Sydney Health Partners Emergency Department (SHaPED) trial

STATISTICAL ANALYSIS PLAN

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Trial registration

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STATISTICAL ANALYSIS PLAN APPROVAL SHEET

Study: Sydney Health Partners Emergency Department (SHaPED) trial

Principal Authors of Analysis Plan

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The undersigned have reviewed this plan and find it to be consistent with the requirements of the protocol as it applies to their respective areas. The principal authors also find this plan to be in compliant with ICH-E9 and The George Institute's SOP ST-SOP-04

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1 Study design

1.1 Overview

The Sydney Health Partners Emergency Department (SHaPED) trial used a stepped wedge cluster randomised controlled trial design to evaluate an implementation strategy of the Agency for Clinical Innovation (ACI) model of care for acute low back pain in emergency departments (ED). 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.

In the SHaPED trial, after a retrospective baseline period of 12 months prior to randomisation, the implementation strategy was sequentially rolled out, with a new ED receiving the implementation strategy every 4 weeks, until all EDs implemented the model of care. Then, all EDs were followed-up and monitored for three months. For the primary analysis, the 'intervention period' was defined as the post-implementation and follow-up periods. The 'control period' is defined as the 12-month retrospective and prospective baseline control periods. Table 1 below illustrates the SHaPED trial design.

Table 1. Sydney Health Partners Emergency Department (SHaPED) trial design																					
Steps (clusters)	2017						2018												2019		
	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	
ED 1														x							
ED 2															x						
ED 3																x					
ED 4																	x				

	12-month retrospective baseline period
	Prospective baseline control period
x	4-week implementation period
	Post-implementation period
	3-month follow-up period

1.2 Objectives

The overall aim of the SHaPED trial was to evaluate a multi-faceted strategy to implement the ACI model of care for acute low back pain in people who present with low back pain in the ED. The outcomes of the trial reflect the key messages in the model of care:

- (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 lumbar imaging in the ED.

Secondary objectives

The secondary objectives 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 ED and the proportion of patients admitted to hospital from ED.
- To determine if patient outcomes are not worse with implementation of the ACI model of care in people who present with low back pain in the ED.
- To determine the cost-effectiveness of the ACI model of care compared with usual ED 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 ED.

1.3 Outcomes

Health service use outcomes were collected for all eligible low back pain presentations between August 2017 and February 2019 directly from participating hospital's electronic medical records. Eligible low back pain presentations included adults >18 years with a discharge diagnosis related to low back pain (with or without radicular symptoms) in the ED identified using selected codes from the Systematised Nomenclature of Medicine Clinical Terms - Australian version, Emergency Department Reference Set (SNOMED CT-AU EDRS) (Table 2). Presentations with a SNOMED CT-AU EDRS diagnosis code related to serious spinal pathologies, such as vertebral fracture, infection or malignancy, were excluded. Re-presentations within 48 hours to the same ED during the study period were also excluded.

Table 2. SNOMED CT-AU codes related to low back pain presentations	
<i>Low back pain with non-specific cause</i>	Codes
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 radicular 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

Patient-reported outcomes were collected using automated text messaging at one week (primary time point) and again at two and four weeks after index ED presentation. Between July 2018 and December 2018, all eligible patients presenting to the participating EDs were invited to complete a brief self-reported online survey at ED discharge. Reminder messages were sent to non-responders, and those who did not respond to the reminder message were contacted via telephone. We invited a total of 807 eligible patients and 416 (52%) agreed to participate and completed week-1 survey. Of those, 360 (87%) completed week-2 and 351 (84%) week-4 surveys.

