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Reinforcing informed medication prescription for low back pain in the emergency department (RIME): a controlled interrupted time series implementation study protocol

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ABSTRACT

Introduction Management guidelines for low back pain (LBP) recommend exclusion of serious pathology, followed by simple analgesics, superficial heat therapy, early mobilisation and patient education. An audit in a large metropolitan hospital emergency department (ED) revealed high rates of non-recommended medication prescription for LBP (65% of patients prescribed opioids, 17% prescribed benzodiazepines), high inpatient admission rates (20% of ED LBP patients), delayed patient mobilisation (on average 6 hours) and inadequate patient education (48% of patients). This study aims to improve medication prescription for LBP in this ED by implementing an intervention shown previously to improve guideline-based management of LBP in other Australian EDs.

Methods and analysis A controlled interrupted time series study will evaluate the intervention in the ED before (24 weeks; 20 March 2023–3 September 2023) and after (24 weeks; 27 November 2024–12 May 2024) implementation (12 weeks; 4 September 2023–26 November 2023), additionally comparing findings with another ED in the same health service. The multicomponent implementation strategy uses a formalised clinical flow chart to support clinical decision-making and aims to change clinician behaviour, through clinician education, provision of alternative treatments, educational resources, audit and feedback, supported by implementation champions. The primary outcome is the percentage of LBP patients prescribed non-recommended medications (opioids, benzodiazepines and/or gabapentinoids), assessed via routinely collected ED data. Anticipated sample size is 2000 patients (n=1000 intervention, n=1000 control) based on average monthly admissions of LBP presentations in the EDs. Secondary outcomes include inpatient admission rate, time to mobilisation, provision of patient education, imaging requests, representation to the ED within 6 months and healthcare costs. In nested qualitative research, we will study ED clinicians' perceptions of the implementation and identify how benefits can be sustained over time.

Ethics and dissemination This study received ethical approval from the Metro North Human Research Ethics Committee (HREC/2022/MNHA/87995). Study findings will be published in peer-reviewed journals and presented at international conferences and educational workshops.

Trial registration number ACTRN12622001536752.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Controlled interrupted time series design will test the effects of the intervention on relevant outcomes while observing and gathering information on implementation in a real-world emergency department (ED) setting.
⇒ Outcomes are not only evaluated before and after implementation at the intervention ED, but also through comparison with a control ED.
⇒ Process evaluation will explore components of the implementation that clinicians found useful, as well as perceived barriers to adoption and sustainability of improved low back pain management in the ED.
⇒ Both participating EDs are within the same health service, and therefore, results may lack generalisability to other settings.

INTRODUCTION

Low back pain (LBP) is the fifth most common presentation to Australian emergency departments (EDs).[1] Management guidelines for LBP recommend an initial exclusion of serious pathology (eg, spinal fracture, infection, cancer), followed by the use of simple analgesics, superficial heat therapy, early mobilisation to improve function and the provision of patient education to enable self-management.[2] Research to date has evidenced inconsistent use of best practice guidelines for LBP in Australian EDs.[3]

In line with previous research, a recent audit of ED routinely collected data at a large metropolitan tertiary hospital in Queensland, Australia, identified a high rate of medication

prescription for LBP, particularly opioids (prescribed for 65% of LBP patients) but also muscle relaxants (benzodiazepine, 17%). These are not recommended first-line medications for LBP and have known side effects including dependence, poisoning and death.[4] Other concerning audit findings were that 20% of patients with LBP were admitted as an inpatient (to either the short stay unit (SSU) or hospital wards), had long waits until they received support to mobilise (6 hours on average until they were supported to walk) and may not have received patient education (48% of patients' records had no documented evidence of education/advice).[5] In response, an intervention was sought to promote guideline-based management of LBP in this metropolitan hospital ED to improve patient care, particularly with regard to medication prescription.

