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INPLASY

# Use of the Early Warning Score as an Outcome Measure: Protocol for a Systematic Reviewof Methodologies

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**ADMINISTRATIVE INFORMATION**

**Support -** N/A.

**Review Stage at time of this submission -** The review has not yet started.

**Conflicts of interest -** None declared.

**INPLASY registration number:** INPLASY202540054

**Amendments -** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 16 April 2025 and was last updated on 16 April 2025.

## INTRODUCTION

**Review question / Objective** The use of the Early Warning Score (EWS) as a clinical outcome measure to evaluate the effectiveness of various interventions is growing in importance, as it allows clinicians to monitor patient conditions and adjust treatments more efficiently. Given its potential to improve patient outcomes by facilitating timely interventions, there is increasing interest in examining the statistical methods used to analyse EWS data in clinical research. The effectiveness of an intervention often involves monitoring changes in the EWS scores over time, which presents unique challenges in statistical analysis due to the repeated measures, skewed distributions, and potential for non-linear changes in patient conditions. No single statistical model has been highlighted as the most appropriate when using the EWS to evaluate the effectiveness of an intervention. This systematic review aims to bridge this literature gap by providing a comprehensive overview of the statistical approaches employed in studies that evaluate changes in EWS as a clinical outcome.

**Rationale** By reviewing existing literature, this review will provide an overview of the various statistical methodologies in use and will identify state of the art methodologies to better direct future research on the topic.

**Condition being studied** Early Warning Scores (EWS) are used in clinical settings to assess a patient's risk of deterioration and trigger appropriate interventions such as increased nursing attention, alerting responsible clinicians or activating an emergency response team.

## METHODS

**Search strategy** The search strategy will be developed with expert guidance from an information specialist (KW) and one of the senior authors (JS). It will follow the Preferred Reporting Items for systematic Reviews and Meta-Analyses

(PRISMA) guidelines. The OVID Medline database will be searched, which encompasses MEDLINE, Embase, and CENTRAL databases at a minimum. Reference lists of included studies will be screened for additional relevant studies. The search terms will be identified through a literature review of the PubMed and Embase databases. Along with the assistance of an information expert, refinement of search terms will be carried out.

**Participant or population** Adult (including maternity) and paediatric inpatients where EWS was used to measure clinical status . Acute and non-acute hospital settings . Medically stable and unstable patients.

**Intervention** Use of Early Warning Scores (EWS) as a clinical outcome measure.

**Comparator** Studies that report comparisons before and after the implementation of EWS. Studies that compare EWS with other clinical outcome measures or monitoring methods. Studies comparing the effectiveness of different EWS systems (modified EWS, maternal EWS, paediatric EWS).

**Study designs to be included** Any study (observational, comparative, trial) where the Early Warning Score is used as a clinical outcome to measure the effectiveness of an intervention.

**Eligibility criteria** Inclusion criteria is per above. Exclusion criteria is as follows:
Patient/Participant/Population: Studies involving outpatient studies or studies that focus on populations without EWS application or measurement will be excluded.
Intervention: Studies that focus on clinical decision-making or outcome monitoring without the use of EWS will be excluded. Studies where EWS is not used or reported as part of the intervention will be excluded.
Comparison: Studies that do not report a comparative analysis (no baseline or post-intervention data) or studies without control groups will be excluded.
Outcome: Studies that do not address EWS as an outcome measure will be excluded. Studies that focus on other clinical measures unrelated to EWS (e.g. vital sign recording without integrating EWS) will be excluded. Studies that do not provide statistical analysis relating to the role of EWS in clinical outcomes will be excluded.

**Information sources** The OVID database which encompasses MEDLINE, Embase, and CENTRAL databases will be used as the primary information source. Following this, reference lists of included studies will be searched.

