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Implementation evaluation of an evidence-based emergency nursing framework (HIRAID): study protocol for a step-wedge randomised control trial

Kate Curtis [1,2] Margaret Fry,[3,4] Sarah Kourouche [1] Belinda Kennedy,[1] Julie Considine [5,6] Hatem Alkhouri,[7] Mary Lam,[8] Steven M McPhail,[9] Christina Aggar,[10] James Hughes [11,12] M Murphy [13] Michael Dinh,[14,15] Ramon Shaban[1,16,17]

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For numbered affiliations see end of article.

Correspondence to
Dr Kate Curtis;
kate.curtis@sydney.edu.au

ABSTRACT

Introduction Poor patient assessment results in undetected clinical deterioration. Yet, there is no standardised assessment framework for >29 000 Australian emergency nurses. To reduce clinical variation and increase safety and quality of initial emergency nursing care, the evidence-based emergency nursing framework HIRAID (History, Identify Red flags, Assessment, Interventions, Diagnostics, communication and reassessment) was developed and piloted. This paper presents the rationale and protocol for a multicentre clinical trial of HIRAID.

Methods and analysis Using an effectiveness-implementation hybrid design, the study incorporates a stepped-wedge cluster randomised controlled trial of HIRAID at 31 emergency departments (EDs) in New South Wales, Victoria and Queensland. The primary outcomes are incidence of inpatient deterioration related to ED care, time to analgesia, patient satisfaction and medical satisfaction with nursing clinical handover (effectiveness). Strategies that optimise HIRAID uptake (implementation) and implementation fidelity will be determined to assess if HIRAID was implemented as intended at all sites.

Ethics and dissemination Ethics has been approved for NSW sites through Greater Western Human Research Ethics Committee (2020/ETH02164), and for Victoria and Queensland sites through Royal Brisbane & Woman's Hospital Human Research Ethics Committee (2021/QRBW/80026). The final phase of the study will integrate the findings in a toolkit for national rollout. A dissemination, communications (variety of platforms) and upscaling strategy will be designed and actioned with the organisations that influence state and national level health policy and emergency nurse education, including the Australian Commission for Quality and Safety in Health Care. Scaling up of findings could be achieved by embedding HIRAID into national transition to nursing programmes, 'business as usual' ED training schedules and university curricula.

Trial registration number ACTRN12621001456842.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Strengths of this study are the stepped-wedge randomised controlled pragmatic design.
⇒ A thorough implementation plan supported by implementation theory and national partnerships will inform nationwide implementation scale-up.
⇒ A limitation is that this is not a double-blinded design as this was not feasible.
⇒ Another limitation is that some data collection will rely on retrospective medical record review.

INTRODUCTION

In 2020–2021, Australia's 292 hospital emergency departments (EDs) treated >8.8 million patients, or 24 000 patients per day.[1] EDs are uniquely complex and challenging healthcare environments making them high risk for adverse events, a high proportion (36%–71%) of which are potentially preventable.[2] Undetected clinical deterioration in Australian EDs occurs in up to one in seven patients and is implicated in high-mortality adverse events.[3] Failure to recognise and respond to clinical deterioration during emergency care increases the risk of high-mortality adverse events during and after emergency care, irrespective of whether the patient is admitted to hospital or discharged.[4]

Emergency nurses are the first ED clinicians to see patients and their practice is fundamental to patient safety. They are responsible for the initial and ongoing clinical assessment, interpretation of data, initiation and evaluation of interventions and safety of patients of all ages with varying degrees of severity and urgency of illness or injury. ED patients often have extended wait times for

medical review. Across Australia in 2020–2021, only 63% of patients requiring urgent care were seen by medical officers within 30 min of ED arrival,[5] with emergency nurses solely responsible for care of these patients during this time. Early recognition of, and response to, deteriorating ED patients is primarily an emergency nursing responsibility. Poor patient assessment and reassessment results in unrecognised clinical deterioration or delays to recognition and, or response to deteriorating patients.[6] Despite the key role emergency nurses play in patient assessment, reassessment and safety, there is no standardised emergency nursing assessment framework in use for Australia's 29 000+emergency nurses.[7] To address this major gap in emergency nursing practice and the quality and safety of emergency care more broadly we need: (1) robust evidence to enable consistent, high-quality emergency nursing care and (2) tailored implementation solutions coupled with sustained practice change for different emergency care settings (metro, regional, rural, low resourced) with patient-centred outcomes. These are established as some of the highest Australian emergency care research priorities.[8]

We aim to reduce clinical variation and deliver safe, quality and consistent emergency care by implementing the emergency nursing framework HIRAID (History, Identify Red flags, Assessment, Interventions, Diagnostics, communication and reassessment) for all ED patients.