A recent randomised trial conducted in other Australian EDs was identified that showed improvement in the use of LBP best practice guidelines by clinicians.[6] The Sydney Health Partners Emergency Department (SHaPED) trial successfully reduced opioid prescription by over 12% (50.5% in intervention EDs vs 62.8% in control) (OR 0.57, 95% CI 0.38 to 0.85), with no adverse effects on patients' pain scores or satisfaction with care.[6] Improvements were also observed regarding clinicians' beliefs and knowledge regarding the management of LBP.[6] The SHaPED trial specifically intervened to change ED clinician behaviour regarding the use of LBP guidelines.[6] The SHaPED trial used a multicomponent implementation strategy that was informed not only by a review of practice but also included locally driven strategies that clinicians identified as potential facilitators and barriers to the uptake of LBP guidelines in the participating Sydney EDs.[7]

This protocol paper describes the Reinforcing Informed Medication prescription for LBP in the emergency department (RIME) study. The aim of the RIME study is to improve the management of LBP in our Queensland-based ED, by implementing and evaluating the intervention shown to be effective in the SHaPED trial in Sydney EDs. The primary and secondary objectives of the study are as follows.

Primary objective

Objective 1: To evaluate the impact of the intervention on the percentage of patients with LBP who are prescribed non-recommended medications (ie, opioids, benzodiazepines and/or gabapentinoids) in the ED (primary outcome).

Secondary objectives

Objective 2: Evaluate the impact of the intervention on the percentage of patients with LBP who are admitted to hospital, or who receive support to mobilise (including time to support to walk), appropriate advice/education, lumbar spine imaging and who represent to ED within 6 months (secondary outcomes).

Process evaluation

Objective 3: Undertake a cost analysis of implementing the intervention from a hospital resources perspective.

Objective 4: Understand the perspectives (eg, acceptability, adoption, appropriateness, feasibility, sustainability) of ED clinicians towards the intervention, the implementation strategy and sustainability of changes in LBP management in the ED.

Objective 5: Determine the fidelity to which each component of the implementation strategy was delivered, including the percentage of appropriate clinician encounters with the RIME training team during implementation.

METHODS AND ANALYSIS

Study design

RIME is a controlled interrupted time series (ITS) study design evaluating outcomes across study phases with nested process evaluation. This design permits evaluation of changes in outcomes both preimplementation and postimplementation in the intervention ED, as well as intervention and control ED comparisons to exclude confounders due to cointerventions or other events occurring during the study timeline.[8] The study is a prospective effectiveness-implementation hybrid model (type 1), testing intervention effects on relevant measurable outcomes (objectives 1–3) while observing and gathering information on implementation (objectives 4–5) in a real-world setting.[9]

Scheduled activity over the three study phases is shown in table 1 and includes phase 1/preimplementation usual care—during which primary and secondary clinical outcome data will be collected over a 6-month period for adult patients (aged 18 years and over) presenting with LBP to either the intervention or control EDs; phase 2/implementation—during which the intervention will be implemented with clinicians over a 12-week period at the intervention ED only and phase 3/postimplementation care—which repeats the identical data collection procedure of phase 1 over a 6-month period at both intervention and control EDs.

Patient and public involvement

None.

Study setting

The study will be conducted in two large metropolitan tertiary hospital EDs in Queensland, Australia. One ED will serve as the intervention site and the other the control site. Both EDs are governed by the same Hospital and Health Service, and the catchment populations of both are almost identical, projected to be approximately 368 000 persons by 2026.[10] The median age of residents in the intervention ED catchment area is slightly younger (approximately 34 years) than for the control ED (approximately 37 years),[11] however, both catchment areas have over 1000 LBP patients presenting to their ED each year (January to December 2021 data; intervention ED 1046

Table 1 Schedule of procedures during the RIME study with weeks (W) 1–24 representing the preimplementation phase (pre), weeks 25–36 the implementation phase and weeks 37–60 the postimplementation phase (post)

	Pre		Implementation												Post	
Procedures/measurements	**W2**	**W24**	**W25**	**W26**	**W27**	**W28**	**W29**	**W30**	**W31**	**W32**	**W33**	**W34**	**W35**	**W36**	**W38**	**W60**
Measurement of primary and secondary outcomes (fortnightly)	√	➡√		√		√		√		√		√		√	√	➡√
Study information sheets provided			√													
Educational seminars delivered			√	√	√	√	√	√	√	√	√	√	√	√		
Educational materials provided			√	√	√	√	√	√	√	√	√	√	√	√		
Provision of alternative LBP treatment options			√	√	√	√	√	√	√	√	√	√	√	√		
Fast-track referral to outpatient services			√	√	√	√	√	√	√	√	√	√	√	√		
Audit and feedback						√				√				√		
Implementation champion actioned			√	√	√	√	√	√	√	√	√	√	√	√		
Cost data collection	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Audit and observation measures recorded				√		√		√		√		√		√		
Qualitative interviews commence															√	

