

# BMJ Open Understanding the use of the National Early Warning Score 2 in acute care settings: a realist review protocol

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## ABSTRACT

**Introduction** Failure to recognise and respond to patient deterioration in an appropriate and timely manner has been highlighted as a global patient safety concern. Early Warning Scores (EWSs) using vital signs were introduced to address this concern, with the aim of getting the patient timely and appropriate treatment. The National Early Warning Score 2 (NEWS2) is in use across the NHS, and many other settings globally. While patient improvements have been shown, research has identified that the NEWS2 is not always used as intended. Therefore, this review will use a realist approach to understand what the mechanisms are that influence appropriate use (or not) of the NEWS2 in acute care settings, how, for whom and in which contexts. The findings will inform clinicians of what helps and/or hinders appropriate use of the NEWS2 in clinical practice, thus helping to facilitate successful implementation.

**Methods and analysis** Our realist review will follow Pawson's iterative six step process: (1) Development of initial programme theory. (2) Searching the literature; an information scientist will develop, pilot and refine the search strategy. A systematic search will be completed, based on subject relevancy on the following databases: Cumulative Index to Nursing and Allied Health Literature (CINAHL), Medline, Embase (OvidSP), Web of Science (Science Citation Index and Social Science Citation), Cochrane Database of Systematic Reviews, Joanna Briggs Institute, Ethos, Proquest Dissertations and Theses Global, and Google Scholar for documents dating from 1997 (date of the first published EWS) to present. To retrieve additional relevant data 'snowballing' (finding references and authors by hand, contacting authors, searching reference lists and citation-tracking using Google Scholar) will be used. Inclusion criteria include all documents (including grey literature) that relate to the use of EWSs/NEWS2 in the English language only. Documents set in the paediatric, maternity and primary care settings will be excluded. (3) Selecting documents and quality appraisal. (4) Extracting and organising the data. (5) Synthesising the data. (6) Disseminating the findings. We will recruit a group of stakeholders comprised of experienced clinicians who use the NEWS2 as part of their clinical practice to provide feedback throughout the review. Step 1 has already begun with the development of an initial programme theory. This initial programme theory presents how the NEWS2 is supposed to work (or not), it will now be developed, tested and refined.

## Strengths and limitations of this study

- ⇒ The realist review approach employed will enable us to develop an in-depth understanding of the mechanisms by which the National Early Warning Score 2 works, which can be used to inform its appropriate use.
- ⇒ A strength is that we have built in processes to ensure the programme theory and findings are relevant to knowledge users by stakeholder input and drawing on grey literature.
- ⇒ Our review may be limited by a second reviewer screening only a random 10% of the included/excluded documents, however, explicit screening criteria arguably helps mitigate selection bias.
- ⇒ A realist review will not produce universally transferable findings because these are context dependant; however, it is likely that findings can be extrapolated to settings where similar mechanisms may be operating.

**Ethics and dissemination** Ethical approval is not required for this study as it is secondary research. Dissemination will include a peer-reviewed publication and conference presentations. Findings will also be amplified through social media platforms with user friendly summaries. Our stakeholder group will also contribute to dissemination of findings in their clinical areas and among existing networks.

**PROSPERO registration number** CRD42022304497.

## INTRODUCTION Background

Failure to recognise and respond to the deteriorating adult patient in a timely manner has been identified as an international patient safety concern.<sup>1–7</sup> Research has shown deficiencies in assessing, recording and acting on abnormal vital signs to prevent critical events, namely unplanned intensive care admissions or death.<sup>6 8–10</sup> Despite efforts to address this problem,<sup>3–5 11–14</sup> there is evidence that adverse events, are still occurring as a result of failure to recognise and respond to acute deterioration in an effective and timely manner.<sup>5 15–17</sup>

Patient deterioration can be defined as a transition from one clinical state to a worse clinical state, thereby increasing the risk of morbidity, prolonged hospital stays, disability, organ dysfunction or death.<sup>10</sup> Studies have shown that serious adverse events such as cardiac arrest, admission to intensive care or death are precluded by abnormal vital signs that were not acted on in a timely manner.<sup>2 16 18</sup> This is often referred to as a 'failure to rescue'. Failure to rescue occurs when there is an inadequate or delayed response to clinical deterioration in a hospitalised patient.<sup>19</sup> Many efforts, such as the introduction of Early Warning Scores (EWSs), have been introduced to address this growing concern.