In a pilot study across four EDs in the Illawarra Shoalhaven Local Health District (LHD) (NSW, Australia) use of HIRAID resulted in a reduction in clinical deterioration related to emergency nursing care, improved clinical documentation, and local cost savings of US$1 914 252.[9] Emergency nursing and medical staff reported HIRAID to be a valuable tool to improve the quality of documentation[10] and clinical handover.[11]

Research question

Does implementation of HIRAID improve: (A) emergency nursing assessment; (B) recognition and escalation of clinical deterioration; (C) pain management; (D) patient experience and (E) clinical handover?

Hypotheses

Implementation of HIRAID will result in:

H1: a 20% reduction in inpatient deterioration events within 72 hours of admission via the ED.

H2: a 20% reduction in inpatient deterioration events within 72 hours of admission related to emergency nursing care.

H3: a 20% reduction in time to first analgesia during ED care.

H4: a 5% increase in patient/carers who report their ED experience as very good.

H5: a 10% increase in the perceived quality of nursing to nursing, and nursing to medical handover during in ED care.

METHODS AND ANALYSIS

Study design

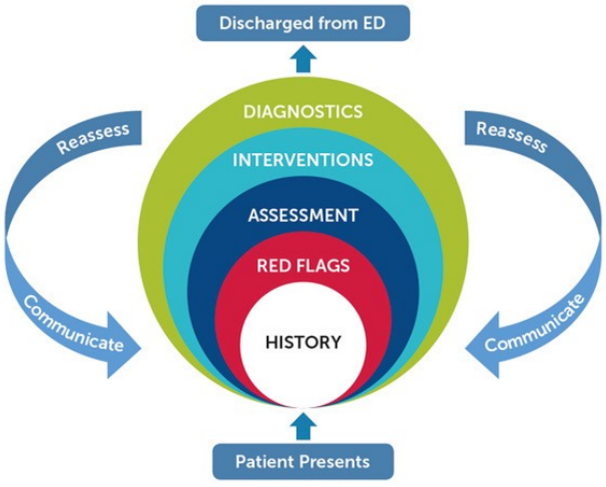
We will use an effectiveness-implementation hybrid design[12] including a stepped-wedge cluster randomised controlled trial (SW-cRCT) with interventions being commenced at three -month intervals across three Australian States to evaluate: (1) the outcomes of the implementation of HIRAID at scale (effectiveness); and (2) strategies that enable optimal uptake of HIRAID (implementation). The hybrid design allows testing of the implementation strategy at the same time as observing the outcomes of the intervention. The SW-cRCT is appropriate for evaluating health service interventions as it simplifies data collection procedures, better supports logistical processes, aligns with ethical principles, accommodates temporal issues and optimises financial constraints.[13] The SW-cRCT addresses the ethical dilemmas of RCT design where essential investigations and/or best-practice treatments may be withheld from control participants. The pragmatic trial based on our pilot data will enable translation of best practice evidence, since all participating sites will receive the intervention (HIRAID). The study will also include an analysis on factors influencing future implementation, ecological validity, usability and relevance. The study protocol complies with the SPIRIT (standard protocol items: recommendations for interventional trials) 2013 statement[14] and the extension for the CONSORT (consolidated standards of reporting trials) statement for SW-RCT.[13]

The intervention

The intervention is the HIRAID framework. HIRAID (figure 1) is an emergency nursing framework and clinical safety system[15] to address the need for a more consistent approach to patient assessment in emergency care.[16] HIRAID provides a framework to support the systematic assessment and management of patients after triage by emergency nurses. HIRAID was tested in the simulated environment where it significantly improved nurse detection of clinical indicators of urgency, prioritisation, deterioration and initiation of treatment, clinical handover, reassessment and escalation of care to medical officers. HIRAID also reduced nurse anxiety and increased self-efficacy which are associated with better clinical performance.[17]

Study process

This study will consist of four steps to test the hypotheses (figure 2) over several years (table 1). Step 1 (Baseline data collection and behavioural diagnostics) will see the collection of baseline data and determine 'who needs to change what'.[18] Online surveys will be distributed to all emergency nursing and medical staff at each cluster to collect baseline data to inform implementation. Routinely collected clinical and administrative data will also be extracted retrospectively from databases and electronic and paper medical records to establish baseline measures and enable the evaluation of the HIRAID Framework



HISTORY: Collection of the presenting problem and health history, infectious risk.