1.3.1 Primary outcome

- Proportion of patients receiving any lumbar imaging (yes/no). Any lumbar imaging will include the following radiology procedures:
 - XR Chest and Spine 2 Regions

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- XR Chest and Spine 3 Regions
- XR Coccyx
- XR Lumbar Sacrum
- XR Pelvis
- XR Pelvis and Hip Left
- XR Pelvis and Hip Right
- XR Pelvis Hip and Femur Left
- XR Pelvis Hip and Femur Right
- XR Sacroiliac Joints
- XR Sacrum
- XR Skeletal Survey
- XR Spine 4 Region
- XR Spine Lumbar
- XR Spine Lumbosacral
- XR Spine Scoliosis Study
- XR Spine Thoracic Lumbar
- CT Brain and Spine Thoracic and Lumbar
- CT Pelvis
- CT Pelvis and Hip Left
- CT Pelvis and Hip Right
- CT Pelvis and Hips Bilateral
- CT Pelvis and Spine
- CT Sacrum
- CT Spine 2 regions
- CT Spine Lumbar
- CT Spine Lumbar and Pelvis
- CT Spine Cervical Thoracic Lumbar
- CT Spine Thoracic Lumbar
- CT Spine Whole
- MRI Pelvis
- MRI Sacrum
- MRI Spinal Cord Compression
- MRI Spine 2 Regions (User defines)
- MRI Spine Lumbar
- MRI Spine Whole

1.3.2 Secondary outcomes

- Proportion of patients receiving advanced imaging (CT/MRI=yes, X-ray/no imaging=no)

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- Proportion of patients receiving any strong opioid medication. Any strong opioid will include the following medications:
 - Buprenorphine
 - Fentanyl
 - Hydromorphone
 - Morphine
 - Oxycodone
 - Pethidine
 - Tapentadol
- Proportion of patients receiving any opioid medication. Any opioid will include the following medications:
 - Alfentanil
 - Buprenorphine
 - Codeine phosphate
 - Codeine-aspirin
 - Codeine-ibuprofen
 - Codeine-paracetamol
 - Codeine-paracetamol-doxylamine
 - Dextropropoxyphene
 - Dextropropoxyphene-paracetamol
 - Dihydrocodeine
 - Fentanyl
 - Hydromorphone
 - Morphine
 - Nicomorphine
 - Oxycodone
 - Oxycodone-naloxone
 - Pethidine
 - Remifentanil
 - Sufentanil
 - Tapentadol
 - Tramadol
 - Tramadol-paracetamol
- Proportion of patients receiving other analgesic medications (topical, oral, injection). Other medications were classified according to the Anatomical Therapeutic Chemical (ATC) classification system (table 3). The ATC classification is recommended by the WHO and is widely used internationally in medication use studies:
 - Paracetamol (N02BE01)
 - Non-steroidal anti-inflammatory drugs (M01A, M02AA):
 - Aspirin

- Celecoxib
- Diclofenac
- Diclofenac topical
- Etoricoxib
- Ibuprofen
- Ibuprofen topical
- Ibuprofen-paracetamol
- Indomethacin
- Ketoprofen
- Ketorolac
- Mefenamic acid
- Naproxen
- Parecoxib
- Piroxicam
- Piroxicam topical
- Sulindac
- Muscle relaxants (M03):
 - Baclofen
 - Dantrolene
 - Orphenadrine
 - Orphenadrine-paracetamol
 - Vecuronium
- Corticosteroids (H02):
 - Cortisone
 - Dexamethasone
 - Hydrocortisone
 - Methylprednisolone
 - Prednisolone
 - Prednisone
 - Triamcinolone
- Benzodiazepine derivatives (N05BA):
 - Alprazolam
 - Bromazepam
 - Clobazam
 - Clonazepam
 - Diazepam
 - Flunitrazepam
 - Lorazepam
 - Midazolam
 - Nitrazepam
 - Oxazepam
 - Temazepam
 - Zolpidem

- Zopiclone
- Antiepileptics (N03A):
 - Carbamazepine
 - Ethosuximide
 - Gabapentin
 - Lacosamide
 - Lamotrigine
 - Levetiracetam
 - Oxcarbazepine
 - Phenobarbital
 - Phenytoin
 - Pregabalin
 - Sodium valproate or valproic acid
 - Tiagabine
 - Topiramate
 - Vigabatrin
 - Zonisamide
- Antidepressants (N06A):
 - Amitriptyline
 - Bupropion
 - Clomipramine
 - Dosulepin
 - Doxepin
 - Duloxetine
 - Duloxetine
 - Fluoxetine
 - Imipramine
 - Mianserin
 - Mirtazapine
 - Moclobemide
 - Nortriptyline
 - Paroxetine
 - Reboxetine
 - Sertraline
 - Venlafaxine
 - Vortioxetine
- Proportion of patients admitted from ED to:
 - Hospital ward
 - Emergency Medical Unit (EMU) or Short Stay Unit (EDSSU)
- Time in ED (triage time to discharge or admission time)
- Proportion of patients referred for a consultation in the ED:
 - Pain management

