Project Title: Reducing Inappropriate Medications for low back pain in the Emergency department (RIME): a controlled interrupted time-series implementation study

Investigators: Ms Janelle Heine[1,2], Dr Gary Mitchell[2], Dr William See[3], Prof Nadine Foster[4], Dr Tanya Smyth[5], Ms Jacelle Warren[5], A/Prof Tracy Comans[6], Dr Gustavo Machado[7], Dr Panagiotis Barlas[5], Dr Michelle Cottrell[1], A/Prof Shaun O'Leary[1,8]

Affiliations:

1. Physiotherapy Department, Royal Brisbane and Women's Hospital
2. Emergency Department, Royal Brisbane and Women's Hospital
3. Emergency Department, The Prince Charles Hospital
4. Surgical Treatment and Rehabilitation Service (STARS), Metro North Health and The University of Queensland
5. Jamieson Trauma Institute, Royal Brisbane and Women's Hospital
6. Centre for Health Services Research, The University of Queensland.
7. Institute for Musculoskeletal Health, University of Sydney
8. School of Health and Rehabilitation Sciences, The University of Queensland

1.0 SCIENTIFIC ABSTRACT

Management guidelines for Low Back Pain (LBP) recommend exclusion of serious pathology, followed by simple analgesics, superficial heat therapy, early mobilisation, and patient education. Our RBWH Emergency Department (ED) audit revealed high rates of inappropriate medication prescription for LBP (65% of patients prescribed opioids, 17% prescribed benzodiazepine). These medications are not recommended for LBP and have serious negative consequences (dependence, poisoning, death). We also observed high inpatient admission rates (20% of ED LBP patients), delayed patient mobilisation, and inadequate patient education. In RIME, we adapt, implement, and evaluate the only intervention shown to effectively reduce inappropriate medication prescription for LBP in EDs (Sydney SHaPED trial; reduced opioid prescription by 12.3% sustained over 30 months). The adapted intervention uses a formalised clinical flow chart to support clinical decision-making and changes in clinician behaviour, bolstered by clinician education, provision of alternative treatments, educational resources, audit and feedback, and implementation champions. RIME is a controlled Interrupted Time Series study evaluating the adapted intervention in our RBWH ED pre- to post-implementation and will compare findings with a control ED in the same health district. The primary outcome is the proportion of LBP patients prescribed inappropriate medications, assessed via routinely collected record data. Total sample size is 2000 patients (n=1000 intervention, n=1000 control). Secondary outcomes include inpatient admission rate, time to mobilisation, provision of patient education, imaging requests, re-presentation to ED, healthcare costs. In nested qualitative research we will understand clinicians' perceptions of the intervention and determine how benefits will be sustained benefits over time.

2.0 LAY SUMMARY

People frequently present to Emergency Departments (EDs) with back pain. Following the exclusion of serious conditions requiring urgent medical care, guidelines recommend that all other patients with LBP are managed with simple pain relief medicines, are assisted to remain mobile, and are provided with advice and strategies to self-manage their recovery. However, medications, such as potentially addictive opioids and strong muscle-relaxants that are not recommended as initial treatments back pain, are often used. These have serious side effects and contribute to the global opioid addiction crisis. "This RIME study will, for the first time in Queensland, implement and evaluate a Sydney-developed intervention that has been shown to reduce prescription of the wrong medications for back pain". The study will involve two metropolitan EDs from within the same health service, one which will implement the intervention strategies, while the other will act

as the control site, with standard current clinical care. The intervention supports ED clinicians to follow best practice through education, treatment alternatives, and audit/feedback. We aim to reduce inappropriate medication prescription, unnecessary hospital admissions and the time taken to help patients get moving again.