IDENTIFY RED FLAGS: Historical and physiological indicators of urgency to recognise potential and actual serious illness. Notify senior medical officer ASAP.

ASSESSMENT: Include: primary survey; A-G, focused head-to-toe; vital signs; inspection, auscultation, and palpation.

INTERVENTIONS: Should be evidence-based and prioritised based on assessment.

DIAGNOSTICS: Initiate investigations to gain a clinical picture and inform treatment decisions.

REASSESS: The evaluation of care and monitoring of patient progress. Maintain a structured approach, and repeat at appropriate intervals per the condition of the patient.

COMMUNICATE: Verbal/non-verbal skills necessary to effectively communicate with patients, families and clinicians. Use structured approach for clinical handover; graded assertiveness to escalate if needed; accurate and comprehensive clinical

Figure 1 HIRAID emergency nursing framework. HIRAID, History, Identify Red flags, Assessment, Interventions, Diagnostics.

and address H1, H2 and H3. Some data collection has commenced (post registration) from November 2021.

In step 2 (Intervention transition period), we will tailor our implementation tool-kit (developed and tested in 2017–2019) for each site from the baseline data collected in step 1. Behavioural diagnostic data collected in step one will inform the implementation strategy using behaviour change theory. The implementation tool-kit developed in previous work implementing HIRAID[11] will be adapted with mechanisms from the Behaviour Change Techniques Taxonomy[19] and the APEASE criteria that consider affordability, practicality, effectiveness/cost-effectiveness, acceptability, side effects/safety and equity.[20] The implementation strategy will be developed in consultation with end users, nurse educators and executive through an iterative process.

In step 3 (Intervention), HIRAID will be implemented using the SW-cRCT design, implementation fidelity will be monitored and recorded. Roll out will be undertaken using strategies identified as effective in other health districts and previous feasibility research[21] and informed by baseline data as outlined in step 2. These strategies will be applied consistently to ensure implementation fidelity, this will be achieved through HIRAID nurse facilitators or clinical champions.

Step 4 (Data collection) will determine the effectiveness of the application of HIRAID on patient and health service outcomes. We will also evaluate implementation fidelity to assess if the intervention was implemented as intended at all sites. Fidelity will be measured through formal feedback measures such as audit, implementation logs, team meetings and records of informal discussion with staff. To address H1, H2 and H3 data sources used at baseline will be repeated, study population and data sources. To address H4 and H5, surveys used in baseline data collection to assess patient/carer satisfaction and medical officer satisfaction will be repeated.

The findings from all steps will be integrated in step 5 dissemination and knowledge translation.

There will be six sources of data collection (online supplemental file 1):

1. Electronic medical record (eMR, Firstnet) (H1, H2, H3, H4).
2. Performance Planning Unit (Costs) database (H1).
3. Patient/carer satisfaction surveys (H5).
4. Staff surveys (medical and nursing) (H5).
5. Staff interviews.
6. Implementation tracking tools.

Study sites and randomisation

The study will take place in 31 NSW/Victorian/Qld metropolitan and rural EDs across four LHD clusters distributed to ensure geographically and clinically diverse ED settings (table 2). Each LHD will commence the trial in the control condition and sequentially cross over to the intervention condition. Each cluster will be randomised to one of four dates to cross to the intervention until all EDs have been exposed to the intervention.