### National Early Warning Score

In 2012, the Royal College of Physicians (RCP) published the National Early Warning Score 2 (NEWS2),<sup>20</sup> which has been widely adopted across the National Health Service (NHS). Five years after its introduction, it underwent a review to ensure that it was still fit for purpose, which led to the introduction of the NEWS2.<sup>14</sup> Notably, the NEWS2 is sensitive to detecting deterioration in patients with COVID-19.<sup>21 22</sup> For the NEWS2 to predict deterioration, accurate assessment of all required vital sign data is key.<sup>14</sup> Research has identified that EWSs are often completed inaccurately, with either errors or omissions of vital signs.<sup>23–26</sup> These errors lead to patients not being referred for review, resulting in a failure to rescue.<sup>26</sup> A key focus of the NEWS2 is to prompt ward staff carrying out vital sign assessment to identify potential deterioration.<sup>14</sup> An indication of possible deterioration is meant to trigger increased frequency of monitoring and escalation of care.<sup>4 27</sup>

Rapid response teams (RRTs), also referred to as critical care outreach teams or medical emergency teams, comprise of experienced critical care clinicians, proficient in managing patient deterioration.<sup>28</sup> These teams were established as a preventive measure against serious adverse events in acute hospitals.<sup>9 29 30</sup> Research shows RRTs reduce hospital mortality and cardiopulmonary arrests.<sup>31</sup> The NEWS2 needs to be used in conjunction with RRTs or a clinician with core competencies in the care of acutely ill patient to ensure appropriate interventions are made in response to deterioration.

### Suboptimal use

The NEWS2 is the most used EWS in use across the NHS and many other settings globally; despite this, there are still concerns regarding the recognition and response to patient deterioration. Research has shown that EWSs are not always used as intended, for example, incorrect assessment of vital signs, miscalculation of scores and/or failure to escalate or respond as per protocol.<sup>32–40</sup> A common problem is related to failure to assess respiratory rate,<sup>35 39 40</sup> ineffective and poor communication, especially among healthcare workers.<sup>41–43</sup> Lack of staff and time have also been shown to negatively affect the use of EWSs.<sup>35 40 43</sup> A recent systematic review identified that

escalation was largely influenced by perceptions; notably, junior doctors' perception of threatened deskilling and appearing incompetent due to the presence of RRTs. As clinical experience of healthcare professionals is fundamental in recognising the need for escalation,<sup>44</sup> it may be construed that appropriate use of the NEWS2 would improve the recognition and response to patient deterioration. The value of the NEWS2 is dependent on appropriate implementation, appropriate use and an effective clinical response.<sup>4 14</sup>

In order to support the appropriate use of the NEWS2 in clinical practice, it is important to consider how the context of the workplace affects (either positively or negatively) its use, so that adjustments can be made to facilitate successful implementation. An abundance of research exists on the reasons why patient deterioration often goes unnoticed or escalated appropriately, however, there is a paucity of literature published on how to improve the use of EWSs, in particular the NEWS2.<sup>45–47</sup> Therefore, the gap in evidence this research is seeking to address, is, to better understand how the recognition of and response to patient deterioration can be improved through the appropriate use of the NEWS2. The NEWS2 is a simple tool,<sup>20</sup> however, because it relies on various resources and knowledge to ensure appropriate use, it is complex in nature when implemented in the 'real world' setting of the NHS. One way to make sense of complex interventions, such as the NEWS2, is to use theory-driven approaches. One such approach designed to make sense of complex interventions is realist reviews.<sup>48</sup>

### Review aim

The aim of this realist review is to use the literature to understand what helps or/and hinders the appropriate use of the NEWS2 in the acute setting.

