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Implementation of an evidence-based model of care for acute low back pain in emergency departments: Protocol for the SHaPED trial

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ABSTRACT

Introduction: Patients with low back pain often seek care in emergency departments, but the care is often sub-optimal. The problem is that many patients receive unnecessary or ineffective care, and at the same time miss out on the basics of care, such as advice on how to self-manage the condition. This pattern of care has important consequences for patients (poor health outcomes) and for the healthcare system (expensive and inefficient). We hypothesised that the implementation of an evidence-based model of care will improve the care delivered to patients with acute low back pain presenting to emergency departments.

Methods and analysis: A stepped wedge cluster randomised controlled trial will be conducted to implement and evaluate the use of the Agency for Clinical Innovation (ACI) model of care for acute low back pain at four emergency departments in New South Wales, Australia. Acute low back pain presentations will be identified using SNOMED codes. The 4-week intervention period, targeting emergency department clinicians, will comprise educational materials and seminars, and an audit and feedback approach. The effectiveness of the intervention will be assessed by comparing the post-intervention period with the retrospective baseline control period prior to implementation. Outcomes are routinely collected measures of imaging referrals (primary outcome), opioid prescription, and inpatient admission, which will be extracted directly from participating emergency departments' electronic record systems.

Ethics and dissemination: The study received ethical approval from the Sydney Local Health District (RPAH zone) Ethics Committee (04/2017). The results of this study will be published in peer-reviewed journals and presented at international conferences.

Trial registration number: Australia New Zealand Clinical Trials Registry: ACTRN 12617001160325.

Strengths and limitations of the study

- This is a novel implementation trial looking at reducing unnecessary tests and treatments for acute low back pain in emergency departments
- The stepped wedge design is particularly suited to interventions aiming to improve healthcare systems as all sites receive the intervention; intervention effects are estimated from within-emergency department differences while controlling for time trends
- The use of routinely collected measures reduces the burden of data collection in the emergency departments
- Incorporation of only four clusters (emergency departments) in the trial may limit generalisability
- The absence of patient-outcome measures may limit the understanding of the effects of the implementation on patient outcomes

INTRODUCTION

Background and rationale

Low back pain is a common presenting complaint in emergency settings. In 2015-16 alone, there were 104,072 low back pain presentations to emergency departments in Australia, placing this condition among the top 10 reasons for emergency visits.[1] This condition is also a common reason for emergency department presentations across the globe, accounting for 4.4% of all presentations.[2] Unfortunately, many patients receive the wrong care for their low back pain in the emergency department. Examples of low-value care include unnecessary imaging, liberal use of opioid analgesics, and unnecessary admission to hospital, which provide little or no benefit, and may cause harm.

Multiple clinical guidelines exist for the management of low back pain in primary care.[3 4] Although it is unclear whether these guidelines should be applied in the emergency department, much of their recommendations may be relevant to emergency physicians and are often used to guide their practice.[5] However, the mixture of providing inappropriate care and failing to provide appropriate care in the emergency department is a clear indication that healthcare is not following clinical guidelines. For instance, about 30% of patients with non-specific low back pain receive imaging in the emergency department,[6] when guidelines explicitly recommend no imaging for these cases. Imaging in the absence of suspected serious pathology does not improve patient outcomes,[7] and can potentially cause harms.[8-10] Against guideline advice, around 62% of low back pain patients are prescribed opioids in the emergency department,[11] although efficacy in pain relief has not been established for acute low back pain[12] and side effects are often serious,[13] including dependence, overdose and death. Another issue is the increasing rate of hospital admissions. More than one third of low back pain presentations to the emergency department lead to the patient being admitted to hospital,[6] where care is no more effective than what could be provided in primary care.

The significant deviations from evidence-based recommendations occurring in Australian emergency departments makes them an appropriate setting to trial an intervention based on improving care for acute low back pain. The Agency for Clinical Innovation (ACI) has recently launched a model of care for acute low back pain that could be applied in both primary care and emergency department settings.[14] The ACI model of care was developed in collaboration with policy makers, clinicians, consumers and researchers, and distils the high quality evidence in this area to formulate key messages for practice. Briefly, the model

provides different care pathways according to a classification based on a diagnostic triage[15] (non-specific low back pain, low back pain with leg pain, suspected serious spinal conditions). Then, risk stratification[16] is used to guide the amount and type of treatment provided; including personalised evidence-based health education and treatment. Lastly, follow-up reviews are scheduled to monitor individuals' progress. Passive dissemination of guidelines, such as the ACI model of care, is unlikely to change practice. We are proposing a multi-faceted strategy to implement and evaluate the ACI model of care to see if this improves care for acute low back pain at emergency department settings.

Objectives

The overall aim of the Sydney Health Partners Emergency Department (SHaPED) trial is to implement and evaluate the ACI model of care for acute low back pain. The outcomes of the trial reflect the key messages in the model: 1) patients with acute non-specific low back pain do not require imaging; 2) where medicines are used, simple analgesics should be the first option; 3) patients with acute non-specific low back pain should be managed as outpatients.

Primary objective

The primary objective of this study is to evaluate if implementation of the ACI model of care for acute low back pain improves care provided in the emergency department.

Secondary objectives

The secondary aims of the study are:

1. To determine the cost-effectiveness of the ACI model of care for acute low back pain compared with current practice.
2. To determine the barriers and facilitators to the implementation strategy of the ACI model of care for acute low back pain.

METHODS AND ANALYSIS

Study design

SHaPED will use a stepped wedge cluster randomised controlled trial design.[17] In this study design, clusters are randomised to cross from the control period (i.e., unexposed to intervention) to the intervention period at regular intervals ('steps') until all clusters have crossed to the intervention under evaluation. This design is particularly suited to interventions aiming to improve healthcare systems as all groups eventually receive the intervention.

Moreover, the process allows for comparison with control sites that have not yet implemented the intervention. For this protocol, we completed the Consort 2010 statement checklist extension for cluster randomised trials.[18]

In the SHaPED trial, after a retrospective baseline observation control period of 12 months prior to randomisation, the intervention will be sequentially rolled out, with a new emergency department receiving the intervention every four weeks, until all participating emergency departments have received the intervention. After the implementation of the ACI model of care, the emergency departments will continue using the pathways of care outlined in the model until the end of the trial (Table 2).

Study setting

The emergency departments of one rural and three urban hospitals in NSW, Australia will participate in the study: Royal Prince Alfred Hospital, Concord Repatriation General Hospital, Canterbury Hospital, and Dubbo Base Hospital. The SHaPED trial has been approved (X17-0043) by the Ethics Review Committee of the Sydney Local Health District (RPAH zone), and by the Chief Executive of each participating institution. The trial was registered with the Australia New Zealand Clinical Trials registry: ACTRN 12617001160325.

Participants

Participants included in this study will be emergency clinicians, such as physicians, nurses, and physiotherapists, who routinely manage patients presenting to emergency departments with a primary complaint of acute low back pain (lasting less than 3 months) or acute exacerbation of chronic low back pain. We will use codes from the Systematised Nomenclature of Medicine – Clinical Terms – Australian version, Emergency Department Reference Set (SNOMED CT-AU [EDRS])[19] to identify acute low back pain presentations.

Potential clinician participants will be invited by the local investigators at each emergency department and will receive a Participant Information Statement. Research staff will verbally explain the information provided in this document to fully inform potential clinician participants of the risks and benefits of participation. In addition, the research staff will be available to answer any questions in order to ensure that potential clinician participants fully

understand the implications of their decision. A written Participant Consent Form will be obtained from all participating clinicians prior to randomisation.

Randomisation

Before the beginning of the implementation process, the four hospitals will be randomly allocated the step when the intervention will commence at their emergency department. Randomisation will be conducted using computer-generated random numbers. Only the research team will be aware of cluster allocation.

Implementation intervention

A framework has been proposed to facilitate the implementation of research evidence into clinical practice, known as The Knowledge-to-Action Process.[20] This framework links the various types of research enquiry with the key steps in the research translation cycle. The process consists of the knowledge creation cycle and the action cycle, and involves end users of research (e.g., policymakers, clinicians and patients) to facilitate engagement with the implementation strategy. We will use this framework to develop a tailored intervention strategy to implement the ACI model of care at the participating emergency departments.

Engagement of local opinion leaders that are respected and influential at each site is an important element in promoting and maintaining local interest in the implementation process. Thus, implementation will begin with visits to each participating emergency department to establish collaborations and approvals, and to further assess organisational issues and potential barriers to the implementation program, such as intake and flow of patients with low back pain, assessment of current practices, acceptability of new model, and specific roles of emergency clinicians. We will map existing models of care at each emergency department that are used to guide management of patients presenting with acute low back pain. Then, we will work with local clinical staff to incorporate important features of existing models to the recommendations and principles outlined in the ACI model of care.

A multi-faceted intervention package will be used to implement the ACI model of care at the emergency departments. Briefly, the initial 4-week intervention will consist of printed and electronic educational materials, educational seminars and educational outreach, website support, posters, and an audit and feedback approach. Clinician participants will receive a copy of the model and other printed educational materials, as well as access to additional

online support tools. Experienced clinicians, research staff, and local opinion leaders will deliver the interactive educational seminars and educational outreach. An audit and feedback approach focussed on the outcomes of the study will also be used to enhance our implementation program. A detailed description of the implementation plan for the SHaPED trial can be found in Supplementary Appendix 2.

The implementation intervention will be tailored for each site by adapting knowledge resources (e.g., printed decision aids, patient resources) to the local context and by working with local opinion leaders (e.g., directors of emergency department) to address potential barriers to implementing the ACI model of care. These instructions, measures, and training materials will be hosted online during the implementation phase on the University of Sydney website. Due to the nature of the intervention, it will not be possible to blind clinician participants to the intervention.

Sample size

Based on the effect size of 10% absolute reduction (from 30%[6] to 20%) in imaging referrals, combined with an alpha of 0.05 and assuming an Intraclass Correlation Coefficient (ICC) of 0.1, a total number of 1,920 low back pain presentations (on average 480 per cluster) to emergency departments is needed for this stepped-wedge cluster trial with 80% power. A preliminary analysis revealed that there were over 2,500 low back pain presentations to the participating emergency departments in 2015-16, showing feasibility of this trial.