3.0 BACKGROUND

The Health and Service Issue: The Low Back Pain (LBP) is the 5th most common presentation to Australian EDs.[1] Guidelines for the management of LBP recommend first excluding rare cases of serious pathology (eg. fracture, infection, cancer), followed by the use of simple analgesics for pain relief, superficial heat therapy, early mobilisation to improve function, and the provision of patient education to promote self-management to minimise hospital admission.[2] In contrast our recent RBWH (the largest Queensland hospital) ED audit of medical records (n=208) confirmed what other Australian EDs have also reported[3] inconsistent use of best practice guidelines by RBWH ED clinicians.[4]

Our audit observed a high rate of inappropriate medication prescription for LBP, particularly opioids (65% of ED LBP patients) but also muscle relaxants (benzodiazepine 17%). These medications are not recommended for LBP and have known side-effects including dependence, poisoning and death.[5] More broadly, inappropriate opioid prescriptions in EDs may contribute to the opioid crisis in Australia.[6] Other concerning audit findings were that 20% of RBWH ED LBP patients were admitted as inpatients (to the Short Stay Unit or wards), had long waits until they received support to mobilise (6 hours on average), and may have received inadequate patient education.[4] There is a convincing argument for better uptake of LBP guidelines by RBWH ED clinicians.

The Intervention and Justification: The Sydney Health Partners Emergency Department (SHaPED) trial tested an intervention to promote the use of guidelines for the management of LBP in EDs.[7] The LBP management guideline used in SHaPED was the NSW Agency for Clinical Innovation (ACI) model of care developed collaboratively between policymakers, clinicians, consumers, and researchers.[2] The guidelines are appropriate for both primary care and the ED setting. The main messages of the ACI guidelines include: (1) patients with non-serious LBP do not require lumbar imaging; (2) where medicines are used, simple analgesics should be the first option; and (3) patients with non-serious LBP should be managed as outpatients, encouraged through early mobilisation, and patient education to promote self-management.[2]

The SHaPED multifaceted intervention was guided by the Knowledge-to-Action framework,[8] targeting changes in ED clinician behaviour.[7] The intervention was designed to address the barriers to uptake of guidelines in the ED context including local LBP treatment processes, and relevant stakeholders' views about how to improve clinical care (including local opinion leaders, clinicians and patients). The chosen implementation strategies followed evidence from Cochrane EPOC (Effective Practice and Organisation of Care) reviews (e.g., clinician education, site champions, audit and feedback), and include locally driven strategies that clinicians identified as potential facilitators to reduce opioid prescription (e.g., education about alternative medications, provision of alternative non-drug treatment -heat wraps) and hospital admission (e.g., fast-track referral to the linked outpatient physiotherapy department).[9]

The key SHaPED trial finding relevant to our RIME study was an improved ED clinician uptake of LBP guidelines, successfully reducing opioid prescription by over 12% (50.5% in intervention EDs v 62.8% in control) (OR=0.57, 95% CI 0.38-0.85), with no adverse effects on patients' pain scores or satisfaction with care.[7] Improvements were also observed regarding clinicians' beliefs and knowledge regarding the management of LBP.[7] Given the importance of context to successful implementation we have considered our previous audit findings and interviews with ED clinicians at RBWH to ensure the SHaPED trial intervention is suitably adapted for the RIME study. Embedding the lead of the SHaPED trial in the new RIME study (AI Machado) also ensures the intervention adaptations are informed by the learning from their trial.

Adapting the SHaPED trial intervention to the RBWH ED context: Many interacting factors affect the success of efforts to improve clinical practice. Examples relevant to RIME include individual factors such as clinician's usual practice pattern, organisational factors such as time in ED consultations and skill-mix in the ED team, and policy level factors such as whether prescribing inappropriate medications can be restricted or prohibited through changes in ED policy. Therefore prior to implementing interventions to change practice initial consultation with relevant stakeholders (RBWH ED clinicians) was needed to gain a deeper understanding of the factors influencing current practice at the RBWH ED, and the perceived challenges to implementing the SHaPED intervention.

Alongside our RBWH ED audit, five focus group interviews were undertaken with 18 ED clinicians (medical, nursing and Allied Health) to gain their perspectives on current practice, LBP guidelines, and barriers and enablers underpinning the successful uptake of LBP guidelines at the RBWH.[4] The focus groups indicated that adherence to guidelines are primarily driven by (i) clinician beliefs and behaviours; (ii) patient expectations and behaviours; and (iii) 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 (e.g. 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 Short Stay Unit (SSU). Through methodological triangulation our focus group data provided a deeper understanding of the audit results. Strategies suggested to improve guideline adherence within the RBWH ED context included 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 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 IT and clinical management systems, to support clinicians to adopt best practice routinely.