### Objectives

1. To conduct a realist review on how, for whom and in what contexts the NEWS2 helps (or not) detect patients at risk of deterioration in the acute setting.
2. To develop a programme theory that explains the role of the NEWS2 in the identification and management of deteriorating patients in the acute setting, how, for whom and in which contexts.
3. To make recommendations on how best to support the implementation of the NEWS2 in acute settings.

### Review question

How, when, for whom, why and to what extent is the NEWS2 used in the acute setting to detect and respond to patient deterioration?

## METHODS AND ANALYSIS

### Study design

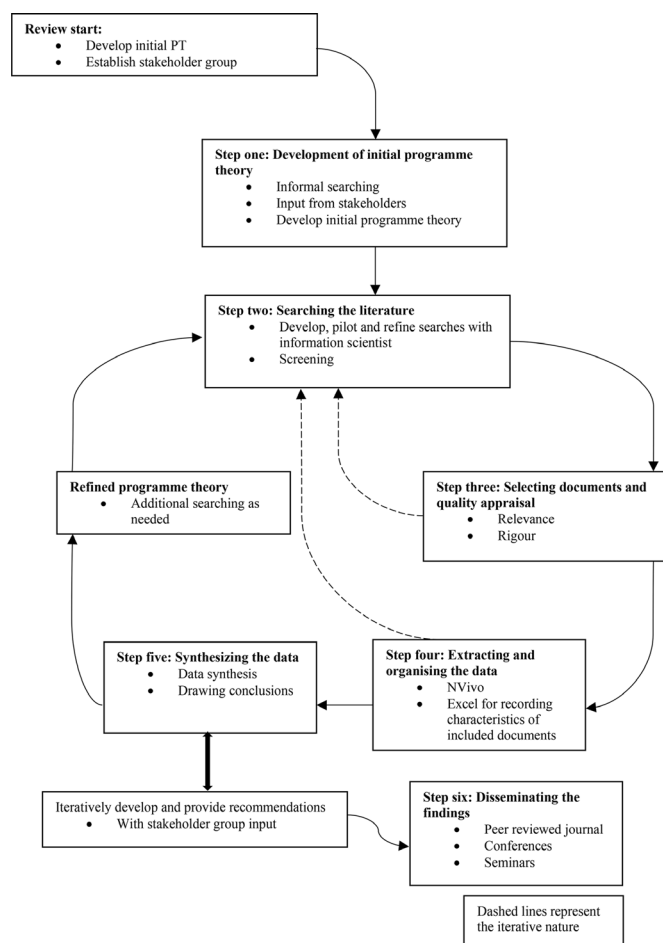
#### Realist approach

The study uses a realist approach to focus on understanding and unpacking the influence of context on the mechanisms by which an intervention causes outcomes

(or not), thereby providing an explanation, as opposed to a judgement about how it works.<sup>48</sup> The principal focus of a realist review is ‘to determine what works, for whom, in what circumstances, in what respects and why’.<sup>49</sup> The assumption is that an intervention may work well in one context, but then not at all or poorly in another context.<sup>50</sup> A realist review aims to address this issue by unearthing and then developing and refining the realist programme theory underlying an intervention. The approach acknowledges that interventions are embodied theories and that within such theories outcomes can be explained by understanding the interaction of context (C), mechanism (M), which determines outcome—hence context + mechanism = outcome (O). The review will identify the various elements of the intervention that change contexts and seek to understand how a change in contexts lead to desired outcomes. These explanations of causation will take the form of context–mechanism–outcome–configurations (CMOCs), which will form the basis of the programme theory to explain the role of the NEWS2 in the identification and management of deteriorating patients in the acute setting, how, for whom and in which contexts.