Outcome Measures

Clinician participants will complete a baseline questionnaire, including demographic questions. They will also be asked to indicate whether they have special interests in low back pain or musculoskeletal medicine, and if they had attended previous continuing medical education or postgraduate training on low back pain management. The baseline questionnaire also includes the Back Beliefs Questionnaire,[21] and questions[22] about clinicians' knowledge and attitudes towards low back pain management. The outcomes to evaluate the effectiveness of the ACI model of care for acute low back pain are routinely collected emergency department measures.

Primary outcomes:

- Proportion of patients receiving any imaging (yes/no)

Secondary outcomes:

- Proportion of patients receiving advanced imaging (CT or MRI = yes, x-ray or no imaging = no)
- Proportion of patients receiving prescription or administered analgesic medications (topical, oral, injection):
  - Simple analgesics (e.g., paracetamol)
  - Non-steroidal anti-inflammatory drugs (NSAIDs)
  - Muscle relaxants
  - Weak opioids
  - Strong opioids
  - Neuropathic pain medicines
  - Other
- Time in emergency department (triage time to discharge or admission time)
- Proportion of patients admitted to:
  - Emergency medical unit
  - Rheumatology department
- Proportion of patients referred to surgical specialist (referral for a post-discharge surgical consultation by the emergency department)
- Proportion of patients re-presenting to any emergency department within 28 days
- Proportion of patients re-admitted to any hospital within 48 hours
- Total health system costs (including intervention costs and health service utilisation costs)

Medicines will be classified according to the Anatomical Therapeutic Chemical (ATC) classification system (Table 3). The ATC classification is recommended by the World Health Organisation and is widely used internationally in drug utilisation studies.

Data collection methods

In the week prior to the intervention program and in the week after the 4-week intervention period, clinician participants will be asked to answer the questionnaires. Outcome measures will be extracted every week directly from participating hospitals' electronic record systems, such as the Sydney Local Health District Targeted Activity and Reporting System (STARS). STARS is an electronic system which monitors service utilisation across the SLHD hospitals.

Data collection through hospitals' electronic systems will avoid additional workloads within the emergency departments.

Research staff, blinded to the intervention allocation, will be responsible for accessing the hospitals' electronic systems and for extracting relevant information for our study. Data will be securely stored in password-protected spreadsheets and transferred to appropriate statistical software for analysis. Spreadsheets will be regularly scrutinised for omissions and errors. Data will be archived at the Sydney School of Public Health, The University of Sydney for 15 years, after which data will be destroyed.

Statistical methods

Data analysis will be performed according to an intention-to-treat analysis, i.e. clusters will be analysed according to their randomised crossover time irrespective of whether crossover was achieved at the desired time. Firstly, we will investigate temporal trends in healthcare outcomes across the 12-month baseline observation period. In the situation of an underlying temporal trend, we will only include data for the previous three months as the baseline observation period. In our primary analysis, the 4-week intervention period will be excluded, but a secondary exploratory analysis will be performed including the intervention period into the intervention group. For the primary outcome analysis, logistic regression models with a random effect for cluster, a fixed effect indicating the group assignment of each cluster at each step, and a fixed effect of time (each step) will be used. A detailed statistical analysis plan will be developed prior to unblinding. Data will be analysed using SAS version 9.1.3 (SAS Institute Inc., Cary, NC).

Economic evaluation

An economic evaluation of the ACI model of care compared with current practice will be undertaken from the health system perspective. Firstly, we will measure the costs related to the delivery of the implementation intervention (i.e., training component, staff time, printed resources). Then, the costs related to health resource utilisation will be measured via data captured by the hospitals' electronic record systems. Costs will be valued based on government charges, using publicly available data. All costs will be reported in Australian dollars. Where necessary, costs will be converted to 2017 prices using the health consumer price index published by the Australian Bureau of Statistics. The incremental cost-effectiveness ratio will be presented as the incremental cost per patient avoiding imaging (any

and advanced), medicine prescription, and hospital admission. Sensitivity analyses will be conducted to examine uncertainty in key parameters.

Process evaluation

A process evaluation will be conducted in order to provide an indication of which elements of the implementation intervention are effective and worthwhile. Clinician participants' reviews about the content of educational materials will be analysed, as well as their knowledge in managing low back pain before and after the intervention. Potential barriers and facilitators will be described.

ETHICS AND DISSEMINATION

The SHaPED trial received ethical approval from the Sydney Local Health District (RPAH zone) Ethics Committee, Sydney, Australia (04/2017). Our hypothesis is that implementation of the ACI model of care will improve care in participating emergency departments for patients presenting with acute low back pain: specifically decreasing the rates of imaging referrals, opioid prescription, and hospital admission. If the trial results are positive we will build upon our existing strong relationships with the ACI, Sydney Health Partners, and the Local Health Districts to support implementation of the model of care in other emergency departments across NSW. As a branch of the NSW Ministry of Health, the ACI will be well positioned to facilitate transferability of findings. We will also disseminate the results of the trial at conferences and in scientific journals and we will continue our successful approach of using the media to reach a lay audience and health consumers. The study resources will be made freely available on relevant websites so that jurisdictions beyond NSW can adopt the implementation strategy outlined in this study.

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Contributors: GCM, BR, CN, RB, IH, and CM conceptualised the research design, drafted the research protocol, and are coordinating the project team. JE, ER, RF, DLC contributed to the design of the study protocol, and are lead site investigators. MO, RK, and HS are responsible for the acquisition of data. MV, NM, KM, RD, RL, MJ, RS, NA, NM, MF, PF, and CL contributed to funding applications. LB advised on the trial design and was responsible for the sample size calculation and statistical analysis methods. KH was responsible for the design of the economic evaluation. KM was responsible for the design of the process evaluation. MO, RP, MC, MM, DC, DH, and LB are site investigators contributing to the implementation of the model. All authors contributed to refinement of the study protocol and approved the final manuscript.

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Competing interests: None declared.

Patient consent: Consent of the clinician participants will be obtained.

Ethics approval: The study received ethical approval from the Sydney Local Health District (RPAH zone) Ethics Committee, Sydney, Australia (04/2017).

Provenance and peer review: Not commissioned; externally peer reviewed.

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Table 1. The key principles of the ACI model of care for acute low back pain

Principle 1	Assessment: history and examination
Principle 2	Risk stratification
Principle 3	Patient education
Principle 4	Active physical therapy encouraged
Principle 5	Begin with simple analgesic medicines
Principle 6	Judicious use of complex medicines
Principle 7	Cognitive behavioural approach
Principle 8	Only image those with suspected serious spinal pathology
Principle 9	Pre-determined times for review
Principle 10	Timely referral and access to specialist services

Source: NSW Agency for Clinical Innovation. Management of people with acute low back pain: model of care. Chatswood; NSW Health; 2016. 39 p, available at: https://www.aci.health.nsw.gov.au/resources/musculoskeletal/management-of-people-with-acute-low-back-pain/albp-model

Table 2. SHaPED trial design

Steps (clusters)	Year 1												Year 2						
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7
ED 1																			
ED 2																			
ED 3																			
ED 4																			

12-month retrospective control period
4-week initial intervention period
Clusters continue with intervention
3-month follow-up period

Table 3. Medicines per ATC classification

Group	**ATC code**
Analgesics	N02B
NSAIDs	M01A M02AA
Opioid single	N02A (except for combinations listed below)
Opioid combinations	N02AA51 Morphine, combinations N02AA55 Oxycodone, combinations N02AA59 Codeine, combinations excluding psycholeptics N02AC54 Dextropropoxyphene, combinations excluding psycholeptics N02AX52 Tramadol, combination
Neuropathic pain medicines	N03 N06A

ATC, Anatomical Therapeutic Chemical. NSAIDs, Non-steroidal anti-inflammatory drugs

Supplementary Appendix 1. The SHaPED trial investigators

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Supplementary Appendix 2. Implementation strategy and intervention description

The implementation plan for the SHaPED trial has been adapted from Jabbour et al.[23]

1. Create implementation team:

a) Obtain support from clinical leads and administration heads at the four emergency departments. Formalise a partnership agreement between institutions.
b) Recruit and engage study champions at each emergency department. Team members to include: emergency physicians, physiotherapists, nurses, managers, and clinical educators.
c) Develop a working group and form a steering committee at each emergency department to provide oversight on implementation progress.
d) Establish meeting schedule: local steering committee to meet twice a week and report to study supervisors every week during the implementation period.

2. Assessment:

a) Review and discuss the existing models of care for acute low back pain at the four emergency departments and recommend adaptation to facilitate adoption of the new model.
b) Conduct an environmental assessment and identify typical pathway of care for a patient presenting with low back pain at each emergency department.
c) Identify practices and processes that require development or change in order to support the implementation strategy.
d) Identify internal and external stakeholders who will be impacted by the new model and therefore require education and support to implement it.

3. Plan strategy for change

a) Identify leadership support required for implementation phase.
b) Identify and engage influential clinical champions who will effectively drive change.
c) Revise or develop policies as needed.
d) Develop a knowledge translation strategy to support practice change, such as shared staff meetings, educational rounds, peer-to-peer mentoring.
e) Identify factors that will support practice change, such as engaging all potential stakeholders, scheduling champions and clinicians to enable attendance at meetings and face-to-face education sessions, facilitating the development of relationships between

emergency physicians and other clinical staff, conducting audits or monitor specific data indicators that will support practice change.

f) Identify factors that may create a barrier for practice change in the emergency department, including attitudes and beliefs about low back pain management, and lack of clinician expertise/comfort to treat this population.

g) Develop strategies to manage barriers, such as communication, education, opportunities to develop relationships within and between clinicians and service provider.