Implementation weeks and implementation strategies are shaded grey. Black arrows denote continuous periods of outcome measurements recorded fortnightly, thus initial recordings are W2 and W38 of the preimplementation and postimplementation phases, respectively.
LBP, low back pain; RIME, Reinforcing Informed Medication prescription for low back pain in the Emergency department.

patients, control ED 1485 patients), and each hospital has a similar skill-mix in their ED clinical teams. These clinical teams include senior and junior ED doctors and nurses, as well as emergency physiotherapy practitioners (EPPs). The EPPs work relatively independently within the ED and are usually responsible for the assessment, investigation and management of LBP patients.

Participants

There are three participant groups in this study.

Patients with LBP

Data from adult patients (18+ years) presenting to either the intervention or control ED with LBP will be included in the study. A waiver of consent has been granted for the use of the anonymous (deidentified) ED patient data. Only routine ED service data will be required for the study, there is no foreseeable risk or additional burden placed on patients, and it is impractical to gain individual consent for the use of these routine service data. It was also not deemed necessary to burden patients with patient-reported outcome data collection, given the previous SHaPED trial already showed the intervention to be effective in reducing opioid prescription without compromising patient reported pain or satisfaction.[6]

Potentially eligible LBP patient cases will be identified at the two sites using the electronic medical record (EMR) system—emergency department information system (EDIS)—with the following parameters:

- Seen in a low-acuity area of the ED.
- Presenting complaint related to 'back pain', 'altered sensation', 'mechanical strain', 'requesting investigation' or 'requesting medication/certificate/results'.
- Primary diagnosis code related to LBP using the International Statistical Classification of Diseases and Related Health Problems, Tenth Revision, Australian Modification (ICD-10-AM) coding system.

Exclusions are patient cases with spinal fracture, infections, severe neurological disorders, cauda equina syndrome, major or multitrauma, malignancy, psychiatric disorders and mental health disorders, and other non-spinal causes of LBP. These exclusions will be identified through screening EDIS information (see online supplemental table 1 for a full list of EDIS extraction parameters). Potentially eligible LBP patients will then be manually screened by site-based study staff who will review the presenting problem free text in the ED data to further refine the study sample to those with LBP who do not present with one of the exclusions. Reasons for exclusion during manual review will be collected and summarised.

ED clinicians

All ED clinicians at the intervention ED will be informed about the intervention as a service improvement activity but their level of involvement will be at their discretion. Individual ED clinician consent to participate will not be sought. This approach ensures these ED clinicians do not feel pressured to undertake activities or practices they do not wish to. The research team will attempt to facilitate uptake by offering all ED clinicians all components of the implementation strategy. Only the intervention ED clinicians will be given a RIME study information sheet to minimise the risk of potential contamination at the control ED.

ED clinicians who take part in the nested interviews

Following the implementation phase, up to 20 ED clinicians will be invited to participate in a qualitative semistructured interview exploring their views of the intervention, its implementation and potential sustainability of improvements in practice. This sample size will enable representation from the three ED clinician disciplines (ie, EPPs, nurses, medical) and is similar to our earlier ED clinician qualitative study.[5] Consent from these participants will be implied by their voluntary participation in the interviews.

Sample size

Based on recommendations[12 13] and given the number of observations within each time period and effect on statistical power, the study will use 12 time periods spaced 2 weeks apart (6 months total) for all outcomes in both the preimplementation and postimplementation phases (phases 1 and 3). Results from the SHaPED trial[6] showed a difference in any opioid medication prescription between control (62.8%) and intervention (50.5%) groups of 12.3%. Simulations based on these findings using SAS V.9.4 suggest the power to detect at least a 12% reduction in non-recommended medication prescription (the primary outcome) at the intervention ED is between 70% and 80%.[14] Anticipating 500 LBP ED presentations in 6 months at the intervention ED allows for approximately 45 patients in each 2-week time period before and after implementation. The total anticipated sample size is 2000 (500 in each of the two EDs, in each of the preimplementation and postimplementation periods); (n=1000 intervention, n=1000 control).