Understanding how outcomes (within any intervention) are influenced by contexts and mechanisms allow researchers to understand how programmes result in both intended and unintended outcomes.<sup>51</sup> For example, because NHS England<sup>52</sup> advocate the use of the NEWS2 in clinical practice; this does not equate to a direct improvement in the recognition and response to patient deterioration. Rather the NEWS2 may be considered a complex intervention that seeks to change the context around its users. It is the interaction between the changed contexts (or not) brought about by the NEWS2 and how users interpret and act on these (the mechanisms) which results in intended and unintended outcomes. This understanding will enable us to identify what influences clinicians’ appropriate use of the NEWS2. In effect, the NEWS2 is a complex intervention as it requires multiple actions and decision making. Clinicians may go through the steps in a variety of ways, however, their actions are restricted and altered by the wider contextual features. In other words, a clinician’s use of the NEWS2 is shaped by the context. The NEWS2 must work within a complex social system and the realist review will combine theoretical understanding with empirical evidence (drawn from a wide range of sources) in order to explain the relationship between contexts, the mechanisms by which it works and the outcomes that are generated.<sup>48</sup>

Theoretical explanations produced from the realist review—which take the form of CMOCs are middle-range theories. Middle-range theories involve abstraction but are close enough to the observed data to be incorporated into propositions that permit empirical testing<sup>53</sup> yet abstract enough to provide transferable explanations to other situations where the same mechanism may be occurring.<sup>54</sup> In this review, the empirical ‘testing’ (confirmation, refutation and refinement) will be against data



**Figure 1** Flow diagram of the project. Adapted from Wong *et al.*<sup>57</sup> PT, Programme Theory.

from research and grey literature. Following current accepted realist review practice there will be no limits on the grey literature screened for inclusion, as it may contribute in various ways of explaining the programme theory.<sup>50</sup>

### Realist review

This realist review will go by the process outlined by Pawson<sup>55</sup> and will follow the Realist and Meta-narrative Evidence Synthesis: Evolving Standards quality and publication standards.<sup>56</sup> The steps and processes for the review are summarised as a flow diagram, adopted from Wong *et al.*<sup>57</sup> (see figure 1). This study began on 18 January 2022, the current study status is at initial document screening; the expected date of completion is 31 January 2023.

### Patient and public involvement

In order to achieve maximal end-user relevance, consultation with stakeholders throughout the review is strongly advised.<sup>50</sup> Therefore, a diverse stakeholder group (maximum of 20); consisting of healthcare assistants, nursing associates, registered nurses, junior and consultant doctors, as well as members of RRTs will be recruited. The stakeholders must use the NEWS2 as part of their practice in the acute setting. The British Association of Critical Care Nurses will be contacted to invite



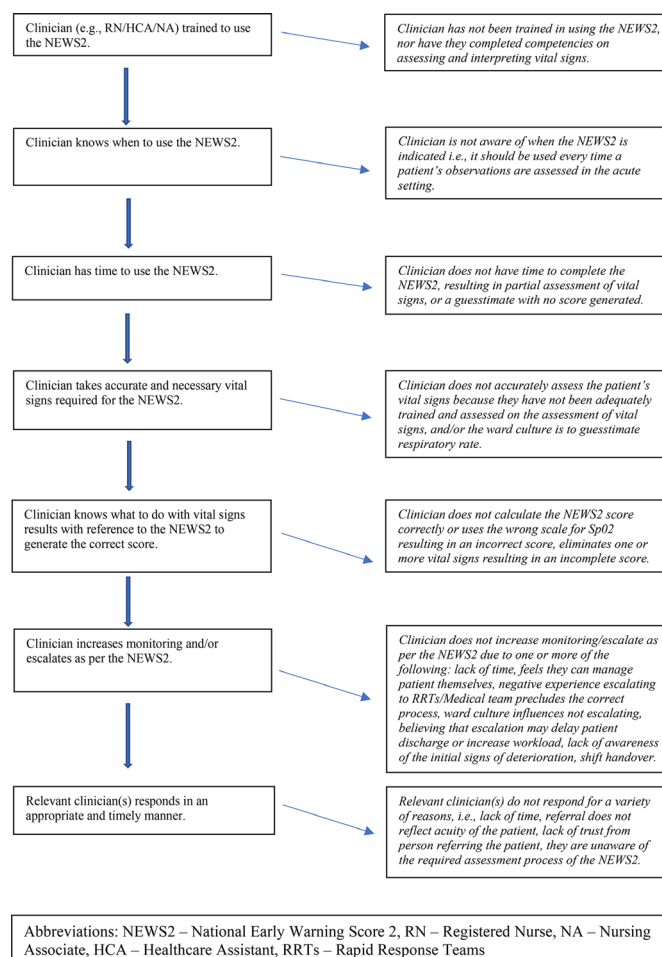
their members to join the stakeholder group. The RCP's will also be contacted to invite members of the NEWS2 committee to join as stakeholders. Finally, staff at a large district general NHS hospital (where a member of the review team works) will be invited to join as stakeholders. Stakeholders will have the option to join group or individual meetings, held online via a secure platform. The initial programme theory will be shared with stakeholder's ahead of the meetings and they will be asked for their feedback. During the meetings, electronic notes will be kept and on completion of the review, a compilation of stakeholder's feedback will be made available to readers. Consultation with stakeholders will be an iterative process throughout the review. A pragmatic approach derived from consultation with stakeholders will be used to prioritise the programme theories chosen to develop. Records of how which theories chosen to develop will be kept and made accessible to readers.<sup>58</sup> Stakeholders will also be asked for their feedback on emerging findings as the review progresses,<sup>58</sup> and for their advice on how best to disseminate findings.