4. Implementation:

a) Provide Clinician information package:

- Deliver printed copies of the ACI Model of care (full version and executive summary) to clinician participants.
- Create a list of "red flags" to screen for serious pathologies from the ACI Model of care and deliver a printed version to clinician participants.
- Create posters outlining the '10 principles' of the ACI model of care, as well as the clinical pathways and place them at key locations of each participating emergency department.
- Inform clinician participants about and provide them access to online videos and other electronic educational materials to recommend patients with acute low back pain at discharge.

b) Provide patient information package:

- Encourage clinician participants to provide a printed copy of the ACI Consumer Information document to patients with acute low back pain during emergency department visit.
- Where the majority of the patient population do not speak English, encourage clinician participants to provide a copy of the Emergency Care Institute (ECI) Patient Factsheet for acute low back pain (available in six languages).
- Create posters outlining four myths of acute low back pain management and placed them at the reception area of each emergency department.

c) Deliver clinician education:

- Educational seminars will be delivered by an experienced clinician (Dr Chris Needs) at week 1 of the intervention period. Booster sessions in the first week will also be conducted by local investigators (e.g., directors of emergency department, clinical educators) as required, as well as in weeks 2-4.
- The educational seminars will be conducted primarily during the existing regular clinical staff meetings, but additional sessions will be scheduled to reach all clinician participants. The format of the seminars consists of a mini-lecture and interactive group discussions and will last for 20-40 minutes.
- During the educational seminars, clinician participants will be trained on history taking and examination of patients with acute low back pain, on how to use SNOMED diagnosis codes, and will be encouraged to follow the recommendations in the ACI model of care to manage these patients, with focus on the key outcomes of this study (i.e., imaging, opioids, and inpatient admission).
- During weeks 1-4, individual meetings with clinician participants will be scheduled as required to cover the key messages and principles outlined in the ACI model of care. There will be at least one educational outreach visit to each clinician in weeks 1-4 and they can request additional if they have concerns or problems. Clinicians can also seek advice by email.

d) Develop audit and feedback focussed on study outcomes

- Each emergency department and clinician participant will receive at the first educational seminar session emergency department level feedback on the 12-month retrospective data performance against the outcomes of this study (e.g., imaging, opioid prescribing, inpatient admission).
- This audit and feedback approach will be repeated each month after the implementation of the model of care during the regular emergency staff meetings until the end of the follow-up period.

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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

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ABSTRACT

Introduction: Patients with low back pain often seek care in emergency departments, but the problem is that many patients receive unnecessary or ineffective interventions, and at the same time miss out on the basics of care, such as advice on self-management. This pattern of care has important consequences for the healthcare system (expensive and inefficient) and for patients (poor health outcomes). We hypothesised that the implementation of an evidence-based model of care for low back pain will improve emergency care by reducing inappropriate overuse of tests and treatments and improving patient outcomes.

Methods and analysis: A stepped wedge cluster randomised controlled trial will be conducted to implement and evaluate the use of the Agency for Clinical Innovation (ACI) model of care for acute low back pain at four emergency departments in New South Wales, Australia. Clinician participants will be emergency physicians, nurses and physiotherapists. Codes from the Systematised Nomenclature of Medicine – Clinical Terms – Australian version will be used to identify low back pain presentations. The implementation intervention, targeting emergency clinicians, will comprise educational materials and seminars, and an audit and feedback approach. Health service delivery outcomes are routinely collected measures of imaging (primary outcome), opioid use, and inpatient admission. A random sub-sample of 200 patient participants from each trial period will be included to measure patient-reported outcomes (pain intensity, physical function, quality of life, and experience with emergency service). The effectiveness of the implementation intervention will be assessed by comparing the post-intervention period with the retrospective baseline control period.

Ethics and dissemination: The study received ethical approval from the Sydney Local Health District (RPAH zone) Ethics Committee (X17-0043). The results of this study will be published in peer-reviewed journals and presented at international conferences.

Trial registration number: Australia New Zealand Clinical Trials Registry: ACTRN 12617001160325.

Strengths and limitations of the study

- This is a novel implementation trial looking at reducing inappropriate overuse of tests and treatments for low back pain in emergency departments
- The stepped wedge design is particularly suited to interventions aiming to improve healthcare systems as all sites receive the intervention
- In this study design, intervention effects are estimated from within-emergency department differences while controlling for time trends
- The use of routinely collected measures reduces the burden of data collection of health service delivery outcomes in the emergency departments
- The inclusion of patient-reported measures will allow the understanding of the effects of the implementation on patient outcomes
- Incorporation of only four clusters (emergency departments) in the trial may limit the generalisability of results to other health districts

INTRODUCTION

Background and rationale

Low back pain is a common presenting complaint in emergency settings. In 2015-16 alone, there were 104,072 low back pain presentations to emergency departments in Australia, placing this condition among the top 10 reasons for emergency visits.[1] This condition is also a common reason for emergency department presentations across the globe, accounting for 4.4% of all presentations.[2] Unfortunately, many patients receive low-value care for their low back pain in the emergency department. Low-value care is broadly defined as the use of an intervention that provides patients with little-to-no benefits, or cause harm.[3] Examples of low-value care of low back pain in emergency departments include inappropriate overuse of imaging, liberal use of opioid analgesics, and unnecessary admission to hospital.

Multiple clinical guidelines exist for the management of low back pain in primary care.[4 5] Although it is unclear whether these guidelines should be applied in the emergency department, much of their recommendations may be relevant to emergency physicians and are often used to guide their practice.[6] However, the mixture of providing inappropriate care and failing to provide appropriate care in the emergency department is a clear indication that healthcare is not following clinical guidelines. For instance, about 30% of patients with non-specific low back pain receive imaging in the emergency department,[7] when guidelines explicitly recommend no imaging for these cases. Imaging in the absence of suspected serious pathology does not seem to improve patient outcomes,[8] and can potentially cause harms.[9-11] Against guideline advice, around 62% of low back pain patients receive opioids in the emergency department,[12] although efficacy in pain relief has not been established for acute low back pain[13] and side effects are often serious,[14] including dependence, overdose and death. Another issue is the increasing rate of hospital admissions. More than one third of low back pain presentations to the emergency department lead to the patient being admitted to hospital,[7] where care is likely to be similar to what could be provided in primary care.

The significant deviations from evidence-based recommendations occurring in Australian emergency departments[15] makes them an appropriate setting to trial an intervention based on improving care for low back pain. The Agency for Clinical Innovation (ACI) has recently launched a model of care for acute low back pain that could be applied in both primary care and emergency department settings.[16] The ACI model of care was developed in collaboration with policy makers, clinicians, consumers and researchers, and distils the high quality

evidence in this area to formulate key messages for practice (Table 1). Briefly, the model provides different care pathways according to a classification based on a diagnostic triage[17] (acute or chronic non-specific low back pain, low back pain with leg pain, and suspected serious spinal conditions). Risk stratification[18] is recommended to guide the amount and type of treatment provided; including personalised evidence-based health education and treatment. Lastly, follow-up reviews are scheduled to monitor individuals' progress. Passive dissemination of guidelines, such as the ACI model of care, is unlikely to change practice. We are proposing a multi-faceted strategy to implement and evaluate the ACI model of care to see if this improves health service delivery and patient-reported outcomes for low back pain at the emergency department.

Objectives

The overall aim of the Sydney Health Partners Emergency Department (SHaPED) trial is to implement and evaluate the ACI model of care for acute low back pain. The outcomes of the trial reflect the key messages in the model: 1) patients with non-specific low back pain do not require imaging; 2) where medicines are used, simple analgesics should be the first option; 3) patients with non-specific low back pain should be managed as outpatients.

Primary objective

The primary objective of this study is to evaluate if implementation of the ACI model of care significantly reduces the proportion of patients presenting with low back pain who receive imaging in the emergency department.

Secondary objectives

The secondary aims of the study are:

- To determine if implementation of the ACI model of care significantly reduces the proportion of patients presenting with low back pain who receive opioids in the emergency department, and the proportion of patients subsequently admitted to hospital.
- To determine if implementation of the ACI model of care significantly improves patient-reported outcomes in people who present with low back pain in the emergency department.

- To determine the cost-effectiveness of the ACI model of care compared with current emergency department practice for people who present with low back pain.
- To determine the barriers and facilitators to the implementation intervention of the ACI model of care for people who present with low back pain in the emergency department.

METHODS AND ANALYSIS

Study design

The SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) guidelines were followed in this report of the protocol.[19] SHaPED will use a stepped wedge cluster randomised controlled trial design.[20] In this study design, clusters are randomised to cross from the control period (i.e., unexposed to intervention) to the intervention period at regular intervals ('steps') until all clusters have crossed to the intervention under evaluation. This design is particularly suited to interventions aiming to improve healthcare systems as all groups eventually receive the intervention. Moreover, the process allows for comparison with control sites that have not yet implemented the intervention.

In the SHaPED trial, after a retrospective baseline observation control period of 12 months prior to randomisation, the implementation intervention will be sequentially rolled out, with a new emergency department receiving the implementation intervention every four weeks, until all participating emergency departments have received the implementation intervention. After the implementation of the ACI model of care, the emergency departments will continue using the pathways of care outlined in the model until the end of the trial (Table 2).

Study setting

The emergency departments of one rural and three urban hospitals in New South Wales, Australia will participate in the study: Royal Prince Alfred Hospital, Concord Repatriation General Hospital, Canterbury Hospital, and Dubbo Base Hospital. The SHaPED trial has been approved (X17-0043) by the Ethics Review Committee of the Sydney Local Health District (RPAH zone), and by the Chief Executive of each participating institution. The trial is registered with the Australia New Zealand Clinical Trials registry: ACTRN 12617001160325.

Clinician participants

Clinician participants included in the SHaPED trial will be emergency clinical staff, such as physicians, nurses, and physiotherapists, who routinely manage patients presenting to emergency departments with a primary complaint of low back pain. Potential clinician participants will be invited by the Principal Investigator of each emergency department and will receive a Participant Information Statement. Research staff will verbally explain the information provided in this document to fully inform potential clinician participants of the risks and benefits of their participation. In addition, the research staff will be available to answer any questions to ensure that potential clinician participants fully understand the implications of their decision. A written Participant Consent Form will be obtained from all participating clinicians prior to randomisation.

Patient participants

We will use codes from the Systematised Nomenclature of Medicine – Clinical Terms – Australian version, Emergency Department Reference Set (SNOMED CT-AU [EDRS])[21] to identify low back pain presentations (Supplementary Appendix 2) to the emergency departments. Presentations with codes related to low back pain with non-specific cause or those associated with neurological signs and symptoms (such as sciatica and lumbar spinal stenosis) will be included. Re-presentations to the emergency department, or low back pain presentations related to serious spinal pathologies (such as lumbar fracture or cauda equina syndrome) will be excluded. A random sub-sample of 200 patient participants from each trial period will be referred to a brief self-reported online questionnaire to evaluate the effectiveness of the implementation of the ACI model of care on patient-reported outcomes.

Randomisation

Before the beginning of the implementation intervention, the four hospitals will be randomly allocated the 'step' when the intervention will commence at their emergency department. Randomisation will be conducted using computer-generated random numbers by research staff. Only the research team will be aware of cluster allocation.