The RIME Intervention: The resulting adapted RIME intervention is based on the learnings from the SHaPED trial team and our RBWH ED audit and focus groups. The RIME intervention is underpinned by a formalised clinical flow chart to support clinical decision-making and comprises 6 complimentary components: 1/education seminars for ED clinicians that incorporates the formalised clinical flow chart and safe mobilisation practices for all clinical staff, 2/ high quality educational materials in different media to support the core recommendations about best practice for LBP in ED including patient educational resources, 3/ provision of alternative treatment options for LBP, 4/ a fast-track referral option to outpatient physiotherapy, 5/ clinician audit and feedback, and 6/ dedicated time and support for a RIME intervention implementation champion within the ED team. Further details including the practical implementation of the RIME intervention components are detailed below within the Implementation Plan.

4.0 STUDY AIMS AND OBJECTIVES

Research Aims: To implement and evaluate the RIME intervention to improve the management of LBP in the RBWH ED. Specific objectives are to evaluate the impact of the intervention on the primary and secondary outcomes pre-post intervention at RBWH ED, and compared to a control ED (TPCH ED), and to understand the process of implementation to guide sustainability beyond this study. This is an effectiveness-implementation hybrid design (Type 1) that tests effects of an intervention on relevant outcomes while observing and gathering information on implementation in a real-world situation.[10]

Primary Outcome

Proportion of patients with LBP who are prescribed inappropriate medications (opioids/benzodiazepines) (Objective 1).

Secondary Outcomes

Proportion of patients with LBP who are admitted to hospital, received mobilisation (including time to mobilisation), advice/education, lumbar imaging, who re-present to ED within 6 months (Objective 2).

Cost analysis from a hospital perspective (Objective 3).

Process Evaluation

In nested interviews, explore the perspectives of ED clinicians regarding the intervention, and understand their clinical behaviours to inform plans for sustainability beyond the study (Objective 4).

To determine the fidelity to which each intervention component was delivered, including the proportion of appropriate encounters in which the intervention was delivered (Objective 5).

Hypothesis: We hypothesise that the RIME intervention will reduce the rate of inappropriate medication prescription for patients with LBP in our ED (Objective 1); reduce inpatient admissions, improve early mobilisation, improve the provision of patient education, and reduce re-presentation to ED (Objective 2); improve the cost of healthcare from the hospital perspective (Objective 3), through behavioural change in the clinical practice of ED clinicians (Objective 4).

5.0 METHODS

Implementation Plan

The RIME study is a prospective, implementation, and evaluation research study, of controlled Interrupted Time Series design. This design is recommended by Cochrane EPOC as it permits evaluation of outcomes before and after the intervention implementation and compares the intervention site with a control site in order to detect potential confounding from simultaneous events. It is a stronger design than a pre/post evaluation in one ED only and allows robust conclusions about change in outcomes *OVER* time in our RBWH ED as well as *COMPARED* with a control site.[11] The setting is two Metro North Health tertiary EDs: the RBWH ED (intervention site and the largest hospital in Queensland) and TPCH ED (control site).

The study comprises three phases:

Phase 1 Usual Care before the intervention (6 months): will comprise data collection during a usual care phase at both the intervention (RBWH) and control (TPCH) sites. Data will be extracted from routinely collected ED medical records on medication prescriptions (primary outcome) for a consecutive sample of patients presenting with LBP to the ED over a period of 6 months, and the secondary outcomes of patient admissions, provision of patient education, time to mobilisation, imaging requests, and hospital healthcare use.

Phase 2 Intervention implementation (12 weeks): during which the multifaceted intervention will be introduced within the RBWH ED, and clinicians trained and supported to improve their practice. At the control site (TPCH) ED, clinicians will continue with usual care without any intervention.