Patient and public involvement

Patients were unable to be directly involved in setting the research design due to the nature of emergency medicine,

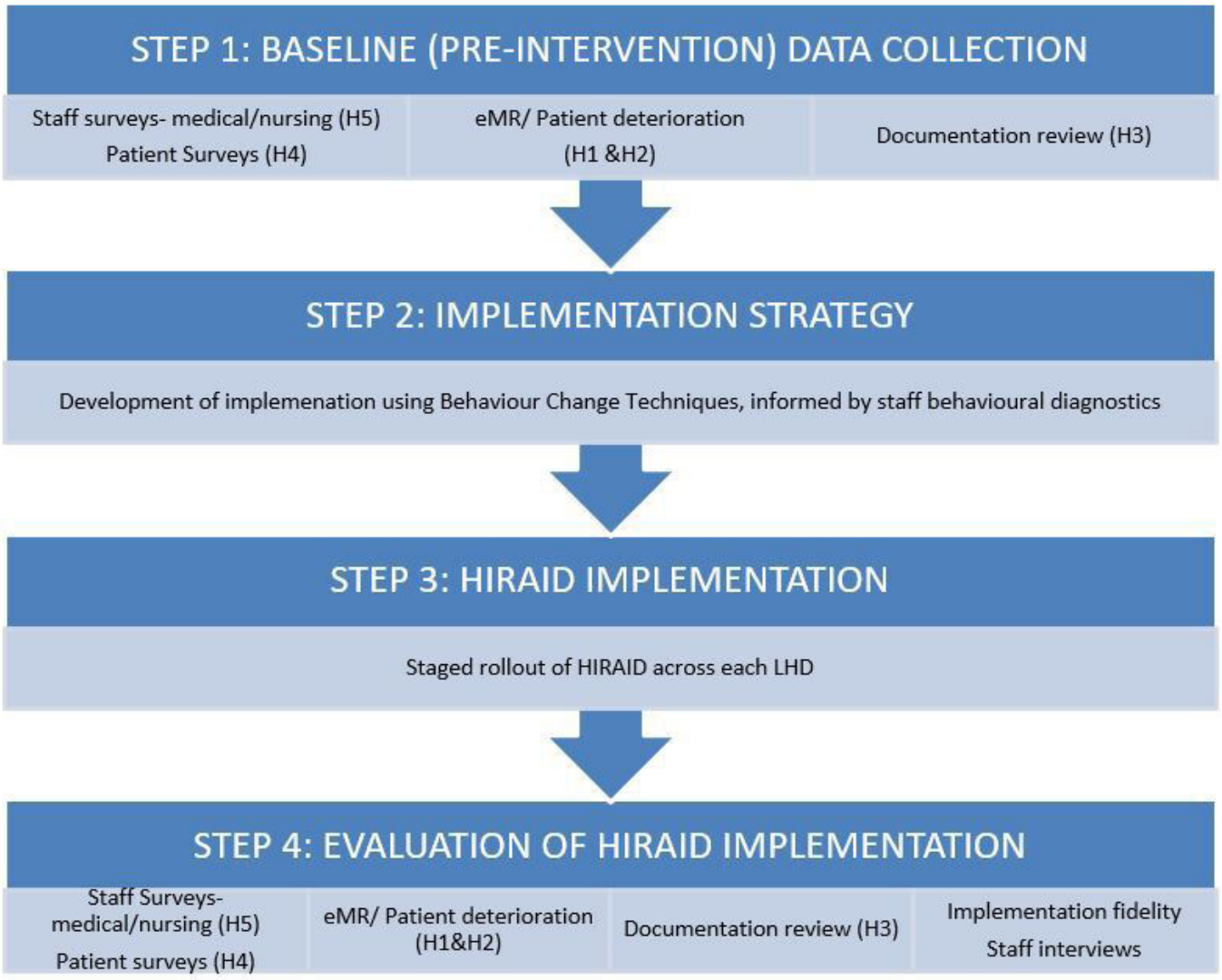


Figure 2 HIRAID study process. eMR, electronic medical record; HIRAID, History, Identify Red flags, Assessment, Interventions, Diagnostics; LHD, Local Health District.

however, industry partners were involved during the development, progress and writing of this project, and will continue to be involved.

Data management

Research nurses at the study site will have access to the

Table 1 Planned timetable and site(s) for the study

Activity and year	2022			2023			2024			2025	2026
Cluster 1		B+BD	B+BD	T	T	I-D	I-D				
Cluster 2			B+BD	B+BD	T	T	I-D	I-D			
Cluster 3				B+BD	B+BD	T	T	I-D	I-D		
Cluster 4					B+BD	B+BD	T	T	I-D	I-D	
Linkage											
Analysis											
National tool-kit											
Dissemination											

B+BD: Baseline data collection and behavioural diagnostics (step 1).