Implementation intervention

A framework has been proposed to facilitate the implementation of research evidence into clinical practice, known as The Knowledge-to-Action Process.[22] This framework links the various types of research enquiry with the key steps in the research translation cycle. The process consists of the knowledge creation cycle and the action cycle, and involves end users

of research (e.g., policymakers, clinicians and patients) to facilitate engagement with the implementation strategy. We will use this framework to develop a tailored intervention strategy to implement the ACI model of care at the participating emergency departments.

Implementation will begin with visits to each participating emergency department to establish collaborations and approvals. We will also assess organisational issues and potential barriers to the implementation intervention, such as intake and flow of patients with low back pain, assessment of current practices, acceptability of new model, and specific roles of emergency clinicians in managing these patients. We will identify existing models of care that are used to guide management of patients presenting with low back pain at each emergency department. Then, we will work with local clinical staff to ensure that each site practices according to the full ACI model of care.

A multi-faceted intervention package will be used to implement the ACI model of care at the emergency departments. Briefly, the initial 4-week implementation intervention will consist of printed and electronic educational materials, educational seminars and educational outreach, website support, posters, and an audit and feedback approach. Clinician participants will receive a copy of the model and other printed materials, including the ACI consumer information booklet, as well as access to additional online support tools outlined in the ACI model of care, such as webpages and videos, to help them educate their patients. Experienced clinicians, research staff, and local opinion leaders (i.e., Directors of Emergency Medicine) will deliver the interactive educational seminars and educational outreach. An audit and feedback approach focussed on the outcomes of the study will also be used to enhance our implementation program. A detailed description of the implementation plan for the SHaPED trial can be found in Supplementary Appendix 3.

The implementation intervention will be tailored for each site by adapting knowledge resources (such as printed decision aids and patient resources) to the local context and by working with local opinion leaders to address potential barriers to implementing the ACI model of care. These instructions, measures, and training materials will be hosted online during the implementation phase on The University of Sydney's website. Due to the nature of the intervention, it will not be possible to blind clinician participants to the intervention.

Sample size

Based on the effect size of 10% absolute reduction (from 30%[7] to 20%) in imaging referrals, combined with an alpha of 0.05 and assuming an Intraclass Correlation Coefficient (ICC) of 0.1, a total number of 1,920 low back pain presentations (on average 480 per cluster) to emergency departments is needed for this stepped-wedge cluster trial with 80% power. A preliminary analysis revealed that there were over 2,650 low back pain presentations to the participating emergency departments in 2016, showing feasibility of this trial.

Outcome Measures

Clinician participants will complete a baseline questionnaire, including demographic questions. They will also be asked to indicate whether they have special interests in low back pain or musculoskeletal medicine, and if they had attended previous continuing medical education or postgraduate training on low back pain management. The outcomes to evaluate the effectiveness of the ACI model of care on health service delivery are routinely collected emergency department measures.

Primary outcome:

- Proportion of patients receiving any imaging (yes/no)

Secondary outcomes:

- Proportion of patients receiving advanced imaging (CT/MRI=yes, X-ray/No imaging=no)
- Proportion of patients receiving analgesic medications (topical, oral, injection). Medications will be classified according to the Anatomical Therapeutic Chemical (ATC) classification system (Table 3). The ATC classification is recommended by the World Health Organisation and is widely used internationally in medication utilisation studies:
  - Paracetamol
  - Non-steroidal anti-inflammatory drugs (NSAIDs)
  - Muscle relaxants
  - Opioids
  - Neuropathic pain medications
  - Other
- Proportion of patients admitted to:
  - Hospital
  - Emergency Medical Unit (EMU)

- Short Stay Unit (SSU)
- Time in emergency department (triage time to discharge or admission time)
- Proportion of patients referred to specialists (referral for a consultation by the emergency department):
  - Pain Management
  - Rheumatology
  - Surgery
- Proportion of patients re-presenting to the emergency department within 48 hours
- Proportion of patients re-admitted to the hospital within 28 days
- Total health system costs (including intervention costs and health service delivery costs)

Patient-reported outcomes will be collected using a brief online questionnaire that will measure pain intensity (Numeric Rating Scale, range 0–10). We will also use the Patient-Reported Outcomes Measurement Information System (PROMIS) to measure physical function (PROMIS Short Form – Physical Function 4a) and quality of life (PROMIS Scale – Global Health item 1) as advocated by the National Institutes of Health. We have chosen these outcomes as they are considered the three core outcome domains for clinical trials in low back pain identified in a recent Delphi study,[23] and by the International Consortium for Health Outcomes Measurement (ICHOM).[24] Patient experience with emergency service will be assessed using item 31 of the Emergency Department Patient Experience of Care (EDPEC) survey advocated by the American College of Emergency Medicine.[25]

Data collection methods

In the week prior to the implementation intervention, the 12-month retrospective baseline health service delivery data will be extracted directly from participating hospitals' electronic record systems. The Sydney Local Health District (SLHD) Targeted Activity and Reporting System (STARS) will be used to access and extract data from SLHD emergency departments. STARS is data analytics program which monitors clinician performance and service utilisation. At Dubbo Base Hospital, health service delivery data will be extracted from its electronic record system. During the implementation intervention, health service delivery measures will be extracted from all participating emergency departments every week until the end of the 3-month follow-up period. Data extraction will be conducted remotely for all participating emergency departments by research staff blinded to intervention allocation.

Data collection through hospitals' electronic systems will also avoid additional workloads within the emergency departments.

Patient-reported outcome measures will be collected using automated text messaging at one week (primary time point) and again at two and four weeks after index emergency department presentation. A random sub-sample of patient participants will be referred to a brief self-reported online questionnaire containing the Patient Information Statement. Completion of the online questionnaire indicates patient consent to participate in the study. Reminder messages will be used to ensure a high response rate.

Data will be securely stored in password-protected spreadsheets and transferred to appropriate statistical software for analysis. Spreadsheets will be regularly scrutinised for omissions and errors. Data will be archived at the Sydney School of Public Health, The University of Sydney for 15 years, after which data will be destroyed.

Statistical methods

Data analysis will be performed according to an intention-to-treat analysis, i.e. clusters will be analysed according to their randomised crossover time irrespective of whether crossover was achieved at the desired time. Firstly, we will investigate temporal trends in healthcare outcomes across the 12-month baseline observation period. In the situation of an underlying temporal trend, we will only include data for the previous three months as the baseline observation period. In our primary analysis, the 4-week implementation intervention period will be excluded, but a secondary exploratory analysis will be performed including the implementation period into the intervention group. For the primary outcome analysis, logistic regression models with a random effect for cluster, a fixed effect indicating the group assignment of each cluster at each step, and a fixed effect of time (each step) will be used. Data will be analysed using SAS version 9.1.3 (SAS Institute Inc., Cary, NC).

Economic evaluation

An economic evaluation of the ACI model of care compared with current emergency practice will be undertaken from the health system perspective. Firstly, we will measure the costs related to the delivery of the implementation intervention (that is, training component, staff time, and printed resources). Then, the costs related to health service delivery will be measured via data captured by the hospitals' electronic record systems. Costs will be valued

based on government charges, using publicly available data. All costs will be reported in Australian dollars. Where necessary, costs will be converted to 2017 prices using the health consumer price index published by the Australian Bureau of Statistics. The incremental cost-effectiveness ratio (ICER) will be presented as the incremental cost per patient avoiding any imaging, opioid prescription, and hospital admission.

Univariate sensitivity analyses will be conducted around key parameters likely to influence cost-effectiveness, including cost and efficacy estimates. For example, effectiveness parameters used in the economic evaluation will be varied over the 95% confidence intervals to assess impact on the ICER. Intervention costs, including training costs, staff time and resource costs will be collected from individual emergency departments and similarly analysis will examine the effect on the ICER of varying these values over the range reported by participating sites. Bootstrapping will be used to estimate a distribution around costs and health outcomes, and to estimate the confidence intervals around the ICER. Results will be plotted on the cost-effectiveness plane.

Process evaluation

A process evaluation will be conducted to provide an indication of which elements of the implementation intervention are effective and worthwhile. In the week before the implementation period and in the week after it, clinician participants will be asked to answer a questionnaire containing the Back Beliefs Questionnaire.[26] The Back Beliefs Questionnaire is a widely validated questionnaire[27] designed to measure beliefs about low back pain and will be used in our trial to assess whether the use of the ACI model of care improves beliefs about low back pain among emergency clinicians. This instrument was found to be reliable and responsive to change in a wide range of contexts, including in Australia.[28] We will also use a set of questions aimed at eliciting knowledge about the management of low back pain and attitudes of emergency clinicians toward these patients.[29] At the end of the implementation period, clinician participants will also be asked to review the content of educational materials. Potential barriers and facilitators will be investigated using qualitative interviews with clinician participants.

ETHICS AND DISSEMINATION

The SHaPED trial received ethical approval from the Sydney Local Health District (RPAH zone) Ethics Committee, Sydney, Australia (X17-0043). Our hypothesis is that

implementation of the ACI model of care will improve health service delivery in participating emergency departments for patients presenting with low back pain: specifically decreasing the proportion of patients receiving imaging, opioids, and hospital admission. If the trial results are positive we will build upon our existing strong relationships with the ACI, Sydney Health Partners, and the Local Health Districts to support implementation of the ACI model of care in other emergency departments across New South Wales. As a branch of the New South Wales Ministry of Health, the ACI will be well positioned to facilitate transferability of findings. We will also disseminate the results of the trial at conferences and in scientific journals and we will continue our successful approach of using the media to reach a lay audience and health consumers. The study resources will be made freely available on relevant websites so that jurisdictions beyond New South Wales can adopt the implementation strategy outlined in this study.

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Contributors: GCM, BR, CN, RB, IH, KH, KM, LB, and CM conceptualised the research design, drafted the research protocol, and are coordinating the project team. JE, ER, RF, DLC provided expert advice and are lead site investigators. MO, NB, HS, and RK are responsible for the acquisition of data and data monitoring. MV, NM, KM, RD, RL, MJ, RS, NA, NM, MF, PF, and CL are collaborators and contributed with expert advice and funding applications. LB advised on the trial design and was responsible for the sample size calculation and statistical analysis methods. KH was responsible for the design of the economic evaluation. KM was responsible for the design of the process evaluation. MO, DC, RP, MC, MM, DH, LB, and KH are site investigators contributing to the implementation of the model of care. All authors contributed to refinement of the study protocol and approved the final manuscript.

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Study sponsor: The University of Sydney, NSW 2006 Australia.