Intervention and implementation plan

The intervention addresses ED clinician behaviour to improve their use of best-practice LBP management guidelines, specifically the New South Wales (NSW) Agency for Clinical Innovation model of care for acute LBP[2] and the more recent Australian LBP Clinical Care Standard.[15]

To best inform the implementation approach for the local ED context, 5 focus groups with 18 ED clinicians (medical, nursing, EPPs) were previously conducted.[5] These interviews gained the local perspective on current practice, LBP guidelines, and barriers and enablers potentially impacting the uptake of guidelines for LBP management at the intervention ED.[5] Findings indicated that adherence to guidelines is primarily driven by (1) clinician beliefs and behaviours; (2) patient expectations and behaviours and (3) workflow processes. Clinicians' beliefs around role scope and accountability were perceived to

serve as barriers to providing recommended treatments such as prescription of simple analgesics and early mobilisation. Patients' expectations of care (eg, specifically requesting stronger analgesics) were perceived to influence clinical decisions regarding medication prescription. Limited access to out-of-hours physiotherapy, along with National Emergency Access Target pressures, were also felt to influence clinical decisions, particularly inpatient admissions to the SSU.[5]

Through methodological triangulation (audit, survey, focus groups), the focus group data provided a deeper understanding of the previous ED audit results.[5] Strategies suggested to improve best practice within the intervention ED context included materials such as a formalised clinical flow chart (to support clinical decision-making that aligns with best practice), targeted education to medical and nursing staff around safe mobilisation practices and best practice management of LBP patients, and patient education resources to better support patient self-management. Additionally, it was identified that the multifaceted intervention would require organisational support to embed the strategies within clinical management systems including the EMR, to facilitate clinicians to adopt best practice routinely.[5]

Implementation of the intervention will be underpinned by the knowledge-to-action framework (as per the SHaPED trial),[16] incorporating evidence-based implementation strategies specifically targeting the behaviour of ED clinicians at the intervention ED. The capability-opportunity-motivation=behaviour (COM) behaviour change theoretical framework[17] has been used to shape the implementation plans to support behaviour change in ED clinicians to enhance COM to improve uptake of guidelines when managing LBP patients in the ED.

Figure 1 depicts the multicomponent implementation strategy, including:

1. Educational seminars: These will comprise structured best practice updates from experienced ED clinicians (ie, EPPs, emergency medical consultants) that focus on knowledge and skills for assessing, managing, educating and referring patients in line with LBP guidelines.[2] Preparation of these best practice updates will be assisted by the investigator team. These best practice sessions will be offered on numerous occasions throughout the 12-week implementation period in protected ED teaching time. All ED clinicians will be invited to participate and clinician participation in the education sessions will be tracked through a logbook, with reminders sent and personal communication from the study team and ED clinical leads where needed.
2. Educational materials: ED clinicians will receive a hard copy of the LBP guidelines and LBP Clinical Standards,[2 15] a link to an established, contemporary evidence-based patient-facing website (https://mybackpain.org.au/) and the formalised clinical flow chart to support clinical decision-making such as the appropriate use of analgesic medicines. Posters highlighting key messages about benefits and harms of opioid medicines, lumbar imaging and inpatient admission will be displayed throughout the intervention ED. Anonymised patient cases from study phase 1 will be discussed, illustrating examples of non-recommended practice and best practice. Patient educational materials (based on the LBP guidelines) and scripts to guide conversations with patients will be provided so that clinicians can use these with patients.
3. Provision of alternative treatment options for LBP: Non-opioid pain medicines will be made more easily accessible to clinicians as an evidence-based alternative to opioid medicines or muscle relaxants. Heat wraps (used as a non-pharmacological modality for pain relief) will also be made available to clinicians with encouragement to use these as alternatives to non-recommended pharmacological treatments.
4. Fast-track referral to outpatient services: Clinicians will be educated on available referral pathways, for whom these are appropriate and how to collaboratively facilitate the referral process with the patient. Referral pathway options include private physiotherapy services within the primary care setting, onsite public physiotherapy outpatient services or onsite advanced-practice musculoskeletal physiotherapy screening services.
5. Audit and feedback: During the implementation phase, routinely collected ED data will be audited and clinicians provided with structured ED-level and discipline-level audit and feedback reports, includ-

Figure 1 Diagram depicting the six components of the implementation plan designed to change clinician behaviour towards the use of best-practice LBP management guidelines, specifically the NSW Agency for Clinical Innovation model of care for acute LBP[2] and the more recent Australian LBP Clinical Care Standard.[15] LBP, low back pain. NSW, New South Wales.

ing medication prescription data. These reports are planned to be provided at 4, 8 and 12 weeks after the start of the implementation phase.