The implementation of the RIME intervention will be underpinned by the Knowledge-to-Action framework (as per the SHaPED trial),[8] incorporating evidence-based implementation strategies specifically targeting the behaviour of ED clinicians at the RBWH. Our intervention components target the previously identified barriers of knowledge (through education and educational materials), skills (through education, time for simulated practice in education sessions), workflow uncertainty (through formal patient flow-charts in the ED), patients' expectations (through patient focused educational material), treatment alternatives (recommended medications and non-pharmacological interventions, time in patient consultations in the ED (high quality patient educational material) and variation in practice (audit and feedback with individualised feedback at the level of each ED clinician). The COM-B behaviour change theoretical framework[12] has been

used to shape the implementation plans to support behaviour change in ED clinicians to enhance capability, opportunity, and motivation to improve clinical practice for LBP patients in the ED.

Specifically, the RIME intervention will comprise the following 6 components:

1. **Educational Seminars:** This will include structured Best Practice Updates from experienced ED clinicians (i.e. Emergency Physiotherapy Practitioners, Emergency Medical Consultants) that focus on knowledge and skills for assessing, managing, educating, and referring patients according to the Agency for Clinical Innovation model of care for LBP.[2] Additional training from experts in the management of low back pain (CI Foster) and rehabilitation (PI O'Leary, AIs Barlas and Cottrell), will reinforce the significance of best practice management principles focusing on the importance of early mobilisation. These Best Practice sessions will be offered on numerous occasions throughout the 12-week intervention period in protected teaching time, either in teaching rooms or in the RBWH ED itself. 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:** Materials provided to ED clinicians will include a hard copy of the model of care document, a link to an already established and contemporary evidence-based 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 ED. Anonymised patient cases from phase 1 will be discussed showing examples of poor practice and good practice. Patient educational materials (based on the ACI and mybackpain websites) and scripts to guide conversations with patients will be provided so that clinicians can use these to educate patients more easily.
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 inappropriate pharmacological treatments.
4. **Fast-track referral to outpatient services:** Clinicians will be educated on the referral pathways options available for follow-up physiotherapy management, when such referrals are warranted, and how to facilitate the referral process in collaboration with the patient. Referral pathways include private physiotherapy services within the primary care setting, public physiotherapy outpatient services, and advanced-practice musculoskeletal physiotherapy screening services (e.g. RBWH Spinal Physiotherapy Screening Clinic).
5. **Audit and feedback:** Clinicians will be provided with structured audit and feedback reports on department-level and individual clinician-level medication prescriptions, inpatient admission rates, time to mobilisation, provision of patient education, and lumbar spine imaging requests. Data from phase 1 (actual ED practice data) will be analysed and key findings summarised at departmental level and clinician level (reports will compare each clinician's practice patterns in phase 1, each clinician will be able to identify themselves in the reports but not other clinicians). Phase 1 data will be used to stimulate discussion about variation in practice in the management of LBP in the ED. During Phase 2, we will continue to extract routinely collected data on the primary and secondary outcomes, conduct audits and provide reports at department level and individual clinician level, anticipated to be monthly (4 weeks after the start of Phase 2, and at 8 weeks and 12 weeks).
6. **Support from an ED 'RIME Implementation Champion':** A key feature of our implementation is inclusion of a dedicated 'Implementation Champion' who will be an experienced ED clinician and have direct oversight and influence of the implementation on the ground within the ED. We have specifically targeted an experienced ED clinician (AI Heine) to 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.[13] The RIME implementation champion will support reinforcement of implementation aims with staff,

provide personal feedback sessions, and offer one-to-one or small group discussions with ED staff as needed.

Phase 3 Care after the intervention (6 months): the same data will again be extracted from the routinely collected data in the ED medical record, as per Phase 1. Clinicians will be able to continue to use the knowledge and materials introduced in phase 2. A new cohort comprising a consecutive sample of patients presenting with LBP to the ED over a period of 6 months will form the sample in phase 3. We will collect the same patient anonymised data from the medical records at both the intervention ED (RBWH) and control (TPCH).

Phase 3 will also include the nested process evaluation, comprising qualitative semi-structured interviews to gain a deeper understanding of ED clinician perspectives of the intervention and to understand how best to sustain the benefits of the intervention beyond the study, as well as the fidelity assessment.