Competing interests: None declared. Study sponsor and funders have no role in the study design; collection, management, analysis, and interpretation of data; writing of the report; or the decision to submit the report for publication.

Patient consent: Consent of the clinician and patient participants will be obtained.

Ethics approval: The study received ethical approval from the Sydney Local Health District (RPAH zone) Ethics Committee, Sydney, Australia (X17-0043).

Provenance and peer review: Not commissioned; externally peer reviewed.

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Table 1. The key principles of the ACI model of care for acute low back pain

Principle 1	Assessment: history and examination
Principle 2	Risk stratification
Principle 3	Patient education
Principle 4	Active physical therapy encouraged
Principle 5	Begin with simple analgesic medicines
Principle 6	Judicious use of complex medicines
Principle 7	Cognitive behavioural approach
Principle 8	Only image those with suspected serious spinal pathology
Principle 9	Pre-determined times for review
Principle 10	Timely referral and access to specialist services

Source: NSW Agency for Clinical Innovation. Management of people with acute low back pain: model of care. Chatswood; NSW Health; 2016. 39 p, available at: https://www.aci.health.nsw.gov.au/resources/musculoskeletal/management-of-people-with-acute-low-back-pain/albp-model

Table 2. SHaPED trial design

Steps (clusters)	Year 1												Year 2						
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7
ED 1																			
ED 2																			
ED 3																			
ED 4																			

12-month retrospective baseline control period
4-week initial implementation intervention period
Sites continue with intervention plus follow-up period

Table 3. Medications per ATC classification

Group	**ATC code**
Analgesics	N02B
NSAIDs	M01A M02AA
Muscle relaxants	M03
Opioids	N02A N01AH
Neuropathic pain medicines	N03 N06A

ATC, Anatomical Therapeutic Chemical. NSAIDs, Non-steroidal anti-inflammatory drugs

Supplementary Appendix 1. The SHaPED trial investigators

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Supplementary Appendix 2. SNOMED CT-AU (EDRS) codes related to low back pain presentations

DESCRIPTION	CODES
Low back pain with non-specific cause	
Acute low back pain (finding)	278862001
Back pain complicating pregnancy (disorder)	91957002
Backache (finding)	161891005
Blunt injury to back (disorder)	424270008
Chronic back pain (finding)	134407002
Chronic low back pain (finding)	278860009
Coccyx sprain (disorder)	209571002
Complaining of low back pain (finding)	161894002
Degeneration of lumbar intervertebral disc (disorder)	26538006
Displacement of lumbar intervertebral disc without myelopathy (disorder)	20021007
Exacerbation of backache (finding)	135860001
Low back pain (finding)	279039007
Low back strain (disorder)	300956001
Lower back injury (disorder)	282766005
Lumbar spondylosis (disorder)	239880009
Lumbar sprain (disorder)	209565008
Mechanical low back pain (finding)	279040009
Pain in the coccyx (finding)	34789001
Sacral back pain (finding)	61486003
Spasm of back muscles (finding)	203095000
Sprain of ligament of lumbosacral joint (disorder)	209548004
Stiff back (finding)	249921008
Strain of back muscle (disorder)	262965006
Strain of tendon of back (disorder)	262975009
Low back pain with neurological signs and symptoms	
Acute back pain with sciatica (finding)	247366003
Acute sciatica (disorder)	307176005
Chronic sciatica (disorder)	307177001
Injury of lumbar nerve roots (disorder)	24300005
Injury of sciatic nerve (disorder)	86269002
Lumbago with sciatica (finding)	202794004
Lumbago-sciatica due to displacement of lumbar intervertebral disc (disorder)	46960006
Lumbar disc prolapse with radiculopathy (disorder)	202735001
Lumbar radiculopathy (disorder)	128196005
Sciatica (disorder)	23056005
Spinal stenosis of lumbar region (disorder)	18347007
Low back pain due to serious pathology	
Abscess of back (disorder)	309083007
Abscess of back, except buttock (disorder)	19284003
Cauda equina syndrome (disorder)	192970008
Closed fracture lumbar vertebra (disorder)	207957008
Collapse of lumbar vertebra (disorder)	308758008
Compression fracture of lumbar spine (disorder)	426646004
Concussion and edema of lumbar spinal cord (disorder)	212360005
Contusion of back (disorder)	11437003
Contusion of lower back (disorder)	284062002
Crush fracture of lumbar vertebra (disorder)	281933002
Disc prolapse with myelopathy (disorder)	202728009

Discitis (disorder)	2304001
Fracture of coccyx (disorder)	125871005
Fracture of lumbar spine (disorder)	125608002
Fracture of lumbar spine and/or pelvis (disorder)	207986006
Injury of cauda equina (disorder)	230614002
Lumbar disc prolapse with myelopathy (disorder)	202731005
Multiple fractures of lumbar spine and/or pelvis (disorder)	207993005
Open dislocation of coccyx (disorder)	44237008
Open fracture of lumbar vertebra with spinal cord injury (disorder)	48956000
Open fracture of sacrum AND/OR coccyx with spinal cord injury (disorder)	65491009
Traumatic dislocation of joint of lumbar vertebra (disorder)	129166009
Traumatic dislocation of lumbosacral joint (disorder)	129161004

SNOMED CT-AU (EDRS), Systematized Nomenclature of Medicine – Clinical Terms – Australian Version (Emergency Department Reference Set).

Supplementary Appendix 3. SHaPED Implementation strategy and intervention description

The implementation plan for the Sydney Health Partners Emergency Department (SHaPED) trial has been adapted from: Jabbour M, Reid S, Polihronis C, Cloutier P, Gardner W, Kennedy A, Gray C, Zemek R, Pajer K, Barrowman N, Cappelli M. Improving mental health care transitions for children and youth: a protocol to implement and evaluate an emergency department clinical pathway. *Implement Sci*. 2016;11:90.

1. Create implementation team:

a) Obtain support from clinical leads and administration heads at the four emergency departments. Formalise a partnership agreement between institutions.
b) Recruit and engage study champions at each emergency department. Team members to include: emergency physicians, physiotherapists, nurses, managers, and clinical educators.
c) Develop a working group and form a steering committee at each emergency department to provide oversight on implementation progress.
d) Establish meeting schedule: local steering committee to meet twice a week and report to study supervisors every week during the implementation period.

2. Assessment:

a) Review and discuss the existing models of care for low back pain at the four emergency departments and recommend adaptation to facilitate adoption of the new model.
b) Conduct an environmental assessment and identify typical pathway of care for a patient presenting with low back pain at each emergency department.
c) Identify practices and processes that require development or change in order to support the implementation strategy.
d) Identify internal and external stakeholders who will be impacted by the new model and therefore require education and support to implement it.

3. Plan strategy for change

a) Identify leadership support required for implementation phase.
b) Identify and engage influential clinical champions who will effectively drive change.
c) Revise or develop policies as needed.
d) Develop a knowledge translation strategy to support practice change, such as shared staff meetings, educational rounds, peer-to-peer mentoring.

e) Identify factors that will support practice change, such as engaging all potential stakeholders, scheduling champions and clinicians to enable attendance at meetings and face-to-face education sessions, facilitating the development of relationships between emergency physicians and other clinical staff, conducting audits or monitor specific data indicators that will support practice change.

f) Identify factors that may create a barrier for practice change in the emergency department, including attitudes and beliefs about low back pain management, and lack of clinician expertise/comfort to treat this population.

g) Develop strategies to manage barriers, such as communication, education, opportunities to develop relationships within and between clinicians and service provider.

4. Implementation:

a) Provide clinician information package:

- Deliver printed copies of the ACI Model of care (full version and executive summary) to clinician participants.
- Create a list of "red flags" to screen for serious pathologies from the ACI Model of care and deliver a printed version to clinician participants.
- Create posters outlining the '10 principles' of the ACI model of care, as well as the clinical pathways and place them at key locations of each participating emergency department.
- Inform clinician participants about and provide them access to online videos and other printed (such as the ACI consumer information booklet) and electronic educational materials to educate patients with low back pain at emergency discharge.

b) Provide patient information package:

- Encourage clinician participants to provide a printed copy of the ACI consumer information booklet to patients with low back pain during emergency department visit.
- Where most of the patient population do not speak English, encourage clinician participants to provide a copy of the Emergency Care Institute (ECI) Patient Factsheet for low back pain (available in six languages).
- Create posters outlining four myths of low back pain management and placed them at the reception area of each emergency department.

c) Deliver clinician education:

- Educational seminars will be delivered by an experienced clinician (Dr Chris Needs) at week 1 of the intervention period. Booster sessions in the first week will also be conducted by local investigators (such as Directors of Emergency Medicine, clinical educators) as required, as well as in weeks 2 to 4.
- The educational seminars will be conducted primarily during the existing regular clinical staff meetings, but additional sessions will be scheduled to reach all emergency clinicians. The format of the seminars consists of a mini-lecture and interactive group discussions and will last for 40 to 60 minutes.
- During the educational seminars, clinician participants will be trained on history taking and examination of patients with low back pain, on how to use SNOMED diagnosis codes, and will be encouraged to follow the recommendations in the ACI model of care to manage these patients, with focus on the key outcomes of this study (that is, imaging, opioids, and inpatient admission rates).
- During weeks 1 to 4, individual meetings with clinician participants will be scheduled as required to cover the key messages and principles outlined in the ACI model of care. There will be at least one educational outreach visit to each clinician in weeks 1 to 4 and they can request additional if they have any concerns. Clinician participants can also seek advice from clinical educators by email.

d) Develop audit and feedback focussed on study outcomes

- Each emergency department and clinician participant will receive at the first educational seminar session an emergency department level feedback on the 12-month retrospective data performance against the outcomes of this study (that is, imaging, opioids, inpatient admission rates).
- This audit and feedback approach will be repeated each month after the implementation of the model of care during the regular emergency staff meetings until the end of the follow-up period.
- Clinician participants at the Sydney Local Health District (SLHD) will be encouraged to use the SLHD Targeted Activity and Reporting System (STARS) to monitor the emergency department performance during and after the implementation period.