6. Support from an ED 'implementation champion': A key feature of the implementation is the inclusion of a dedicated 'implementation champion'. An experienced ED clinician (investigator Heine) will undertake this role, as champions are considered vital to successful implementation and change in their own sphere of influence, particularly when intrinsically motivated and enthusiastic about the practices they promote.[18] The implementation champion will support reinforcement of implementation aims with ED staff, provide personal feedback sessions, and offer one-to-one or small group discussions with ED staff as needed.

Study outcomes

Study outcomes include primary and secondary clinical outcomes, as well as a nested process evaluation.

Data related to the primary and secondary clinical outcomes, in addition to key demographic characteristics and ED management data, will be obtained using either routine electronic data from EDIS, or via manual extraction from the medical records. Data validation rules will be implemented to reduce data transcription errors and improve data quality. Following completion of the data extraction, patient identifying information will be removed and replaced with an anonymised ID code.

Data obtained from EDIS include patient presentation date/time, demographic characteristics (age, gender, postcode) and ED management details (triage category, arrival mode (ambulance, walk in, etc), primary clinician, consultations performed, ED discharge destination, time to treatment, etc). Data obtained via manual extraction from the medical record include a history of LBP, pain severity, ED treatment details (attempted mobilisation, provision of education/advice, heat pack used, imaging requested, etc), and medications prescribed while in the ED and on discharge. Data relating to representations within 6 months will also be obtained from EDIS.

Primary clinical outcome (objective 1)

- Percentage of patients presenting to the ED with LBP prescribed non-recommended medications in the ED. Non-recommended medications are grouped under the Anatomical Therapeutic Chemical (ATC) classification[19] of N02A (opioids), N05B (benzodiazepines) or N02BF (gabapentinoids).[6 7]

Secondary clinical outcomes (objective 2)

- Percentage of patients presenting to the ED with LBP prescribed analgesic medications in the following ATC categories: N02BE01 (paracetamol) or M01A (anti-inflammatory and antirheumatic products, non-steroidal).
- Mean/median time to mobilisation (time to be supported to walk).
- Percentage of patients receiving education about LBP care.
- Percentage of patients receiving lumbar spine imaging.
- Percentage of patients admitted to hospital or short stay.
- Percentage of patients representing to the same ED facility within 6 months.

Process evaluation

The process evaluation of the implementation is underpinned by the framework developed by Proctor *et al*.[20] This framework consists of eight distinct implementation outcomes which serve to understand the implementation process and determine implementation success. Implementation outcomes will be assessed by the approaches shown in table 2.

Cost evaluation (objective 3)

Costs will be estimated based on project staff time to conduct the implementation components/activities, clinical staff time to attend the educational seminars and cost of developing materials. Research specific costs (eg, semi-structured interviews) will be excluded from this analysis, however, will be reported separately. Direct health system costs will be estimated using actual cost data obtained from each hospital's clinical costings department for each eligible ED patient presentation and any related inpatient episodes of care. The cost categories collected include medical, nursing, allied health, pathology, imaging, consumables, hotel and medications. These data will be used to evaluate and compare the cost of treating LBP patients preimplementation to postimplementation at the intervention ED and between intervention and control EDs.

Semistructured interviews (objective 4)

Semistructured interviews will be conducted with ED clinicians addressing Proctor *et al*'s[20] implementation outcome domains of: acceptability, adoption, appropriateness, feasibility and sustainability (table 2). The interview guide will be developed through an iterative review and feedback process involving internal study team consultation and testing. The interview protocol will be tested on available ED clinician/s who have been exposed to the RIME intervention. Interviewing will be conducted following the intervention phase of the study, and a range of ED clinicians (ie, nurses, medical officers, physiotherapists) will be approached to participate. All interviews will be audiorecorded, transcribed verbatim and coded using a hybrid deductive and inductive approach. Other study team members will independently code a subset of the interviews, and any discrepancies will be discussed and reassessed to reach agreement. The remaining interviews will be coded from the agreed approach. The coded data will be used to develop themes, which will be reported to the study team for discussion. The final agreed

Table 2 Implementation outcomes based on Proctor *et al*[20] and adapted for RIME