Evaluation of Outcomes

This is a mixed methods approach involving a quasi-experimental research design for evaluating the primary (Objective 1) and secondary (Objectives 2-3) outcome measures, and a qualitative and quantitative evaluation to address Objective 4 and 5, respectively.

Objective 1-3 Evaluation Design: A controlled Interrupted Time Series (ITS) design will be used to evaluate outcomes for study Objectives 1-3. A controlled ITS design is arguably the strongest quasi-experimental research design for evaluating healthcare quality improvement or implementation initiatives and has advantages over traditional 2-period pre-post designs including the control of secular trends in the data, clear graphical representation of the intervention impact and the ability to evaluate both intended and unintended changes following the intervention.[11] This evaluation will use the RBWH ED as the intervention site, and TPCH ED as the control ED. Data from January to December 2021 showed 1,046 patients presented to RBWH ED with LBP and 1,485 presented to TPCH ED. Both EDs are governed by Metro North Health, have similar numbers of LBP patients, and have similar skill-mix in their ED clinical teams. Key considerations of ITS designs are the number of time-periods used for pre- and post-intervention phases, and the number of observations within each time-period, given their effect on statistical power to detect an intervention effect. Penfold and Zhang advocate for a minimum of 8 time-periods pre- and post-implementation[14] while Wagner et al. suggested a minimum of 12 data-points.[15]

Based on the above, the RIME study will use 12 time-periods spaced 2 weeks apart (6 months total) for all outcomes in both the pre- and post-implementation phases. Anticipating 500 LBP ED presentations in 6 months at RBWH ED, allows for approximately 45 patients in each 2-week time-period before and after intervention. Traditional sample size calculations for ITS are difficult,[11] however simulations run using SAS v9.4 suggests the power to detect at least a 12% reduction in inappropriate medication prescription (the primary outcome, based on the SHaPED trial findings) from the intervention within RBWH ED was between 70% and 80%.[16] With the addition of TPCH ED as a control site, a difference in difference approach to analysis will be used to control for unmeasured confounding. The total anticipated sample size is 2000 (500 in each of the two EDs, in each of the pre- and post-intervention periods); (n=1000 intervention, n=1000 control).

Outcome Measures: All outcome measures are recorded as part of standard practice in participating EDs and therefore impose no additional burden to the services. In addition, the use of routinely recorded data promotes the sustainability of the implementation beyond the study. All outcome measures will be extracted from the RBWH and the TPCH electronic/scanned medical records and recorded on a purposively designed database by the RIME study Research Officer. Data validation rules will be implemented to reduce data transcription errors and improve data quality. Patients will be de-identified through the use of anonymised ID codes.

Primary Outcome

The primary outcome measure is the prescription of any inappropriate medication for LBP in the ED, (this includes opioids and benzodiazepines). As per the SHaPED trial, pain medicines were recorded and grouped according to the Anatomical Therapeutic Chemical classification (ie, paracetamol, non-steroidal anti-inflammatory drugs, muscle relaxants, opioids and neuropathic pain medicines)[7,9] (Objective 1).

Secondary Outcome

These will include time to mobilisation, provision of patient education, inpatient admission rates (e.g., short stay unit, ward admissions), lumbar spine imaging and representation to the ED within 6 months. Key patient characteristics will also be obtained from routinely collected data for each patient to permit description of the sample characteristics (age, gender, previous history of LBP, pain severity, triage category, management location, primary clinician, secondary review details, arrival mode (ambulance, walk in, etc). We deliberately chose not to burden patients with patient-level data collection as the SHaPED trial (n = 4491) showed effective reduction in opioid use without compromising patients' pain or satisfaction[7] (Objective 2).

Cost analysis

Cost of the intervention will be collected during the trial based on staff time materials. Direct health system costs will be estimated from hospital administrative data and will be collected during the trial period including medication, ED and inpatient costs. To assess the value for money of the intervention, total costs will be compared between pre-post and control using appropriate regression modelling that accounts for the non-normal distribution of cost data (e.g. GLM or GEE) (Objective 3).