- Rheumatology
 - Surgery
- Proportion of patients representing to the same ED within 48 hours
- Total health system costs (including intervention costs and health service delivery costs)
- Pain intensity (Numeric Rating Scale, range 0–10)
- Physical function (PROMIS Short Form—Physical Function 4a)
- Quality of life (PROMIS Scale—Global Health item 1)
- Satisfaction (EDPEC survey item 31)

1.3.3 Sample size

Based on the effect size of 10% absolute reduction (from 30% to 20%) in lumbar imaging referrals (primary outcome), combined with an alpha of 0.05 and assuming an intraclass correlation coefficient of 0.1, a total number of 1,920 low back pain presentations (on average 480 per cluster) to EDs is needed for this stepped-wedge cluster trial with 80% power. For patient-reported outcomes, we have run a power calculation for pain intensity (range 0–10). We have assumed a non-inferiority margin of 1-point (i.e. we accept a mean difference in pain scores of up to 1 unit). We also assumed a standard deviation of 2.5 and an ICC of 0.05 based on previous low back pain trials. The sample size required for 80% power is 30 subjects per ED, per period/month. Given that the 'core trial' contains five periods, this means a total of 150 subjects per ED or 600 overall.

2 Statistical analysis

2.1 Analysis principles

- Data analysis will be performed according to an intention-to-treat analysis, that is, clusters will be analysed according to their randomised cross-over time irrespective of whether cross-over was achieved at the desired time.
- All tests are to be two-sided with a nominal level of α set at 5%.
- Subgroup analyses (see Section 2.5.3) will be carried out irrespective of whether there is a significant treatment effect on the primary outcome. These analyses will also be unadjusted.
- No formal adjustments for multiplicity will be applied. However, the outcomes will be categorised by the degree of importance (primary vs secondary), and only a limited number of subgroup analyses are pre-specified. The results will be interpreted in this context.
- Analyses will be conducted primarily using SAS software (version 9.3 or above).

2.2 Data set analysed

The implementation intervention periods occurred on the following dates:

1. Concord Repatriation General Hospital (ED 1): 30/07/18 to 24/08/18
2. Royal Prince Alfred Hospital (ED 2): 27/08/18 to 21/09/18
3. Canterbury Hospital (ED 3): 24/09/18 to 19/10/18
4. Dubbo Base Hospital (ED 4): 22/10/18 to 16/11/18

Due to the cluster design, the group allocation (control or intervention) for a patient will be determined by the site and by the period during which they participated. All patients will be regardless of the interventions actually received, thus adhering to the ITT analysis principle. The different analyses periods are defined in Table 3. A patient will be counted in a period if the day of his/her ED presentation falls into that period.

Table 3. Definition of analysis period for each emergency department (ED)						
Periods	Dates	ED 1	ED 2	ED 3	ED 4	Periods
1	Jul 2017	xxx	xxx	xxx	xxx	12-month retrospective baseline
2	Aug 2017	xxx	xxx	xxx	xxx	
3	Sep 2017	xxx	xxx	xxx	xxx	
4	Oct 2017	xxx	xxx	xxx	xxx	
5	Nov 2017	xxx	xxx	xxx	xxx	
6	Dec 2017	xxx	xxx	xxx	xxx	
7	Jan 2018	xxx	xxx	xxx	xxx	
8	Feb 2018	xxx	xxx	xxx	xxx	
9	Mar 2018	xxx	xxx	xxx	xxx	
10	Apr 2018	xxx	xxx	xxx	xxx	
11	May 2018	xxx	xxx	xxx	xxx	
12	Jun 2018	xxx	xxx	xxx	xxx	
13	01/07/18 to 29/07/18	xxx	xxx	xxx	xxx	Core stepped-wedge trial
14	30/07/18 to 25/08/18	xxx	xxx	xxx	xxx	
15	26/08/18 to 22/09/18	xxx	xxx	xxx	xxx	
16	23/09/18 to 20/10/18	xxx	xxx	xxx	xxx	
17	21/10/18 to 16/11/18	xxx	xxx	xxx	xxx	
18	17/11/18 to 16/12/18	xxx	xxx	xxx	xxx	
19	17/12/18 to 16/01/19	xxx	xxx	xxx	xxx	3-month follow-up
20	17/01/19 to 16/02/19	xxx	xxx	xxx	xxx	

	Pre-implementation (control)
	During implementation (not analysed)
	Post-implementation (intervention)

2.3 Trial profile

The flow of patients through the study will be displayed in a CONSORT diagram, shown in Appendix 1 (Figure 1).