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	2, 6
	2b	All items from the World Health Organization Trial Registration Data Set	N/A
Protocol version	3	Date and version identifier	Footer
Funding	4	Sources and types of financial, material, and other support	14
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	14, Appendix 1
	5b	Name and contact information for the trial sponsor	14
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	14
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	Appendix 1

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4, 5
	6b	Explanation for choice of comparators	N/A
Objectives	7	Specific objectives or hypotheses	5, 6
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	6
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6, 7
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	7
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	7, 8
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	7, 8, 12
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	9, 10
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Table 2

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	8, 9
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	10, 11
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	7
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	7
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	7
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	8, 10
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	10, 11
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	11

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	11
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	11
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	11, 12
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	N/A
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	Appendix 1
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	N/A
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	12, 13
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	13

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	7, 11, 14_____
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A_____
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	In ACTRN ____
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	14_____
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	14_____
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A_____
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	In ACTRN ____
	31b	Authorship eligibility guidelines and any intended use of professional writers	Appendix 1____
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A_____
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	N/A _____
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A_____

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

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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

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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

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*Investigators in the SHaPED trial are listed in Supplementary Appendix 1.

ABSTRACT

Introduction: Patients with low back pain often seek care in emergency departments, but the problem is that many patients receive unnecessary or ineffective interventions, and at the same time miss out on the basics of care, such as advice on self-management. This pattern of care has important consequences for the healthcare system (expensive and inefficient) and for patients (poor health outcomes). We hypothesised that the implementation of an evidence-based model of care for low back pain will improve emergency care by reducing inappropriate overuse of tests and treatments and improving patient outcomes.

Methods and analysis: A stepped wedge cluster randomised controlled trial will be conducted to implement and evaluate the use of the Agency for Clinical Innovation (ACI) model of care for acute low back pain at four emergency departments in New South Wales, Australia. Clinician participants will be emergency physicians, nurses and physiotherapists. Codes from the Systematised Nomenclature of Medicine – Clinical Terms – Australian version will be used to identify low back pain presentations. The implementation intervention, targeting emergency clinicians, will comprise educational materials and seminars, and an audit and feedback approach. Health service delivery outcomes are routinely collected measures of imaging (primary outcome), opioid use, and inpatient admission. A random sub-sample of 200 patient participants from each trial period will be included to measure patient-reported outcomes (pain intensity, physical function, quality of life, and experience with emergency service). The effectiveness of the implementation intervention will be assessed by comparing the post-intervention period with the retrospective baseline control period.

Ethics and dissemination: The study received ethical approval from the Sydney Local Health District (RPAH zone) Ethics Committee (X17-0043). The results of this study will be published in peer-reviewed journals and presented at international conferences.

Trial registration number: Australia New Zealand Clinical Trials Registry: ACTRN 12617001160325.

Strengths and limitations of the study

- This is a novel implementation trial looking at reducing inappropriate overuse of tests and treatments for low back pain in emergency departments
- The stepped wedge design is particularly suited to interventions aiming to improve healthcare systems as all sites receive the intervention
- In this study design, intervention effects are estimated from within-emergency department differences while controlling for time trends
- The use of routinely collected measures reduces the burden of data collection of health service delivery outcomes in the emergency departments
- Incorporation of only four clusters (emergency departments) in the trial may limit the generalisability of results to other health districts

INTRODUCTION

Background and rationale

Low back pain is a common presenting complaint in emergency settings. In 2015-16 alone, there were 104,072 low back pain presentations to emergency departments in Australia, placing this condition among the top 10 reasons for emergency visits.[1] This condition is also a common reason for emergency department presentations across the globe, accounting for 4.4% of all presentations.[2] Unfortunately, many patients receive low-value care for their low back pain in the emergency department. Low-value care is broadly defined as the use of an intervention that provides patients with little-to-no benefits, or cause harm.[3] Examples of low-value care of low back pain in emergency departments include inappropriate overuse of imaging, liberal use of opioid analgesics, and unnecessary admission to hospital.

Multiple clinical guidelines exist for the management of low back pain in primary care.[4 5] Although it is unclear whether these guidelines should be applied in the emergency department, much of their recommendations may be relevant to emergency physicians and are often used to guide their practice.[6] However, the mixture of providing inappropriate care and failing to provide appropriate care in the emergency department is a clear indication that healthcare is not following clinical guidelines. For instance, about 30% of patients with non-specific low back pain receive imaging in the emergency department,[7] when guidelines explicitly recommend no imaging for these cases. Imaging in the absence of suspected serious pathology does not seem to improve patient outcomes,[8] and can potentially cause harms.[9-11] Against guideline advice, around 62% of low back pain patients receive opioids in the emergency department,[12] although efficacy in pain relief has not been established for acute low back pain[13] and side effects are often serious,[14] including dependence, overdose and death. Another issue is the increasing rate of hospital admissions. More than one third of low back pain presentations to the emergency department lead to the patient being admitted to hospital,[7] where care is likely to be similar to what could be provided in primary care.

The significant deviations from evidence-based recommendations occurring in Australian emergency departments[15] makes them an appropriate setting to trial an intervention based on improving care for low back pain. The Agency for Clinical Innovation (ACI) has recently launched a model of care for acute low back pain that could be applied in both primary care and emergency department settings.[16] The ACI model of care was developed in collaboration with policy makers, clinicians, consumers and researchers, and distils the high quality

evidence in this area to formulate key messages for practice (Table 1). Briefly, the model provides different care pathways according to a classification based on a diagnostic triage[17] (acute or chronic non-specific low back pain, low back pain with leg pain, and suspected serious spinal conditions). Risk stratification[18] is recommended to guide the amount and type of treatment provided; including personalised evidence-based health education and treatment. Lastly, follow-up reviews are scheduled to monitor individuals' progress. Passive dissemination of guidelines, such as the ACI model of care, is unlikely to change practice. We are proposing a multi-faceted strategy to implement and evaluate the ACI model of care to see if this improves health service delivery and patient-reported outcomes for low back pain at the emergency department.

Objectives

The overall aim of the Sydney Health Partners Emergency Department (SHaPED) trial is to implement and evaluate the ACI model of care for acute low back pain. The outcomes of the trial reflect the key messages in the model: 1) patients with non-specific low back pain do not require imaging; 2) where medicines are used, simple analgesics should be the first option; 3) patients with non-specific low back pain should be managed as outpatients.

Primary objective

The primary objective of this study is to evaluate if implementation of the ACI model of care significantly reduces the proportion of patients presenting with low back pain who receive imaging in the emergency department.

Secondary objectives

The secondary aims of the study are:

- To determine if implementation of the ACI model of care significantly reduces the proportion of patients presenting with low back pain who receive opioids in the emergency department, and the proportion of patients subsequently admitted to hospital.
- To determine if implementation of the ACI model of care significantly improves patient-reported outcomes in people who present with low back pain in the emergency department.

- To determine the cost-effectiveness of the ACI model of care compared with current emergency department practice for people who present with low back pain.
- To determine the barriers and facilitators to the implementation intervention of the ACI model of care for people who present with low back pain in the emergency department.

METHODS AND ANALYSIS

Study design

The SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) guidelines were followed in this report of the protocol.[19] SHaPED will use a stepped wedge cluster randomised controlled trial design.[20] In this study design, clusters are randomised to cross from the control period (i.e., unexposed to intervention) to the intervention period at regular intervals ('steps') until all clusters have crossed to the intervention under evaluation. This design is particularly suited to interventions aiming to improve healthcare systems as all groups eventually receive the intervention. Moreover, the process allows for comparison with control sites that have not yet implemented the intervention.

In the SHaPED trial, after a retrospective baseline observation control period of 12 months prior to randomisation, the implementation intervention will be sequentially rolled out, with a new emergency department receiving the implementation intervention every four weeks, until all participating emergency departments have received the implementation intervention. After the implementation of the ACI model of care, the emergency departments will continue using the pathways of care outlined in the model until the end of the trial (Table 2).

Study setting

The emergency departments of one rural and three urban hospitals in New South Wales, Australia will participate in the study: Royal Prince Alfred Hospital, Concord Repatriation General Hospital, Canterbury Hospital, and Dubbo Base Hospital. The SHaPED trial has been approved (X17-0043) by the Ethics Review Committee of the Sydney Local Health District (RPAH zone), and by the Chief Executive of each participating institution. The trial is registered with the Australia New Zealand Clinical Trials registry: ACTRN 12617001160325. Investigators in the SHaPED trial are listed in Supplementary Appendix 1.

Clinician participants

Clinician participants included in the SHaPED trial will be emergency clinical staff, such as physicians, nurses, and physiotherapists, who routinely manage patients presenting to emergency departments with a primary complaint of low back pain. Potential clinician participants will be invited by the Principal Investigator of each emergency department and will receive a Participant Information Statement. Research staff will verbally explain the information provided in this document to fully inform potential clinician participants of the risks and benefits of their participation. In addition, the research staff will be available to answer any questions to ensure that potential clinician participants fully understand the implications of their decision. A written Participant Consent Form will be obtained from all participating clinicians prior to randomisation.

Patient participants

We will use codes from the Systematised Nomenclature of Medicine – Clinical Terms – Australian version, Emergency Department Reference Set (SNOMED CT-AU [EDRS])[21] to identify low back pain presentations (Supplementary Appendix 2) to the emergency departments. Presentations with codes related to low back pain with non-specific cause or those associated with neurological signs and symptoms (such as sciatica and lumbar spinal stenosis) will be included. Re-presentations to the emergency department, or low back pain presentations related to serious spinal pathologies (such as lumbar fracture or cauda equina syndrome) will be excluded. A random sub-sample of 200 patient participants from each trial period will be referred to a brief self-reported online questionnaire to evaluate the effectiveness of the implementation of the ACI model of care on patient-reported outcomes.

Randomisation

Before the beginning of the implementation intervention, the four hospitals will be randomly allocated the 'step' when the intervention will commence at their emergency department. Randomisation will be conducted using computer-generated random numbers by research staff. Only the research team will be aware of cluster allocation.

Implementation intervention

A framework has been proposed to facilitate the implementation of research evidence into clinical practice, known as The Knowledge-to-Action Process.[22] This framework links the various types of research enquiry with the key steps in the research translation cycle. The process consists of the knowledge creation cycle and the action cycle, and involves end users

of research (e.g., policymakers, clinicians and patients) to facilitate engagement with the implementation strategy. We will use this framework to develop a tailored intervention strategy to implement the ACI model of care at the participating emergency departments.

Implementation will begin with visits to each participating emergency department to establish collaborations and approvals. We will also assess organisational issues and potential barriers to the implementation intervention, such as intake and flow of patients with low back pain, assessment of current practices, acceptability of new model, and specific roles of emergency clinicians in managing these patients. We will identify existing models of care that are used to guide management of patients presenting with low back pain at each emergency department. Then, we will work with local clinical staff to ensure that each site practices according to the full ACI model of care.