Analyses: Segmented Regression and graphical display of the timeseries data will be used to evaluate the immediate (level) changes in the fortnightly rate of the primary and secondary outcomes, as well as changes in the trend (slope), for the intervention group using the approach proposed by Lopez et al.[11] This first stage involves separate analysis of the intervention and control series. Where a change is observed in the control series, a single model that includes indicator variables for the intervention or control series as interaction terms will be considered, in addition to creating a new series of the ratio or difference between the intervention and control series at each time point for use in a segmented regression. A single-model approach tests the differential effects of the intervention (level or slope change) between the groups and highlights the presence of potential confounders. In addition to assessing for confounding, and considering whether a single-model is required, the autocorrelation between timepoints will be evaluated using the Durbin Watson statistic. Sensitivity analyses concerning the starting point of the 'post-implementation' period will be undertaken, based on the number and distribution of clinicians engaging in the intervention over the 12-week intervention period. Primary and secondary outcomes will also be collected during the intervention period and included in sensitivity analyses of the intervention effect. In addition to the segmented regression, descriptive statistics (mean [standard deviation], median [IQR], count [percentage]) will be used, as appropriate, to describe the cohort at both RBWH and TPCH EDs. Comparisons between the two cohorts will be explored using t-tests, Mann-Whitney U tests and chi-squared tests, depending on the format and normality of the data.

Objective 4-5 Process Evaluation Design:

Interviews

A nested process evaluation, comprising semi-structured interviews with a sample of 18 intervention ED clinicians, regarding their perceptions of the intervention and their recommendations for improvement and sustainability. ED clinicians will be purposefully sampled to ensure representation across disciplines (medical, physiotherapy, nurses) and experience level, and across clinicians observed to provide practice in line with our RIME intervention and those who did not. The interviews will focus on components of the

intervention that clinicians found useful, as well as perceived barriers to adoption and sustainability of the intervention. Permission from Metro North Health will be sought allowing clinicians to complete interviews during work hours. Consent will be obtained from the RBWH ED clinicians to undertake the interviews. This will be implied consent by their participation in an interview. ED clinicians who choose to be interviewed will be notified that they will have the opportunity to review or edit their responses or contributions prior to data analysis or publication by contacting the investigators. ED clinicians will also be informed that they may withdraw their consent to participate in the interviews at any time with no implications (Objective 4).

Analyses: Interviews will be transcribed and analysed using NVivo software (led by CI Smyth). A thematic analysis will be undertaken to determine key themes related to clinician perspectives of the intervention, and its potential sustainability, with key themes mapped onto our theoretical frameworks (Knowledge-to-Action framework and COM-B). Results will inform recommendations about intervention adaptation and sustainability, ready for consideration for implementation across other EDs in Metro North and beyond.

Fidelity (intervention site only)

Fidelity of each proposed intervention component by determining the proportion of encounters where the intervention was actually used, as well as the extent to which the intervention was delivered as intended/prescribed. Fidelity will be regularly monitored throughout the 12-week implementation period (Phase 2) through both chart audits and peer observation, and facilitates an iterative approach in the strategies used to support their implementation. Engagement with the RIME components will be additionally captured by recording attendance to educational sessions and use of resources (recorded within a log book at a department and discipline level, not individual clinician level) as accurately as possible. (Objective 5).

Analysis: Simple descriptive statistics will be employed to measure fidelity of each intervention component at regular components. Repeated measures ANOVAs will be used to determine any changes in fidelity over the implementation period.

6.0 TIMELINE

PHASE	OBJECTIVE/GOAL	COMPLETION DATE
Ethics preparation and submission	Submit ethics approval submission Prepare Site Specific Application for the RBWH and TPCH which provide research governance clearance and sign off.	1st September 2022
Employment and project specific training of research officer	Submit an Expression of Interest advertisement for the RIME study Research Officer position Interview and select most appropriate applicant and undertake employment process of applicant Provide initial training and familiarity for the role and study	1st September 2022
Preparation for Phase 1 – pre-implementation phase	Finalise processes underpinning data collection of the primary and secondary outcomes at the RBWH and TPCH over the 12 measurement points in Phase 1. Develop and test study database	1st September 2022

