016,[129] Nathan 2014,[130] Nathan 2015,[131] Nathan 2015,[132] Nathan 2016,[133] Nathan 2017,[134] Saxena 2015,[135] Thakur 2016,[136] Van Der Nelson 2014,[137] Walker 2017,[138], Weiniger 2017[139]
Outcome not relevant to current review	Kaiser 2017[140]
Effectiveness study but no control group	Merriel 2017,[141] Sheikh 2017[142]

Excluded studies: objective 6

Reason for exclusion	Study references
Commentary/opinion/review	Handley 2010,[143] McCabe 2009,[144] Royal College of Nursing 2010,[145] Subbe 2013,[146] Jevon 2011[147]
Not EWS	Agarwal 2011,[148] Ambati 2014,[149] Baldwin 2008,[150] Considine 2010,[151] Estebanez 2012,[152] Fox 2015,[153] Francis 2015,[154] Jeune 2013,[155] Ritchie 2012[156]
Not an audit	Atkinson 2014,[157] Bick 2014,[110] Bradman 2008,[158] Carle 2013,[159] Corfield 2014,[160] Demmel 2010,[161] Farenden 2017,[162] Finlay 2014,[163] Flannigan 2011,[164] Jarvis 2015,[165] Jenions 2011,[166] Kinney 2015,[167] Kruisselbrink 2016,[168] Ludikhuize 2012,[169] Maupin 2009,[170] Neary 2015,[171] Odell 2002,[172] Oggioni 2012,[173] Oglesby 2011,[174] Parkinson 2015,[175] Parrish 2017,[176] Saxena 2009,[177] Talusan 2012,[178] Thompson 2009,[179] Ward 2014,[180] Whittemore 2015[181]
Outcome not relevant to current review	Moon 2011[182]
Study registration only	Clegg 2012[183]
Duplicate	Helme 2012[184]

Appendix 4 — Summary of findings and recommendations from GAIN report

Summary of findings and recommendations from GAIN report[89]

Performance measurement	Results	Key recommendations
Physiological early warning scoring system (PEWSS) chart completion: 100%	90.8% completed	Lack of PEWSS charts in almost 10% of returns may be related to patients being admitted directly from the emergency department. All patients should have at least one set of observations recorded prior to intensive care unit (ICU) admission.
Identification of patients: 100% PEWSS documentation of patient's hospital number, surname, first name, date of birth	Patient's hospital number: 81.3% Surname: 98.7% First name: 98.9% Date of birth: 81.0%	All hospital trusts should assure completion of patient identifier data on all PEWSS charts
100% patient notes/observation chart clearly indicate how often observations are supposed to be carried out	19.5%	Required frequency of observations should be decided by someone with the skills necessary to make this clinical judgment. Hospital trusts should consider whether or not it is appropriate to record individual elements of a PEWSS score independently of the others and be in a position to justify their conclusions.
100% observations carried out in accordance with the agreed frequency	73.6%	All Hospital trusts should audit compliance with requested frequency of observations, and explore reasons why specified frequency of observations is not met.
100% full set of parameters comprising PEWSS completed/ recorded at least 12 hourly in the 24 hours prior to ICU.	95.4%	Hospital trusts should ensure that staff are aware of the national guidance on frequency of PEWSS scoring and that the frequency should increase in patients at risk of deterioration. Ongoing audit should occur to ensure that compliance remains high with this on all acute hospital sites.
Documented evidence that the following were recorded on the PEWSS chart in the 24 hours prior to ICU. a) Time of all sets of observations: 100% b) Date of observations: 100%	a) Time of all sets of observations: 90.8% b) Date of observations:72.8%	All PEWSS charts should carry the time of all observations, and the date to which all sets relate should be evident on each chart.
Unplanned gaps in sets of observations in the 24 hours prior to ICU admission: 0%	21.1%	The responses to this question render any conclusions sufficiently uncertain that a recommendation based on the data would be unwise. Nevertheless, it would seem wise to encourage hospital trusts to audit compliance with the recommended frequency of observations, and ensure that compliance is satisfactory.
All parameters were completed *within* each set of observations, in line with hospital trust guidance and training for completion, in the 24 hours prior to admission to ICU: 100%	34.1%	All hospital trusts must explore and address the reasons why PEWSS is not being implemented in line with local trust guidance. Potential areas which could be looked at include: (a) availability and content of training (b) competence/skillmix of those responsible for implementing PEWSS (c) staff levels, workload and prioritisation of tasks.
Parameters recorded	The number of PEWSS	All hospital trusts should choose a PEWSS —