### Step 1: development of initial programme theory

Initially, the research question was refined through an exploratory scoping review of the literature and content expertise (from the research team). Once the review question was focused, the initial programme theory was established through discussion among the research team, as well as preliminary reading of primary studies. The initial programme theory presents a simplified and linear explanation of how the NEWS2 is supposed to work and key areas where it may fail to work, thus allowing for the development of CMOCs to explain why success or failure occurs at each step (figure 2). The initial programme theory will now be presented to stakeholders in order to understand if it reflects their experiences and to build on these. Stakeholders will be asked how, why and when they think the NEWS2 works or fails to work in clinical practice. Initial programme theories will be discussed with stakeholders to determine which programme theories seem pertinent to establish a viewpoint on the difficulties of implementation and elucidate the ways in which the intervention may go wrong.

### Step 2: searching the literature

The search process in a realist review needs to retrieve the data necessary to help 'develop, refine or test',<sup>50</sup> the programme theory. Some exploratory searching has already taken place in step 1 to help the development of the initial programme theory, however, the purpose here is to undertake more comprehensive searches that will find the data needed to develop and confirm, refute or refine the initial programme theory.<sup>55</sup> There is no hierarchy of evidence in a realist review, relevancy is crucial.<sup>50 55</sup> A realist review is able to synthesise a range of relevant data such as quantitative, qualitative, mixed-method research and systematic reviews as well as grey



**Figure 2** Initial programme theory of how the NEWS2 is supposed to work (or not). HCA, healthcare assistant; NA, nursing associate; NEWS2, National Early Warning Score 2; RN, registered nurse; RRTs, rapid response teams.

literature,<sup>59</sup> therefore, the search strategy will seek to identify sufficient relevant literature.

An information scientist (NR) will help develop, pilot and refine the searches. Search terms will be chosen as appropriate, drawing on the specialist knowledge of the review team and stakeholders (see online supplemental file 1 for an example of a provisional search strategy). The following databases will be searched based on subject relevancy, from 1997 (this is when the first EWS was published) to present: Cumulative Index to Nursing and Allied Health Literature (CINAHL), Medline, Embase (OvidSP), Web of Science (Science Citation Index and Social Science Citation), Cochrane Database of Systematic Reviews, Joanna Briggs Institute, Ethos, Proquest Dissertations and Theses Global and Google Scholar. Set inclusion and exclusion criteria will be used to screen the main results from the databases.