**Main outcome(s)** One primary, and two co-reviewers will independently apply inclusion and exclusion criteria to citations, abstracts and full texts. Papers will then be chosen for data extraction. Any discrepancies will be reviewed and consensus obtained, or senior authors will be consulted for a final decision.
Studies chosen for data extraction will be reviewed by KG, LL, QF. A selection of highly relevant papers will be analysed to inform important data points for extraction. Variables to be included will be discussed at this stage. Senior authors will be consulted for advice where needed. Following this, a template for data extraction will be created and shared with the named reviewers. A pilot data extraction period will be carried out on a small percentage of included papers to assess for any necessary change to the template prior to large scale data extraction. Any update or changes that may need to be made to the template will be made after discussion with reviewers and senior authors.
For each of the included studies, baseline characteristics will be extracted – author institution, country, study period, year of publication, total number of participants, study setting, study methodology, and statistical methodology utilised for measuring EWS as a clinical outcome.

**Additional outcome(s)** The aim of this systematic review is to provide a synthesis of the current application of statistical methods used to evaluate changes in the Early Warning Scoring as a clinical outcome.

**Data management** Studies from the initial search will be stored using EndNote 20 software. Rayyan AI systematic review software will be utilised to aid the screening process as three researchers are planned to perform this stage of the review.

**Quality assessment / Risk of bias analysis** A quality assessment will not be performed as part of this review, as we are providing an overview of what statistical methods are being used at present in the literature when analysing the use of EWS as a clinical outcome measure. It is not the aim of the authors to make recommendations as an outcome of this review.

**Strategy of data synthesis** Data that is extracted from included studies will be analysed to answer the review's question. For clarity, results will be displayed in tables e.g. a descriptive table, a EWS inclusion table, and an application table (what

statistical methods were used with associated outcomes). Whether a justification for selecting a statistical methodology is provided by authors will be assessed, as well as a review of any associated sensitivity analysis so we can evaluate the degree of robustness of the method.

**Subgroup analysis** Adult, maternity and paediatric data will be included in this review and analysed.

**Sensitivity analysis** Sensitivity analysis will not be performed as part of this review. Outcome data will not be pooled. The authors aim to understand statistical methodology in use, and no intervention is being tested. Quantitative estimates will not be formed.

**Language restriction** Studies published in the English language only are to be included in this review.

**Country(ies) involved** Republic of Ireland.

**Keywords** Early Warning Score; EWS; clinical outcomes; statistical methodology.

**Dissemination plans** The findings of this systematic review of methodology will be submitted for publication in a peer-reviewed academic journal relevant to the field. In addition, we aim to present the results at national or international conferences focused on research methodology or the relevant subject area. Where appropriate, summaries of the findings may also be shared through institutional repositories and social media channels to reach a broader academic audience."

**Contributions of each author**

Author 1 - Katherine Griffin - Developed the protocol. Performed the literature search. Screened titles and abstracts, assessed full-texts for inclusion. Extracted and organised data from included studies, maintained databases, and ensured consistency across sources. Drafted the manuscript, with emphasis on the results and discussion of statistical methodologies identified in the review.
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Author 2 - Jessica Ryan - Conceived the idea for the systematic review, defined the scope and objective of the review, supervised protocol development. Performed the literature search. Supervised drafting of the manuscript.
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Author 5 - Dara Kavanagh - Advised on the protocol for the review including the search strategy, inclusion/exclusion criteria and statistical analysis. Contributed to critical revision of the manuscript for intellectual content. Provided guidance on optimal presentation of findings.
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Author 7 - Jan Sorensen - Advised on the protocol for the review including the search strategy, inclusion/exclusion criteria and statistical analysis. Contributed to critical revision of the manuscript for intellectual content, particularly in relation to statistical interpretation and implications. Provided guidance on methodological and statistical rigour.
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Author 8 - Deborah McNamara - Conceived the idea for the systematic review. Advised on the protocol for the review including the search strategy, inclusion/exclusion criteria and statistical analysis. Contributed to critical revision of the manuscript in relation to statistical interpretation and implications. Provided guidance on best practices in systematic reviewing.
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