	observation sets performed in the 24 hours immediately preceding ICU admission peaked at 6. Oxygen saturation was recorded substantially less frequently (*n* = 270) than any of the 5 commonest parameters.	comprising a particular parameter set, scoring thresholds and relative weighting — on the basis of its discriminatory power (validated ability to identify at risk patients) among a population comparable to that it wishes to monitor. The choice may need to be tempered by feasibility of use but an informed and justifiable choice should be made.
Each parameter allocated to the correct scoring zone for all sets of observations: 100%	64.7%	Hospital trusts should review processes, training and skillmix to assure the quality of data entry. Hospital trusts should consider moving to an electronic PEWSS.
Number of times PEWSS score reached a threshold for action in the 24 hrs prior to ICU admission.	A quarter of patients admitted in emergency circumstances to critical care units did not breach a PEWSS threshold for intervention in the 24 hours prior to ICU admission, that is, they were not identified by the PEWSS in use as requiring an intervention.	a) Indicators in the scientific literature of frequent incidence of physiological disturbance prior to ICU admission should be regarded as pertinent to the Northern Ireland inpatient population. b) Each Health and Social Care in Northern Ireland Trust providing inpatient care should use the best performing PEWSS suitable for its population of patients. c) Following initial choice of PEWSS, rollout and demonstration (by audit) of appropriate use, service evaluation/audit is to be encouraged within each hospital trust to determine sensitivity and specificity of the scoring system in its population. d) Thresholds should not be set to control "excessive" workload when the reason the workload is excessive is a deficiency in staffing levels; rather staff should be deployed in sufficient numbers and with appropriate skills on the basis of the number of patients at risk. Local audit/service evaluation and sensitivity and specificity analysis should help in the determination of what is necessary workload for patient welfare and what is excessive workload resulting from false alarms generated by the scoring system in use. e) Failure of a patient to breach a scoring system trigger threshold should not preclude early treatment or appropriate referral on the basis of clinical judgment alone. Referral/ treatment algorithms should therefore facilitate clinical concern as a prompt for referral/treatment. However, it should be remembered that one of the problems in the literature which underpins the need for PEWSS seems to be deficiencies of clinical judgement so, whilst false alarms will frequently occur given the limitations of existing PEWSS, there should not be casual disregarding by junior clinicians of scores which breach warning thresholds. f) It should be understood that, because of the

		limitations of scoring systems, a failure to predict or prevent deterioration in an individual patient does not necessarily indicate a deficiency in care. However, hospital trusts should consider whether failure to implement properly the PEWSS they choose might be perceived to be a deficiency of care, particularly if a patient were to suffer harm as a result.
Total score for each set of observations calculated correctly in the 24 hours prior to ICU admission: 100%	31.4%	Hospital trusts should use all means possible to ensure minimise errors in, and ensure completion of, PEWSS calculations. Failure to achieve considerable reduction of the error rate is likely to prevent PEWSS being a satisfactory means to optimise patient care and resource use.
Time period between each threshold score reached and the next full set of observations is in accordance with hospital trust's PEWSS protocol/ guidance: 100%	54.9%	All hospital trusts should review their protocols/guidance/algorithms to assure the clinical appropriateness of the required timelines for repeat scoring at score thresholds, or whether they should introduce such timelines. Following this, further similar audit should be conducted and the causes of any failure to meet the timelines should be identified and addressed.
Appropriate person contacted in line with hospital trust's PEWSS protocol/guidance for each occasion a threshold was reached: 100%	a) Occasion 1 92.7% b) Occasion 2 91.2% c) Occasion 3 90.0% d) Occasion 4 85.7% e) Occasion 5 86.1% f) Occasion 6 87.4%	Each hospital trust should continue to review its guidance/protocol/algorithms to ensure that guidance on when appropriate categories of staff should be notified is appropriate. Following this, hospital trusts should aim to maximise adherence to their internal guidance.
Action taken for each of the threshold scores reached	In approximately one quarter of instances the triggers prompted communication, in line with the hospital trust response algorithm. Treatment changes were prompted by threshold scores in around half of cases. A new treatment plan was prompted in a substantial number of patients (29- 48%).	Alteration of PEWSS thresholds in individual patients should not be done lightly, or by inexperienced staff. Prospective identification of groups of patients who will trigger inappropriately is encouraged, such that PEWSS triggers can be optimally set. Best practice would be conduct of validation work to facilitate setting of appropriate thresholds for groups of patients, rather than practice ad hoc alteration of thresholds for individual patients.
Organ systems for which action/treatment occurred (in line with response algorithm)	Interventions to support adequacy of oxygenation and or breathing were the most common, closely followed by those to maintain blood pressure and circulation.	Hospital trusts should examine whether they are maximising the opportunity presented by PEWSS triggering to review resuscitation status of ill or deteriorating patients.
Organ system-directed action/treatment that did not occur which should have occurred, according to either site algorithm or ALERT practice: 0%	3.4%	All hospital trusts should assure through appropriate process, and audit that the opportunities presented by PEWSS triggering to review resuscitation status and document timely treatment decisions, including palliation, are taken advantage of for the benefit of patients
Patient Improvement prior to ICU admission (across Northern Ireland) when PEWSS thresholds for action reached repeatedly	In less than a third of cases of patients breaching PEWSS triggers and admitted to ICU was there improvement at ward level prior to ICU	PEWSS audit/service evaluation/research could usefully be conducted among ward patients not admitted to ICU, as well as those who are, to determine the proportion of patients responding/not responding to algorithm-prompted