Key inclusion criteria include all documents (including grey literature) that relate to the use of EWSs/NEWS2 in the English language only. Documents set in the paediatric, maternity and primary care settings will be excluded (see table 1 for full criteria). Inclusion/exclusion criteria may be amended following discussion with stakeholders

**Table 1** Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
<ul style="list-style-type: none"> <li>▶ English only documents</li> <li>▶ All types of documents which focus or relate to the use of the National Early Warning Score and/or the National Early Warning Score 2 (NEWS2) and/or Track and Trigger Tools and/or Early Warning Scores from 1997 as this is when the first Early Warning Score was published to the present day.</li> <li>▶ All study designs</li> <li>▶ Studies or documents set in the acute setting</li> <li>▶ Studies or documents focused on the adult patient (aged 18 years or more)</li> </ul>	<ul style="list-style-type: none"> <li>▶ Studies or documents set in the paediatric setting, as this review is focused on the adult</li> <li>▶ Studies related to pregnant women as the NEWS2 is not intended for use in pregnancy</li> <li>▶ Studies or documents focused on primary care settings</li> </ul>

and as the programme theory develops. It is predicted that Google Scholar will likely result in insurmountable hits, therefore, screening will cease after the first one hundred results of each search only. This is justified as we anticipate the exhaustive searches on scientific databases will capture significant 'relevant' data. However, if more data are required as the programme theory develops, the scope of screening on Google Scholar will be expanded. To retrieve additional relevant data 'snowballing' (finding references and authors by hand, contacting authors, searching reference lists and citation-tracking using Google Scholar) will be used.<sup>55 60</sup> The stakeholder group will also be asked if they are aware of any documents or authors that may be relevant to the review.

Searching is a purposive and iterative process throughout the review. As the programme theory develops, additional searches may be needed to find more relevant data.<sup>58</sup> The Preferred Reporting Items for Systematic Reviews and Meta-Analyses style diagrams will be used to report the disposition of the searches carried out.<sup>61</sup> MT will do the initial screening against inclusion and exclusion criteria. A member of the supervisory team (GW) will independently screen a 10% random subsample of the documents from searches for consistency. Discrepancies will be resolved through discussion between MT, GW and MO and if needed by voting.

### Step 3: selecting documents and quality appraisal

Initially the full text of all documents included following initial screening will be read in full and screened against the inclusion criteria. The same consistency check and dispute resolution process as described in step 2 will be used. The next stage is to determine if documents contain relevant data and are of sufficient rigour to be included in the review.<sup>55 62</sup> In a realist review, rigour is defined as 'whether the methods used to generate the relevant data are credible and trustworthy'.<sup>62</sup> Pawson's<sup>55</sup> process and publication standards<sup>56</sup> for conducting a realist review will be followed and transparently reported, thus providing readers with sufficient information to make judgements about the plausibility and coherence of the programme theory developed.<sup>63</sup>

### Relevance of data

MT will read in full all included full-text documents identified through screening for relevance to the initial programme theory. Documents of data that will likely

contribute to the programme theory will most certainly have varying trustworthiness, for example some will be from primary research, while others will be from editorial/discussion pieces, which would fall under the evidence hierarchy as 'opinion'. However, this 'opinion' may contribute to programme theory development when used alongside more data to build a coherent argument. Pawson<sup>55</sup> refers to these as 'nuggets' of wisdom. This is a key difference in the realist approach and what counts as evidence to support theory is based more on judgements about its relevance.

### Trustworthiness of sources

Given the nature of realist research, where we are seeking data that can help to corroborate, refute or refine an aspect of the programme theory, regardless of where or how the data has come about, it may be relevant. However, as this is research when data is deemed relevant in the first instance, the trustworthiness of the data will be considered. It will be assumed that any empirical data is unlikely to be fabricated and some kind of method has been used to gather the data. However, if no methods have been used to obtain data such as from an opinion piece, it will be treated with scepticism and additional data will be sought from other included documents; this will mean the CMOC in which the 'less' trustworthy data is used is supported by additional data from other sources. Where this is not possible, data of limited trustworthiness will be included if it can contribute to the programme theory in some way (ie, a nugget of wisdom). In this instance the plausibility of the arguments used to support the CMOC will be considered.<sup>62</sup> Excel spreadsheets will be used to keep a detailed record of all sources used to build the CMOCs and programme theory. A table of all sources that have been drawn on will be transparently reported, along with details about the nature of each source. This information will help the reader to make judgements about the plausibility and trustworthiness of the data used and arguments that underpin the CMOCs and programme theory.