Preparation for Phase 2 - implementation phase	Finalise the intervention components and supporting materials, to best achieve practice change (key contacts, consultation meetings with ED clinicians, preparation and access to implementation materials, planning for changes in staffing)	28th February 2023
Undertake Phase 1 – pre-implementation	Initiate data collection for Phase 1 which will include recording primary and secondary outcome measures over 12 timepoints spaced 2 weeks apart over a total period of 6 months.	1st March 2023
Undertake Phase 2 - Implementation of Intervention	Undertake the delivery of the intervention over a 3-month period. This time period will accommodate expected scheduling challenges for Best Practice Update sessions with ED clinicians and permit time for repeat consultations.	1st July 2023
Undertake Phase 3 – post-implementation phase	Repeat data collection as per Phase 1 which will include recording primary and secondary outcome measures over 12 timepoints spaced 2 weeks apart over a total period of 6 months	6th January 2024
Data cleaning of Phases 1-3 data	Extract, check and clean all data for analysis	1st April 2024
6 months of follow-up (to ensure data capture of patients who represent to the ED within 6 months)	Completion of: - 6 month follow up data (re-presentation data) – Complete the re-presentation data identifying the proportion of patients re-presenting to the ED within 6 months of ED discharge date - complete all semi-structured interviews with the purposive sample of ED clinicians after the implementation of the intervention (objective 4)	6th July 2024
Data Analysis	- Undertake the controlled Interrupted Time Series Analysis addressing Objectives 1-3 - Undertake the qualitative data analysis addressing Objective 4	1st October 2024
Report writing and preparation of translation dissemination activities	Final ethics report and grant reporting Preparation of manuscripts and presentations for dissemination to different audiences Preparation and delivery of implementation dissemination to ED groups involved in the RIME study	30th December 2024

7.0 DATA MANAGEMENT AND STORAGE

All project data will be stored electronically on a research computer of the principal investigator. All electronic copies of data will be kept in a folder on a secure Queensland Health network in which only members of the research team will have access to. To comply with the Australian Code for the Responsible Conduct of Research [17], research data will be retained for a minimum period of 5 years from the date of publication. Subsequent to this electronic documents will be permanently deleted.

8.0 SIGNIFICANCE, IMPACT AND DISSEMINATION

Significance and Impact

Reducing Inappropriate Medication Prescription in the ED: There have been calls for health professionals in Australia to reduce overprescription of opioid and benzodiazepine medications.[18] The known 'opioid crisis' continues to be a major health concern[19] with overprescribing[6] and escalating opioid dispensing in Australia.[20,21] Initial exposure to opioids in EDs may contribute to the development of addiction in some patients.[22] The endpoint of this study is directly aligned with concerted efforts nationally and globally to reduce inappropriate prescribing of medications.

Escalating Patient Recovery: This project addresses the inadequate patient education concerning LBP identified in our audit. This will modify negative patient beliefs and behaviours associated with LBP, improving their understanding of their condition and offering reassurance of their likely favourable prognosis. Furthermore, it will provide patients with the resources to better self-manage LBP, reducing recurrence and healthcare dependency.

Lessening the Burden and Costs to Health Services: Findings should reduce the noted proportion of RBWH ED LBP patients (20%) in the audit admitted as inpatients to the Short Stay Unit or acute wards. Our audit suggests this was potentially underpinned by longer waits until patients received support to mobilise (6hrs on average), as well as inadequate patient education. The RIME intervention will address these issues which should reduce inpatient hospital admissions. Addressing delayed time to mobilisation will have broader positive impacts on the Emergency Department in terms of increasing bed availability and patient flow, as well as reducing overcrowding and long wait times for patients.

Dissemination

Within the successful grant funding provision for dissemination has been made in the following manner:

Publishing fees: Open access funding for 3 papers; protocol paper, results paper, process evaluation paper

Conference: To allow dissemination of findings at high impact ED and LBP conferences.

Stakeholder Engagement: Conduct a national ED online symposium to discuss the findings of the study. Deliver a workshop providing training permitting participants to spread this intervention to other EDs.

Media and promotions: Produce media resources that will permit the widespread dissemination of the study's findings. Provide training on implementation of the intervention (consistent with the information delivered at the stakeholder engagement), engaging clinicians, and ensuring sustainability in change of practice.