Outcome	Definition from Proctor *et al*[20]	Definition as applied to RIME	Timing of measurement	Measurement source
Acceptability	Perception among implementation stakeholders that a given treatment, service, practice or innovation is agreeable, palatable or satisfactory.	ED clinicians' perceptions of the RIME intervention components and implementation strategies, as agreeable, palatable or satisfactory.	Phase 3 postimplementation	Clinician interviews
Adoption	The intention, initial decision, or action to try, or employ, an innovation or evidence-based practice. Adoption also may be referred to as 'uptake'.	The intention and behavioural uptake of the RIME intervention components by ED clinicians to facilitate adherence to LBP Clinical Standards.	Phase 3 postimplementation	Clinician interviews
Appropriateness	The perceived fit, relevance or compatibility of the innovation or evidence-based practice for a given practice setting, provider or consumer, and/or perceived fit of the innovation to address a particular issue or problem.	The extent to which ED clinicians perceive the fit or relevance of the RIME intervention components within their clinical setting to facilitate adherence to LBP Clinical Standards.	Phase 3 postimplementation	Clinician interviews
Feasibility	The extent to which a new treatment, or an innovation, can be successfully used or carried out within a given agency or setting.	The extent to which implementation of the RIME intervention and implementation strategies, is considered feasible for the clinical setting under study, allowing for individual tailoring given the differing needs of clinicians.	Phase 3 postimplementation	Clinician interviews
Fidelity	The degree to which an intervention was implemented as it was prescribed in the original protocol or as it was intended by the programme developers.	The degree to which each RIME intervention component was implemented as described within the original protocol.	Phase 2 implementation	Audit and observation
Implementation cost	The cost impact of an implementation effort. The cost of implementing an intervention includes the costs of the intervention, the implementation strategy used and the service delivery.	The costs involved in the development and implementation of the RIME intervention within the ED setting under study.	Phase 2 Implementation	Health Economic Evaluation
Penetration	The integration of a practice within a service setting and its subsystems. Can also be referred to as 'reach' (using the RE-AIM (Reach, Effectiveness, Adoption, Implementation, and Maintenance) framework).	The extent to which each RIME intervention component was accessed/used by the ED clinicians.	Phase 2 implementation	Audit and observation
Sustainability	The extent to which a newly implemented treatment is maintained or institutionalised within a service setting's ongoing, stable operations.	The extent to which the RIME intervention components could be embedded as standard practice within the ED setting, following the completion of the RIME study.	Phase 3 postimplementation	Clinician interviews

Time points of measurement include phase 2 Implementation or Phase 3 Post-implementation.
ED, emergency department; LBP, low back pain; RIME, Reinforcing Informed Medication prescription for low back pain in the Emergency department.

thematic analysis will be written into final reporting and manuscripts.

Both penetration and fidelity outcomes, as defined by Proctor *et al*[20] (table 2) of each proposed implementation strategy component will be determined by calculating the percentage of encounters where the strategy was actually used, as well as the extent to which the strategy was delivered as intended (%). As feasible, regular monitoring throughout the 12-week implementation period (phase 2) will occur through both chart audits (reviewed treatment notes) and peer observation led by the implementation champion. Engagement with the implementation components will be additionally captured by recording attendance to educational sessions and use of resources (recorded within a logbook at a department and discipline level, not individual clinician level) as accurately as possible.

Data analysis

Primary and secondary clinical outcomes

Two analytical approaches will be considered to assess primary and secondary outcomes: (1) a controlled ITS analysis, where data are aggregated on a fortnightly basis and (2) a segmented regression analysis on all data. The change in trend (slope) between preimplementation and postimplementation periods and the change in level between the end of the preimplementation period and the beginning of the postimplementation periods and between the beginning of the preimplementation period and at the end of the postimplementation period will be described for separate models for each hospital and models including hospital ED as a fixed effect. Additionally for models including hospital ED as a fixed effect, the difference between the two EDs for the change in slope and change in level will be described. All estimates will be reported with 95% CIs. Data will be presented visually, overlayed with the regression line for preimplementation and postimplementation periods for each outcome. Assumptions relating to linearity, autocorrelation, stationarity and heteroscedasticity will be examined, and consideration given to the influence of outliers and the normality of residuals in developing a robust model.