T: Intervention transition period, (step 2), I: Intervention-(step 3) D-data collection (step 4).

Table 2 LHD cluster, ED patient presentations, admissions, nursing staff, patient experience

Clusters	ED patients per year	Admits via ED per year	ED nurse staffing	Description of local health district	NSW patient rating % (n) 'very good' care 2017–2018
Eastern Health VIC (3 EDs) + Royal Brisbane Women's Hospital QLD (1)	169 465 81 762	47 320 22 245	414 197	EH spans 2816 km^2 750 000+ residents RBWH 4000 km^2	N/A
Northern NSW (12 EDs)	213 307	40 539	430	spans 20 732 km^2 350 000+ residents	70 (1194)
Western Sydney (3 EDs)	202 516	67 975	280	spans 780 km^2 946 000+ residents	46 (917)
Southern NSW (12 EDs)	116 836	17 065	180	spans 20 732 km^2 200 000+ residents	66 (696)
Totals: 31 ED	783 886	195 144	1501	Range of remote, rural, regional and metro EDs	61.6

ED, emergency department; LHD, Local Health District; N/A, not available.

data from the eMR that identifies patient's for according to study inclusion criteria. Research nurses require access to determine the patient's required for medical record review and/or rapid response review. Only the researchers in the study who have signed a privacy and confidentiality form will have access to the identifiable data. All data collected through medical record review, and review of rapid response calls, by the research nurses on site will be entered directly into REDcap (Research Electronic Data Capture) (https://catalyst.harvard.edu/services/redcap/), a secure web-based application for data capture managed and maintained in a secure server by The University of Sydney. Once downloaded from REDCap data files will be stored securely on the Research Data Store maintained by The University of Sydney.

Outcomes

There are four primary outcome measures:

1. Inpatient deterioration during the first 72 hours related to ED care.
2. Time to first dose analgesia.
3. Patient and carer experience with emergency care.
4. Nurse and medical officer satisfaction with clinical handover.

Measuring the effect of HIRAID on patient deterioration

This protocol posits two key hypotheses regarding the effect of HIRAID on patient deterioration. Hypothesis 1 (H1) is that implementing HIRAID will improve emergency nurse recognition and response to clinical deterioration during ED care as evidenced by a decrease in admitted patient deterioration calls (rapid response team (RRT) or medical emergency team (MET) calls) on hospital wards during the first 72 hours for patients admitted via ED (see box 1). There is strong association between physiological derangement during ED care and patient deterioration within the first 72 hours of emergency admission).[22] Hypothesis 2 (H2) is that implementing HIRAID will decrease the proportion of inpatient clinical deterioration events during first 72 hours of admission (RRT/MET calls, unplanned intensive care unit (ICU) admission) with suboptimal emergency nursing assessment, observations or monitoring as a causal factor by 20%. For the purposes of this protocol suboptimal emergency nursing care is defined as unreported or delayed reporting (>30 min) of vital sign abnormalities fulfilling ED or hospital RRT criteria. With respect to sample size, using New South Wales (NSW) data, around one in six patients deteriorate in the ED,

Box 1 Measuring the effect of History, Identify Red flags, Assessment, Interventions, Diagnostics (HIRAID) on patient deterioration

Population: Patients admitted via emergency department (ED) with a clinical deterioration call within 72 hours (n=2200). A waiver of consent was sought to access medical records retrospectively for this population.
Intervention: HIRAID.
Control: Usual care.
Outcome (primary): Patient deterioration calls (rapid response team/medical emergency team) within 72 hours of admission from ED relating to nursing observation and monitoring as determined by the clinical excellence commission's validated Human Factors Classification Framework for Patient Safety.[25] The framework considers equipment, work environment, staff action and patient factors.
Secondary outcome measures: Adverse events; Transfer to higher level care within 72 hours (eg, to ICU); Timely initiation rate of existing pathways (sepsis, stroke, chest pain, trauma); Prolonged abnormal vitals without intervention; Quality of nursing documentation (modified D-catch tool[26]; hospital resource use and costs (health service perspective)).