### Plausibility and coherence of the programme theory

Any claims made on the plausibility of the programme theory will be based on both trustworthiness of data and coherence of arguments underpinning the programme theory. In realist research the coherence of the arguments underpinning the programme theory is used to

judge its plausibility. To make judgement on coherence of the programme theory 'inference to the best explanation' will be used. Haig and Evers<sup>63</sup> explain 'inference to the best explanation' means a theory is more likely to have coherence if it offers 'good' explanations. Taking this into consideration, we will use the following criteria drawn from 'inference to best explanation' to judge the coherence of the programme theory, namely: consilience (the theory's ability to detail as much as possible of the theory); simplicity (the theory does not require specific assumptions to explain the data, rather the theory is simple) and lastly; analogy (the theory aligns with what is already known including relevant substantive theory).<sup>62</sup>

Details on how a decision on rigour was reached will be documented for transparency. A random subsample (10%) of documents MT will have judged as being of relevance and demonstrating rigour, will be checked for consistency by a second member (GW) of the review team. Given that 90% of gathered documents will be determined by MT, it is predicted uncertainty will arise at some point; in these instances further discussion/joint reading by a second reviewer (GW) and/or the wider review team will occur until a decision has been reached.<sup>64</sup> This process will be recorded for transparency.

#### Step 4: extracting and organising the data

All documents will be uploaded onto the NVivo QRS International qualitative data analysis tool and again read in full. Analysis will be directed by seeking to interpret and explain why success or failure occurs at each step of using the NEWS2. Initial coding will be informed by the different elements of the initial programme theory, where tentative CMOCs will be developed using inductive and deductive logic. Inductive logic draws conclusions from multiple observations thus it builds theory from observations,<sup>51</sup> thus coding in the form of CMOCs will come from analysing the literature.<sup>65</sup> Deductive logic starts from theory and examines propositions by determining whether associations match expectations,<sup>51</sup> therefore, these are the codes that will be developed from the initial programme theory, stakeholder input and exploratory literature searches.<sup>65</sup>

As the data extraction progresses rereading of documents is probable as new concepts will emerge and a certain aspect of one document may contribute to the refined theory across several areas. Stakeholders will be consulted at this point for feedback on the developing programme theory. All data used for initial refinement of programme theory will be recorded for transparency.<sup>50</sup> As this step will be done exclusively by MT, to allow for consistency a random subsample (10%) will be reviewed by a second reviewer (GW). Any disagreements will be discussed until resolved and recorded for transparency.<sup>65</sup> If needed, MO will be approached to help resolve any remaining disagreement. This process provides an opportunity to check there is consistency among the research team of how the data are being interpreted.

#### Box 1 A realist logic of analysis<sup>66</sup>

##### Relevance

- ⇒ Determine if the data (either some or all) in a document are deemed as relevant, may be of relevance to the programme theory or context-mechanism-outcome-configurations (CMOCs).
- ⇒ Establish if there are data that inform the relationship between the C's, M's or O's or the 'place' of a CMOC within a programme theory.

##### Judgements about trustworthiness and rigour

- ⇒ Decide if the data are sufficiently trustworthy to justify amending the programme theory.

Decisions on trustworthiness will be made as outlined in step 3.

##### Interpretation of meaning

- ⇒ When a section of the document is deemed to be relevant and trustworthy, determine if it provides data that may be interpreted as a context, mechanism or outcome.

##### Interpretations and judgements about CMOCs

- ⇒ Identify either the partial or complete CMOC for the data. Then establish if there are data to develop the CMOCs within the said document or in other included documents. If so, identify the relevant data from across all other documents and consider how the CMOC relates to other CMOCs that have been developed.

##### Interpretations and judgements about programme theory

- ⇒ Establish how the CMOC (either full or partial) relates to the programme theory. Also, within the same said document, judge if there are any data that informs how the CMOC relates to the programme theory.
- ⇒ If not, establish if there is any relevant data in other documents, if so which ones and establish if it warrants changing the programme theory.