Patient characteristics (eg, age, sex, Socio-Economic Indexes for Area, ED arrival mode, severity (ie, Australian Triage Scale 1–5), type of treating clinician and day/time of presentation will be compared between EDs during the preimplementation period and between preimplementation and postimplementation periods within EDs. Associations between these characteristics and outcomes will also be examined. These comparisons will be done using the Pearson χ^2 test or Fisher's exact test for categorical data and Student's t-test or Mann-Whitney U test for continuous data. Categorical data will be presented as frequency and percentage and continuous data as mean and SD or median and IQR if not normally distributed. The distribution of these characteristics overtime will be examined visually and reported. If these characteristics are found to be associated with the intervention or they are associated with the outcome and change over time in both EDs, these variables will be adjusted for in the segmented regression. Stepwise backward elimination will be used to select the most parsimonious model.

Planned exploratory analyses include a three period (pre, implementation, post) analysis and a two period analysis where data from the implementation period are combined with the postimplementation period. Planned sensitivity analyses include analysis of index presentation only, multilevel segmented regression model to account for clustering of observations within patients and observations within clinician groups and controlling for differences in the patient base by including the value of the outcome denominator in the ITS model. The planned subgroup analysis is to understand the ED medication usage in patients who are transported to hospital via ambulance (given ambulance staff may provide medications to patients with LBP before their arrival at the ED).

Potential sources of bias exist and will be monitored and addressed as feasible. For example, if change over time is clearly non-linear, transformation of continuous outcomes would be considered. Seasonality will be examined by plotting outcomes over time, however, determining its effect is challenging due to the relatively short preimplementation and postimplementation periods of 6 months. These short outcome periods also make it difficult to detect observational bias although having a control ED to compare changes over time provides some support.

Other mechanisms have been included to minimise other potential sources of bias such as a data dictionary and formal process for manual extraction of data, data validation rules on variables and single clinician data entry.

Process evaluation

Cost evaluation

To assess the value for money of the intervention, total healthcare costs will be compared between preimplementation and postimplementation phases, and between intervention and control EDs. The costs will be compared using models appropriate for clustered data and the non-normal nature of the cost and variable (eg, generalised linear model with robust standard errors). Confounders will be included in the model if assessed as necessary in the statistical analysis. A final parsimonious model will be selected following data examination and measures of model fit. Following the base case analysis, subgroup analysis will be conducted of the main categories of cost (eg, medication only) to assess where differences have accrued.

Semistructured interviews

Interviews will be transcribed and analysed using NVivo software. The framework method, as described by Gale *et al*,[21] will be employed to deductively analyse interview data based on Proctor *et al*'s predefined implementation outcomes[20] introduced in table 2. In addition, 'open-coding' will be performed for information that does

not readily adhere to the predefined framework, where themes/concepts will be generated using an inductive thematic analysis approach.

Audit and observation

Simple descriptive statistics will be employed to measure fidelity and penetration of each intervention component. Fidelity will be measured at regular intervals (approximately every 2 weeks) and descriptive analysis undertaken to explore any changes in fidelity over the implementation period.

Ethics and dissemination

No risks to patients within this study are foreseeable given its intention to improve the management of LBP in the ED, based on best-practice guidelines. The study is aligned with concerted efforts nationally and globally to reduce the use of opioids which continues to be a major health concern.[4 22–25] It is hypothesised the intervention will reduce the rate of non-recommended medication prescriptions for patients with LBP in the intervention ED (objective 1); reduce inpatient admissions, improve early mobilisation, improve the provision of patient education and reduce representation to the intervention ED (objective 2) and improve the cost of care from the hospital perspective (objective 3), all through behavioural change in the clinical practice of ED clinicians (objective 4). Furthermore, it will provide patients with the resources to better self-manage LBP, reducing recurrence and healthcare dependency.

It is planned to disseminate findings widely including engagement with relevant stakeholders regarding implementation of the intervention at respective sites locally (ie, the control ED), nationally and internationally. This will be facilitated by planned publications (results paper, process evaluation paper) in open-access journals, presentations at high impact ED and LBP conferences, stakeholder engagement via a national ED online symposium and workshops. This includes the provision of training on implementation of the intervention (consistent with the information delivered at the stakeholder engagement), engaging clinicians and ensuring sustainability in change of practice. It is also planned to produce media resources that will permit the widespread dissemination of the study's findings.

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