Box 2 Measuring the effect of History, Identify Red flags, Assessment, Interventions, Diagnostics (HIRAID) on time to first dose analgesia

Population: Patients presenting to the emergency department (ED) with pain. Due to the sheer number of patients presenting at EDs requiring analgesia (up to 80%), all patients cannot be included. Patients presenting with abdominal, hip, limb or chest pain will be eligible for inclusion. These are the most common pain-related presentations to Australian EDs. Patients with a triage category 1 (immediate) are also excluded. A waiver of consent was sought to access medical records retrospectively for this population.
Intervention: HIRAID.
Control: Usual care.
Outcome (primary): time to first dose analgesia in ED (Triage time to documented analgesia).
Secondary outcome measures: Pain assessment; Pain score at 1 hour; Repeat pain assessment; Patient reported outcomes of pain care in the ED.[23]

Box 3 Measuring the impact of History, Identify Red flags, Assessment, Interventions, Diagnostics (HIRAID) on patient and carer experience with emergency care

Population: Patients (or their carers) presenting to the emergency department (ED). Those who are at the end of life will not be approached; Participants will not be approached until clinically appropriate per treating clinician. Potential participants will be approached by the research nurse and if eligible will sign a consent form prior to being surveyed. The research nurse can help the patients complete the survey. Interpreters will be provided if needed.
Intervention: HIRAID.
Control: Usual practice.
Outcome: Experience with nursing care.
Secondary outcome measures: overall ED care experience; Schmidt's subscales: seeing the Individual Patient, Explaining, Responding, Watching Over.

equating to approximately 580 per cluster each year. Adjusting for the design effect (including assumed intracluster correlation) for a SW-cRCT trial, a sample of 2200 is required for 80% power (alpha=0.05, two tailed) to detect a 10% decrease in deterioration calls. Subsequent samples for the other patient outcome research questions will be drawn from this 2200, which is achievable (see table 1).

Measuring the effect of HIRAID on time to first dose analgesia

The third hypothesis (H3) is that implementing HIRAID will result in a 20% reduction in time to first dose analgesia during ED care with improved timely and consistent pain detection and (re)assessment (see box 2). The sample size was determined using Australian ED patient profile statistics and recent ED and analgesic work by the team.[23] It was estimated using GPower V.3.1 and adjusted for the design effect of the stepped-wedge clustered design using the method described in Woertman *et al*[24] with one baseline measurement and one follow-up measurement. A total of 848 patients are required to detect a 20% decrease in time to analgesia, with 80% power at the 5% significance level, using an independent sample two-tailed t-test with a non-clustered design. We will need to recruit 40 patients per LHD per quarter=total of 640, which is achievable (table 1).

Measuring the impact of HIRAID on patient and carer experience with emergency care

The fourth hypothesis (H4) is that implementing HIRAID will increase overall patient satisfaction with care (see box 3). These data will be collected via electronic survey in the post implementation phase and compared with data from the pre implementation phase.

Patient characteristics such as age and presenting condition will be used to adjust for the primary outcome. With respect to sample size, the Schmidt's Perceptions of Nursing Care Survey has 15 questions that are answered using a Likert-type format where 1=strongly disagree and 5=strongly agree. We calculated we need to recruit 311 patients in each LHD for a total of 1244 to demonstrate a 5% increase, which is achievable (see table 1).

Measuring the impact of HIRAID on nurse and medical officer satisfaction with handover

We hypothesise that as a result of using HIRAID (H5), overall nursing and medical satisfaction with the information provided in clinical handover during ED care will increase (see box 4). These data will be collected via electronic survey and be matched to pre implementation responses staff. Based on our pilot work, a sample of 200 in each cohort would detect an effect size of 1 unit increase in satisfaction score taking into consideration the design effect of the SWcRCT, which is achievable (see table 1).