#### Step 5: synthesising the data

Data synthesis will have already begun in parallel with step 4, markedly it is not a linear one document at a time process. A realist logic of analysis will be used to interrogate the data, to develop and test the initial programme theory. To do this, we will move between the data and the process of analysis. The data will already be categorised as per tentative CMOCs, therefore, as we add data to develop, refine and test them, feedback will also be taken on board from the stakeholders to ensure the programme theory is developing in line with the reality of clinical practice. To synthesise the data, MT will follow an iterative process, consisting of analysing examples, refining the programme theory and further searches to test specific elements of the programme theory (as needed). Pawson<sup>55</sup> describes synthesis using a realist logic as 'accumulating explanation', whereby the reviewer is involved in 'juxtaposing, adjudicating, reconciling, consolidating and situating the evidence'. To operationalise this and elicit Pawson's process in more detail, we will follow the steps outlined by Papoutsis *et al*,<sup>66</sup> as presented in box 1.

To work out what is functioning as a context or mechanism, we will be thinking in configurations. We will initially identify an outcome of interest within the programme theory and then work 'backwards' to the mechanism and ultimately the context. We will draw on



our interpretations of the data within the included documents to help do this. Mechanisms are often hidden and/or may be difficult to articulate, therefore, retroductive reasoning will be used to infer and elaborate on mechanisms. Retroductive reasoning involves identifying the concealed causal forces that lie behind the uncovered patterns or changes in those patterns.<sup>51</sup> This will involve going repeatedly from the data to theory, to refine explanations of outcomes identified. The relationship between contexts, mechanisms and outcomes within individual studies and across different sources will be identified. It is presumed that inferred mechanisms from one document can help explain the way contexts influences outcomes in another document. Data from various sources are likely to be required to develop CMOCs, as it is unlikely that all elements will be present in one document alone.

### Use of substantive theory

It is important to theorise how specific contexts trigger particular mechanisms and thus outcomes<sup>67</sup>; use of substantive theory can help with this. In a realist review, substantive theory refers to an established theory operating in different disciplines or domains.<sup>51</sup> Thus, by using substantive theory it may help understanding of the evolving CMOC patterns, hence aiding their development and possibly help situate the causal explanation provided by the CMOCs with what is already known from previous research.<sup>65</sup> The final work will present the programme theory as refined CMOCs and a narrative explanation of them.

## ETHICS AND DISSEMINATION

### Ethics

Ethical approval is not required for the study as it is secondary research. Ethical approval is not required for stakeholders as they are not research participants, rather they are engaged and involved with the review design and dissemination.<sup>68</sup>

### Step 6: disseminating the findings

The review will identify how the NEWS2 may work well in one context but not another, therefore, implementation may involve alterations in practice or policies based on the setting. The review will uncover the complex and inter-related elements of the programme theory; therefore, stakeholders will be consulted on how best to apply these insights to varied NHS settings and practice. Findings will be published in a peer-reviewed journal. Findings will also be shared at conferences. Studies have identified that registered nurses' engagement with evidence-based healthcare can be limited,<sup>69 70</sup> therefore, seminars will also be held at NHS sites across southeast England (and wider if possible) to share findings. The findings will be key in providing policy makers with insight on how to facilitate successful implementation of the NEWS2 in clinical practice. In addition, for educators who deliver courses in the recognising and responding to patient deterioration, accessible and

user-friendly synopses of the findings will be shared with existing networks and on social media platforms.

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**Contributors** MT conceptualised the study. MT designed and wrote the protocol manuscript, GW and MO contributed to the protocol development. GW provided methodological advice and contributed to editing the final version. NR provided document searching advice. All authors read and approved the final manuscript.

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**Competing interests** GW is deputy chair of the UK's National Institute of Health Research Health Technology Assessment Prioritisation Committee: Integrated Community Health and Social Care Panel (A) and a member of Methods Group (A).

**Patient and public involvement** Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

**Patient consent for publication** Not applicable.

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