A multi-faceted intervention package will be used to implement the ACI model of care at the emergency departments. Briefly, the initial 4-week implementation intervention will consist of printed and electronic educational materials, educational seminars and educational outreach, website support, posters, and an audit and feedback approach. Clinician participants will receive a copy of the model and other printed materials, including the ACI consumer information booklet, as well as access to additional online support tools outlined in the ACI model of care, such as webpages and videos, to help them educate their patients. Experienced clinicians, research staff, and local opinion leaders (i.e., Directors of Emergency Medicine) will deliver the interactive educational seminars and educational outreach. An audit and feedback approach focussed on the outcomes of the study will also be used to enhance our implementation program. A detailed description of the implementation plan for the SHaPED trial can be found in Supplementary Appendix 3.

The implementation intervention will be tailored for each site by adapting knowledge resources (such as printed decision aids and patient resources) to the local context and by working with local opinion leaders to address potential barriers to implementing the ACI model of care. These instructions, measures, and training materials will be hosted online during the implementation phase on The University of Sydney's website. Due to the nature of the intervention, it will not be possible to blind clinician participants to the intervention.

Sample size

Based on the effect size of 10% absolute reduction (from 30%[7] to 20%) in imaging referrals, combined with an alpha of 0.05 and assuming an Intraclass Correlation Coefficient (ICC) of 0.1, a total number of 1,920 low back pain presentations (on average 480 per cluster) to emergency departments is needed for this stepped-wedge cluster trial with 80% power. A preliminary analysis revealed that there were over 2,650 low back pain presentations to the participating emergency departments in 2016, showing feasibility of this trial.

Outcome Measures

Clinician participants will complete a baseline questionnaire, including demographic questions. They will also be asked to indicate whether they have special interests in low back pain or musculoskeletal medicine, and if they had attended previous continuing medical education or postgraduate training on low back pain management. The outcomes to evaluate the effectiveness of the ACI model of care on health service delivery are routinely collected emergency department measures.

Primary outcome:

- Proportion of patients receiving any imaging (yes/no)

Secondary outcomes:

- Proportion of patients receiving advanced imaging (CT/MRI=yes, X-ray/No imaging=no)
- Proportion of patients receiving analgesic medications (topical, oral, injection). Medications will be classified according to the Anatomical Therapeutic Chemical (ATC) classification system (Table 3). The ATC classification is recommended by the World Health Organisation and is widely used internationally in medication utilisation studies:
  - Paracetamol
  - Non-steroidal anti-inflammatory drugs (NSAIDs)
  - Muscle relaxants
  - Opioids
  - Neuropathic pain medications
  - Other
- Proportion of patients admitted to:
  - Hospital
  - Emergency Medical Unit (EMU)

- Short Stay Unit (SSU)
- Time in emergency department (triage time to discharge or admission time)
- Proportion of patients referred to specialists (referral for a consultation by the emergency department):
  - Pain Management
  - Rheumatology
  - Surgery
- Proportion of patients re-presenting to the emergency department within 48 hours
- Proportion of patients re-admitted to the hospital within 28 days
- Total health system costs (including intervention costs and health service delivery costs)

Patient-reported outcomes will be collected using a brief online questionnaire that will measure pain intensity (Numeric Rating Scale, range 0–10). We will also use the Patient-Reported Outcomes Measurement Information System (PROMIS) to measure physical function (PROMIS Short Form – Physical Function 4a) and quality of life (PROMIS Scale – Global Health item 1) as advocated by the National Institutes of Health. We have chosen these outcomes as they are considered the three core outcome domains for clinical trials in low back pain identified in a recent Delphi study,[23] and by the International Consortium for Health Outcomes Measurement (ICHOM).[24] Patient experience with emergency service will be assessed using item 31 of the Emergency Department Patient Experience of Care (EDPEC) survey advocated by the American College of Emergency Medicine.[25]

Data collection methods

In the week prior to the implementation intervention, the 12-month retrospective baseline health service delivery data will be extracted directly from participating hospitals' electronic record systems. The Sydney Local Health District (SLHD) Targeted Activity and Reporting System (STARS) will be used to access and extract data from SLHD emergency departments. STARS is data analytics program which monitors clinician performance and service utilisation. At Dubbo Base Hospital, health service delivery data will be extracted from its electronic record system. During the implementation intervention, health service delivery measures will be extracted from all participating emergency departments every week until the end of the 3-month follow-up period. Data extraction will be conducted remotely for all participating emergency departments by research staff blinded to intervention allocation.

Data collection through hospitals' electronic systems will also avoid additional workloads within the emergency departments.

Patient-reported outcome measures will be collected using automated text messaging at one week (primary time point) and again at two and four weeks after index emergency department presentation. A random sub-sample of patient participants will be referred to a brief self-reported online questionnaire containing the Patient Information Statement. Completion of the online questionnaire indicates patient consent to participate in the study. Reminder messages will be used to ensure a high response rate.

Data will be securely stored in password-protected spreadsheets and transferred to appropriate statistical software for analysis. Spreadsheets will be regularly scrutinised for omissions and errors. Data will be archived at the Sydney School of Public Health, The University of Sydney for 15 years, after which data will be destroyed.

Statistical methods

Data analysis will be performed according to an intention-to-treat analysis, i.e. clusters will be analysed according to their randomised crossover time irrespective of whether crossover was achieved at the desired time. Firstly, we will investigate temporal trends in healthcare outcomes across the 12-month baseline observation period. In the situation of an underlying temporal trend, we will only include data for the previous three months as the baseline observation period. In our primary analysis, the 4-week implementation intervention period will be excluded, but a secondary exploratory analysis will be performed including the implementation period into the intervention group. For the primary outcome analysis, logistic regression models with a random effect for cluster, a fixed effect indicating the group assignment of each cluster at each step, and a fixed effect of time (each step) will be used. Data will be analysed using SAS version 9.1.3 (SAS Institute Inc., Cary, NC).

Economic evaluation

An economic evaluation of the ACI model of care compared with current emergency practice will be undertaken from the health system perspective. Firstly, we will measure the costs related to the delivery of the implementation intervention (that is, training component, staff time, and printed resources). Then, the costs related to health service delivery will be measured via data captured by the hospitals' electronic record systems. Costs will be valued

based on government charges, using publicly available data. All costs will be reported in Australian dollars. Where necessary, costs will be converted to 2017 prices using the health consumer price index published by the Australian Bureau of Statistics. The incremental cost-effectiveness ratio (ICER) will be presented as the incremental cost per patient avoiding any imaging, opioid prescription, and hospital admission.

Univariate sensitivity analyses will be conducted around key parameters likely to influence cost-effectiveness, including cost and efficacy estimates. For example, effectiveness parameters used in the economic evaluation will be varied over the 95% confidence intervals to assess impact on the ICER. Intervention costs, including training costs, staff time and resource costs will be collected from individual emergency departments and similarly analysis will examine the effect on the ICER of varying these values over the range reported by participating sites. Bootstrapping will be used to estimate a distribution around costs and health outcomes, and to estimate the confidence intervals around the ICER. Results will be plotted on the cost-effectiveness plane.

Process evaluation

A process evaluation will be conducted to provide an indication of which elements of the implementation intervention are effective and worthwhile. In the week before the implementation period and in the week after it, clinician participants will be asked to answer a questionnaire containing the Back Beliefs Questionnaire.[26] The Back Beliefs Questionnaire is a widely validated questionnaire[27] designed to measure beliefs about low back pain and will be used in our trial to assess whether the use of the ACI model of care improves beliefs about low back pain among emergency clinicians. This instrument was found to be reliable and responsive to change in a wide range of contexts, including in Australia.[28] We will also use a set of questions aimed at eliciting knowledge about the management of low back pain and attitudes of emergency clinicians toward these patients.[29] At the end of the implementation period, clinician participants will also be asked to review the content of educational materials. Potential barriers and facilitators will be investigated using qualitative interviews with clinician participants.

ETHICS AND DISSEMINATION

The SHaPED trial received ethical approval from the Sydney Local Health District (RPAH zone) Ethics Committee, Sydney, Australia (X17-0043). Our hypothesis is that

implementation of the ACI model of care will improve health service delivery in participating emergency departments for patients presenting with low back pain: specifically decreasing the proportion of patients receiving imaging, opioids, and hospital admission. If the trial results are positive we will build upon our existing strong relationships with the ACI, Sydney Health Partners, and the Local Health Districts to support implementation of the ACI model of care in other emergency departments across New South Wales. As a branch of the New South Wales Ministry of Health, the ACI will be well positioned to facilitate transferability of findings. We will also disseminate the results of the trial at conferences and in scientific journals and we will continue our successful approach of using the media to reach a lay audience and health consumers. The study resources will be made freely available on relevant websites so that jurisdictions beyond New South Wales can adopt the implementation strategy outlined in this study.

ACKNOWLEDGMENTS

Contributors: GCM, BR, CN, RB, IH, KH, KM, LB, and CM conceptualised the research design, drafted the research protocol, and are coordinating the project team. JE, ER, RF, DLC provided expert advice and are lead site investigators. MO, NB, HS, and RK are responsible for the acquisition of data and data monitoring. MV, NM, KM, RD, RL, MJ, RS, NA, NM, MF, PF, and CL are collaborators and contributed with expert advice and funding applications. LB advised on the trial design and was responsible for the sample size calculation and statistical analysis methods. KH was responsible for the design of the economic evaluation. KM was responsible for the design of the process evaluation. MO, DC, RP, MC, MM, DH, LB, and KH are site investigators contributing to the implementation of the model of care. All authors contributed to refinement of the study protocol and approved the final manuscript.

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Study sponsor: The University of Sydney, NSW 2006 Australia.

Competing interests: None declared. Study sponsor and funders have no role in the study design; collection, management, analysis, and interpretation of data; writing of the report; or the decision to submit the report for publication.

Patient consent: Consent of the clinician and patient participants will be obtained.

Ethics approval: The study received ethical approval from the Sydney Local Health District (RPAH zone) Ethics Committee, Sydney, Australia (X17-0043).

Provenance and peer review: Not commissioned; externally peer reviewed.