ETHICS AND DISSEMINATION

Ethics has been approved for NSW sites through Greater Western Human Research Ethics Committee (2020/ETH02164), and for Victoria and Queensland sites

Box 4 Measuring the impact of History, Identify Red flags, Assessment, Interventions, Diagnostics (HIRAID) on nurse and medical officer satisfaction with handover

Population: Nursing and Medical staff permanently employed in site emergency departments. A participant information and consent form will be emailed to all nursing and medical staff with the invitation to participate, clearly stating the voluntary nature of the survey and anonymity of survey responses. Consent for the surveys will be implied on completion of the survey.
Intervention: HIRAID.
Control: Usual practice.
Outcomes: Satisfaction with structure, content and quality of nurse—nurse and nurse—MO handover. Practice Environment Scale of the Nursing Work Index.

through Royal Brisbane & Woman's Hospital Human Research Ethics Committee (2021/QRBW/80026).

Outcomes from this study will be published in peer-reviewed publications.

A dissemination, communications (variety of platforms) and upscaling strategy will be designed and actioned with the organisations that influence state and national level health policy and emergency nurse education, including the Australian Commission for Quality and Safety in Health Care. Scaling up of findings could be achieved by embedding HIRAID into national transition to nursing programmes, 'business as usual' ED training schedules and university curricula.

Author affiliations
[1]Susan Wakil School of Nursing and Midwifery, Faculty of Medicine and Health, The University of Sydney, Sydney, New South Wales, Australia
[2]Emergency Services, Illawarra Shoalhaven Local Health District, Wollongong, NSW, Australia
[3]Faculty of Health, University of Technology Sydney, Broadway, New South Wales, Australia
[4]Emergency and Critical Care, Northern Sydney Local Health District, Saint Leonards, New South Wales, Australia
[5]School of Nursing and Midwifery, Centre for Quality and Patient Safety Research, & Institute for Health Transformation, Deakin University, Burwood, Victoria, Australia
[6]Eastern Health Foundation, Box Hill, Victoria, Australia
[7]Emergency Care Institute, NSW Agency for Clinical Innovation, North Ryde, New South Wales, Australia
[8]Health and Biomedical Sciences, RMIT University, Melbourne, Victoria, Australia
[9]Australian Centre for Health Service Innovation and School of Public Health & Social Work, Queensland University of Technology, Brisbane, Queensland, Australia
[10]Northern New South Wales Local Health Network, Lismore, New South Wales, Australia
[11]Emergency and Trauma Centre, Royal Brisbane and Women's Hospital, Herston, Queensland, Australia
[12]School of Nursing, Queensland University of Technology, Kelvin Grove, Queensland, Australia
[13]Western Sydney Local Health District, Wentworthville, New South Wales, Australia
[14]Department of Emergency, Royal Prince Alfred Hospital, Camperdown, New South Wales, Australia
[15]Faculty of Medicine and Health, University of Sydney, Sydney, NSW, Australia
[16]Marie Bashir Institute for Infectious Diseases & Biosecurity, University of Sydney, Sydney, New South Wales, Australia
[17]Department of Infection Control, Western Sydney Local Health District, Westmead, New South Wales, Australia

Twitter Sarah Kourouche @Sarah.Kourouche, Julie Considine @julie_considine and Ramon Shaban @ramonshaban

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Contributors KC: conceptualisation, methodology, validation, formal analysis, writing—original draft, writing—review and editing, supervision, project administration, funding acquisition. HA: conceptualisation, methodology, validation, formal analysis, writing—original draft, writing—review and editing, supervision, project administration, funding acquisition. SK: writing—original draft, review and editing, methodology, funding acquisition. ML: review and editing, methodology, formal analysis. MF: conceptualisation, methodology, validation, formal analysis, writing—original draft, writing—review and editing, supervision, project administration, funding acquisition. BK: resources, writing—review and editing, project administration. JC: conceptualisation, methodology, validation, formal analysis, writing—review and editing, supervision, project administration, funding acquisition. SMM: writing—review and editing. CA: writing draft, review and editing. JH: review and editing. MM: conceptualisation, writing—rview and editing, project administration. MD: writing—review and editing. RS: conceptualisation, methodology, validation, formal analysis, writing—original draft, writing—review and editing, supervision, project administration, funding acquisition.

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ORCID iDs
Kate Curtis http://orcid.org/0000-0002-3746-0348
Sarah Kourouche http://orcid.org/0000-0001-6210-6191
Julie Considine http://orcid.org/0000-0003-3801-2456
James Hughes http://orcid.org/0000-0001-9387-2489
M Murphy http://orcid.org/0000-0002-8937-8418

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