All dissemination outlets will not contain any identifiable information. Data will only be presented and published by the research team in aggregate form, and no individual will be able to be identified in any project output.

9.0 REFERENCES

1. Emergency department care. Australian Institute of Health and Welfare (AIHW), Australian Government: Canberra, 2021. In.
2. Management of people with acute low back pain: model of care. NSW Agency for Clinical Innovation. NSW HealthChatswood, NSW, 2016. In:39.
3. Machado GC, Rogan E, Maher CG. Managing non-serious low back pain in the emergency department: Time for a change? *Emerg Med Australas.* 2018;30(2):279-282.
4. Heine JL, Hacker S, Mitchell G, et al. Adherence to recommended guidelines for low back pain presentations to the RBWH Emergency and Trauma Centre. 2022;In preparation.
5. Humphreys K, Shover CL, Andrews CM, et al. Responding to the opioid crisis in North America and beyond: recommendations of the Stanford-Lancet Commission. *Lancet.* 2022;399(10324):555-604.
6. Makary MA, Overton HN, Wang P. Overprescribing is major contributor to opioid crisis. *BMJ.* 2017;359:j4792.
7. Coombs DM, Machado GC, Richards B, et al. Effectiveness of a multifaceted intervention to improve emergency department care of low back pain: a stepped-wedge, cluster-randomised trial. *BMJ Qual Saf.* 2021;30(10):825-835.
8. Graham ID, Logan J, Harrison MB, et al. Lost in knowledge translation: time for a map? *J Contin Educ Health Prof.* 2006;26(1):13-24.
9. Machado GC, Richards B, Needs C, et al. Implementation of an evidence-based model of care for low back pain in emergency departments: protocol for the Sydney Health Partners Emergency Department (SHaPED) trial. *BMJ Open.* 2018;8(4):e019052.
10. Curran GM, Bauer M, Mittman B, Pyne JM, Stetler C. Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. *Med Care.* 2012;50(3):217-226.
11. Lopez Bernal J, Cummins S, Gasparrini A. The use of controls in interrupted time series studies of public health interventions. *Int J Epidemiol.* 2018;47(6):2082-2093.
12. Michie S, van Stralen MM, West R. The behaviour change wheel: a new method for characterising and designing behaviour change interventions. *Implement Sci.* 2011;6:42.
13. Damschroder LJ, Banaszak-Holl J, Kowalski CP, Forman J, Saint S, Krein SL. The role of the champion in infection prevention: results from a multisite qualitative study. *Qual Saf Health Care.* 2009;18(6):434-440.
14. Penfold RB, Zhang F. Use of interrupted time series analysis in evaluating health care quality improvements. *Acad Pediatr.* 2013;13(6 Suppl):S38-44.
15. Wagner AK, Soumerai SB, Zhang F, Ross-Degnan D. Segmented regression analysis of interrupted time series studies in medication use research. *J Clin Pharm Ther.* 2002;27(4):299-309.
16. Interrupted Time Series Power Calculation using DO Loop Simulations (sas.com). In.
17. National Health and Medical Research Council. Australian Code for the Responsible Conduct of Research. In. Canberra: Australian Government; 2007.
18. Caughey GE, Gadzhanova S, Shakib S, Roughead EE. Concomitant prescribing of opioids and benzodiazepines in Australia, 2012-2017. *Med J Aust.* 2019;210(1):39-40.
19. The L. Managing the opioid crisis in North America and beyond. *Lancet.* 2022;399(10324):495.
20. Lalic S, Ilomaki J, Bell JS, Korhonen MJ, Gisev N. Prevalence and incidence of prescription opioid analgesic use in Australia. *Br J Clin Pharmacol.* 2019;85(1):202-215.
21. Donovan PJ, Arroyo D, Pattullo C, Bell A. Trends in opioid prescribing in Australia: a systematic review. *Aust Health Rev.* 2020;44(2):277-287.
22. Butler MM, Ancona RM, Beauchamp GA, et al. Emergency Department Prescription Opioids as an Initial Exposure Preceding Addiction. *Ann Emerg Med.* 2016;68(2):202-208.