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Table 1. The key principles of the ACI model of care for acute low back pain

Principle 1	Assessment: history and examination
Principle 2	Risk stratification
Principle 3	Patient education
Principle 4	Active physical therapy encouraged
Principle 5	Begin with simple analgesic medicines
Principle 6	Judicious use of complex medicines
Principle 7	Cognitive behavioural approach
Principle 8	Only image those with suspected serious spinal pathology
Principle 9	Pre-determined times for review
Principle 10	Timely referral and access to specialist services

Source: NSW Agency for Clinical Innovation. Management of people with acute low back pain: model of care. Chatswood; NSW Health; 2016. 39 p, available at: https://www.aci.health.nsw.gov.au/resources/musculoskeletal/management-of-people-with-acute-low-back-pain/albp-model

Table 2. SHaPED trial design

Steps (clusters)	Year 1												Year 2						
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7
ED 1																			
ED 2																			
ED 3																			
ED 4																			

12-month retrospective baseline control period
4-week initial implementation intervention period
Sites continue with intervention plus follow-up period

Table 3. Medications per ATC classification

Group	**ATC code**
Analgesics	N02B
NSAIDs	M01A M02AA
Muscle relaxants	M03
Opioids	N02A N01AH
Neuropathic pain medicines	N03 N06A

ATC, Anatomical Therapeutic Chemical. NSAIDs, Non-steroidal anti-inflammatory drugs

Supplementary Appendix 1. The SHaPED trial investigators

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The University of Sydney: Manuela Ferreira, Paulo Ferreira, Chris Lin.

Supplementary Appendix 2. SNOMED CT-AU (EDRS) codes related to low back pain presentations

DESCRIPTION	CODES
Low back pain with non-specific cause	
Acute low back pain (finding)	278862001
Back pain complicating pregnancy (disorder)	91957002
Backache (finding)	161891005
Blunt injury to back (disorder)	424270008
Chronic back pain (finding)	134407002
Chronic low back pain (finding)	278860009
Coccyx sprain (disorder)	209571002
Complaining of low back pain (finding)	161894002
Degeneration of lumbar intervertebral disc (disorder)	26538006
Displacement of lumbar intervertebral disc without myelopathy (disorder)	20021007
Exacerbation of backache (finding)	135860001
Low back pain (finding)	279039007
Low back strain (disorder)	300956001
Lower back injury (disorder)	282766005
Lumbar spondylosis (disorder)	239880009
Lumbar sprain (disorder)	209565008
Mechanical low back pain (finding)	279040009
Pain in the coccyx (finding)	34789001
Sacral back pain (finding)	61486003
Spasm of back muscles (finding)	203095000
Sprain of ligament of lumbosacral joint (disorder)	209548004
Stiff back (finding)	249921008
Strain of back muscle (disorder)	262965006
Strain of tendon of back (disorder)	262975009
Low back pain with neurological signs and symptoms	
Acute back pain with sciatica (finding)	247366003
Acute sciatica (disorder)	307176005
Chronic sciatica (disorder)	307177001
Injury of lumbar nerve roots (disorder)	24300005
Injury of sciatic nerve (disorder)	86269002
Lumbago with sciatica (finding)	202794004
Lumbago-sciatica due to displacement of lumbar intervertebral disc (disorder)	46960006
Lumbar disc prolapse with radiculopathy (disorder)	202735001
Lumbar radiculopathy (disorder)	128196005
Sciatica (disorder)	23056005
Spinal stenosis of lumbar region (disorder)	18347007
Low back pain due to serious pathology	
Abscess of back (disorder)	309083007
Abscess of back, except buttock (disorder)	19284003
Cauda equina syndrome (disorder)	192970008
Closed fracture lumbar vertebra (disorder)	207957008
Collapse of lumbar vertebra (disorder)	308758008
Compression fracture of lumbar spine (disorder)	426646004
Concussion and edema of lumbar spinal cord (disorder)	212360005
Contusion of back (disorder)	11437003
Contusion of lower back (disorder)	284062002
Crush fracture of lumbar vertebra (disorder)	281933002
Disc prolapse with myelopathy (disorder)	202728009

Discitis (disorder)	2304001
Fracture of coccyx (disorder)	125871005
Fracture of lumbar spine (disorder)	125608002
Fracture of lumbar spine and/or pelvis (disorder)	207986006
Injury of cauda equina (disorder)	230614002
Lumbar disc prolapse with myelopathy (disorder)	202731005
Multiple fractures of lumbar spine and/or pelvis (disorder)	207993005
Open dislocation of coccyx (disorder)	44237008
Open fracture of lumbar vertebra with spinal cord injury (disorder)	48956000
Open fracture of sacrum AND/OR coccyx with spinal cord injury (disorder)	65491009
Traumatic dislocation of joint of lumbar vertebra (disorder)	129166009
Traumatic dislocation of lumbosacral joint (disorder)	129161004

SNOMED CT-AU (EDRS), Systematized Nomenclature of Medicine – Clinical Terms – Australian Version (Emergency Department Reference Set).

Supplementary Appendix 3. SHaPED Implementation strategy and intervention description

The implementation plan for the Sydney Health Partners Emergency Department (SHaPED) trial has been adapted from: Jabbour M, Reid S, Polihronis C, Cloutier P, Gardner W, Kennedy A, Gray C, Zemek R, Pajer K, Barrowman N, Cappelli M. Improving mental health care transitions for children and youth: a protocol to implement and evaluate an emergency department clinical pathway. *Implement Sci*. 2016;11:90.

1. Create implementation team:

a) Obtain support from clinical leads and administration heads at the four emergency departments. Formalise a partnership agreement between institutions.
b) Recruit and engage study champions at each emergency department. Team members to include: emergency physicians, physiotherapists, nurses, managers, and clinical educators.
c) Develop a working group and form a steering committee at each emergency department to provide oversight on implementation progress.
d) Establish meeting schedule: local steering committee to meet twice a week and report to study supervisors every week during the implementation period.

2. Assessment:

a) Review and discuss the existing models of care for low back pain at the four emergency departments and recommend adaptation to facilitate adoption of the new model.
b) Conduct an environmental assessment and identify typical pathway of care for a patient presenting with low back pain at each emergency department.
c) Identify practices and processes that require development or change in order to support the implementation strategy.
d) Identify internal and external stakeholders who will be impacted by the new model and therefore require education and support to implement it.

3. Plan strategy for change

a) Identify leadership support required for implementation phase.
b) Identify and engage influential clinical champions who will effectively drive change.
c) Revise or develop policies as needed.
d) Develop a knowledge translation strategy to support practice change, such as shared staff meetings, educational rounds, peer-to-peer mentoring.

e) Identify factors that will support practice change, such as engaging all potential stakeholders, scheduling champions and clinicians to enable attendance at meetings and face-to-face education sessions, facilitating the development of relationships between emergency physicians and other clinical staff, conducting audits or monitor specific data indicators that will support practice change.

f) Identify factors that may create a barrier for practice change in the emergency department, including attitudes and beliefs about low back pain management, and lack of clinician expertise/comfort to treat this population.

g) Develop strategies to manage barriers, such as communication, education, opportunities to develop relationships within and between clinicians and service provider.

4. Implementation:

a) Provide clinician information package:

- Deliver printed copies of the ACI Model of care (full version and executive summary) to clinician participants.
- Create a list of "red flags" to screen for serious pathologies from the ACI Model of care and deliver a printed version to clinician participants.
- Create posters outlining the '10 principles' of the ACI model of care, as well as the clinical pathways and place them at key locations of each participating emergency department.
- Inform clinician participants about and provide them access to online videos and other printed (such as the ACI consumer information booklet) and electronic educational materials to educate patients with low back pain at emergency discharge.

b) Provide patient information package:

- Encourage clinician participants to provide a printed copy of the ACI consumer information booklet to patients with low back pain during emergency department visit.
- Where most of the patient population do not speak English, encourage clinician participants to provide a copy of the Emergency Care Institute (ECI) Patient Factsheet for low back pain (available in six languages).
- Create posters outlining four myths of low back pain management and placed them at the reception area of each emergency department.

c) Deliver clinician education:

- Educational seminars will be delivered by an experienced clinician (Dr Chris Needs) at week 1 of the intervention period. Booster sessions in the first week will also be conducted by local investigators (such as Directors of Emergency Medicine, clinical educators) as required, as well as in weeks 2 to 4.
- The educational seminars will be conducted primarily during the existing regular clinical staff meetings, but additional sessions will be scheduled to reach all emergency clinicians. The format of the seminars consists of a mini-lecture and interactive group discussions and will last for 40 to 60 minutes.
- During the educational seminars, clinician participants will be trained on history taking and examination of patients with low back pain, on how to use SNOMED diagnosis codes, and will be encouraged to follow the recommendations in the ACI model of care to manage these patients, with focus on the key outcomes of this study (that is, imaging, opioids, and inpatient admission rates).
- During weeks 1 to 4, individual meetings with clinician participants will be scheduled as required to cover the key messages and principles outlined in the ACI model of care. There will be at least one educational outreach visit to each clinician in weeks 1 to 4 and they can request additional if they have any concerns. Clinician participants can also seek advice from clinical educators by email.

d) Develop audit and feedback focussed on study outcomes

- Each emergency department and clinician participant will receive at the first educational seminar session an emergency department level feedback on the 12-month retrospective data performance against the outcomes of this study (that is, imaging, opioids, inpatient admission rates).
- This audit and feedback approach will be repeated each month after the implementation of the model of care during the regular emergency staff meetings until the end of the follow-up period.
- Clinician participants at the Sydney Local Health District (SLHD) will be encouraged to use the SLHD Targeted Activity and Reporting System (STARS) to monitor the emergency department performance during and after the implementation period.

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	2, 6
	2b	All items from the World Health Organization Trial Registration Data Set	N/A
Protocol version	3	Date and version identifier	Footer
Funding	4	Sources and types of financial, material, and other support	14
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	14, Appendix 1
	5b	Name and contact information for the trial sponsor	14
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	14
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	Appendix 1

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4, 5
	6b	Explanation for choice of comparators	N/A
Objectives	7	Specific objectives or hypotheses	5, 6
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	6
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6, 7
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	7
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	7, 8
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	7, 8, 12
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	9, 10
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Table 2

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	8, 9
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	10, 11
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	7
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	7
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	7
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	8, 10
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	10, 11
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	11

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	11
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	11
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	11, 12
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	N/A
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	Appendix 1
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	N/A
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	12, 13
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	13

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	7, 11, 14_____
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A_____
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	In ACTRN ____
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	14_____
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	14_____
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A_____
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	In ACTRN ____
	31b	Authorship eligibility guidelines and any intended use of professional writers	Appendix 1____
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A_____
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	N/A _____
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A_____

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.