	admission. Spontaneous improvement was a relatively rare event (1% overall), possibly suggesting (but not demonstrating) that PEWSS intervention thresholds are not set too low.	(and other) ward based interventions. Hospital trusts should review their PEWSS processes both pending and subsequent to such audit, in order to ensure that patients are not receiving suboptimal care.
Length of time repeated thresholds for action existed	Almost half of patients admitted to ICU did not remain at ward level with ongoing triggering of PEWSS thresholds for more than 4 hours	a) Regional PEWSS audit among patients who die without admission to critical care should be conducted to determine whether or not there is room for improvement in scoring/algorithm responses which could impact favourably on potentially avoidable deaths, or on provision of palliative care. b) It would be useful for future audits/service evaluations to look more closely at those who breach PEWSS intervention thresholds for more than 12 hours to determine the nature of the physiological disturbance and whether, for example, this group has chronically altered parameters (for example, relating to long-standing co-morbidity). c) Further hospital trust-specific PEWSS audit should be encouraged to assess the duration of persistence of breaching of PEWSS thresholds among patients not admitted to a critical care unit (in addition to those who are). d) All hospital trusts should ensure that any problems related to timely access to critical care unit beds are identified and addressed. Adequate numbers of staffed critical care beds is obviously important, as is best use of currently funded beds.
Threshold for action reached repeatedly was one which, according to trust/ site algorithm, should prompt immediate ICU referral	Immediate referral to ICU was deemed appropriate by the response algorithm in only 2 patients out of 10 who triggered repeatedly	Further audit should be encouraged which looks in detail at: (i) the appropriateness or otherwise of protracted repeat triggering in the ward settings concerned (ii) best use of discriminatory capability of PEWSS by best choice of triggers, including in the context of repeat triggering (iii) the utility and effectiveness of algorithm prompted responses to repeat triggering.
Identified areas of concern, in terms of clinical management not being consistent with ALERT practice: 0%	15.7%	a) Hospital trusts should review PEWSS processes to ensure they are both feasible and implemented. This will likely require an assessment of staff levels and workload, and explicit determination of priorities within that workload. b) Individual hospital trusts should satisfy themselves that their staff are appropriately trained in good practice with respect to identification and early treatment of patients exhibiting evidence of acute potentially life-threatening events.
In patients triggering PEWSS, deviation from ALERT principles contributed substantially to adverse patient outcome: 0%	2.8%	Hospital trusts should endeavour to maximise detection of deviation from best practice, assess any associated harm and, where necessary, change procedures, staffing levels, training and skillmix to

		minimise harm. Utilisation of suitable audit tools is essential to such a process.

Key: ICU — intensive care unit; HDU — high dependency unit; PEWSS — physiological early warning scoring system

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