2.4 Baseline comparisons

Description of the baseline characteristics will be presented for each of the four EDs. This will be done by aggregating data collected over the 12-month retrospective baseline period. Discrete variables will be summarised by frequencies and percentages. Percentages will be calculated according to the number of clusters with available data. Continuous variables will be summarised by using mean and standard deviation (SD), and median and interquartile range (IQR, Q1-Q3).

In addition, we will investigate temporal trends in health service use outcomes across the 12-month retrospective baseline control period for each ED. This will be done by summarising each primary and secondary outcome for each month within each ED and displaying the estimates (proportion or mean) together with their 95% confidence intervals on a graph. Should a visual inspection of the longitudinal plots suggest an underlying temporal trend, we will only include data for the previous three months (periods 11 to 13) as the baseline period to be used for the main model. The visual assessment of temporal trends over the baseline period will be completed by fitting a regression (logistic or linear) to assess the significance of time (month) slopes. The linear model will include a fixed term for time (months) as a continuous variable and a random effect of ED to account for clustering.

2.5 Patients and clinicians' characteristics and baseline comparisons

Description of the baseline characteristics will be presented by treatment period (i.e. pre-intervention or post-intervention) as outlined in Appendix 1 (Table 2). Discrete variables will be summarised by frequencies and percentages. Percentages will be calculated according to the number of patients in whom data are available. Continuous variables will be summarised by using mean and SD, and median and IQR (Q1-Q3). No adjustment for clustering will be applied when summarising baseline characteristics.

Baseline measures for all eligible low back pain presentations will be tabulated with at least the following variables outlined below:

- Age
- Gender
- Socioeconomic status
- ED Diagnosis
- Day of ED presentation

- ED presentation hour
- ED mode of arrival
- ED triage category
- Length of ED stay
- Proportion of presentations admitted to a hospital ward
- Length of stay in hospital ward

Characteristics of clinician participants will be tabulated with at least the following variables outlined below:

- Gender
- Age
- Main profession
- Country of professional training
- Clinical experience in main profession (years)
- Clinical experience in emergency medicine (years)
- Average number of low back pain patients seen per week

2.6 Analysis of the primary outcome

2.6.1 Main analysis

The primary endpoint is a binary variable indicating whether a patient received any lumbar imaging (yes/no). The primary analysis will be conducted using a logistic regression with a random effect for cluster (hospital ED), a random effect for clinician nested within cluster, a fixed effect indicating the group assignment of each cluster at each step and a fixed effect of time (each step). The model will be specified as follows:

$$\text{logit} [P(Y_{ijk} = 1)] = \alpha + \beta \text{Group}_{ij} + \delta_j + u_i + v_{ijk} + e_{ijk} \quad (1)$$

where:

- Y_{ijk} denotes the outcome of subject k ($k=1, \dots, m_{ij}$) in period j ($j=1, 2$) within ED i ($i=1, \dots, N$) where m_{ij} indicates the number of subjects in period j within ED i
- α is the intercept
- Group_{ij} is a dummy variable indicating group allocation during period j for cluster i with $\text{Group}_{ij} = 1$ post-intervention, and $\text{Group}_{ij} = 0$ pre-intervention
- β is the parameter of interest estimating the treatment effect and where e^β is the odds ratio (OR)
- δ_j is a fixed period effect
- u_i is a random cluster effect with $u_i \sim N(0, \sigma_u^2)$

v_{ijk} is a random clinician effect which is nested within cluster with $v_{ijk} \sim N(0, \sigma_v^2)$
 e_{ijk} are individual-level errors following a binomial distribution

The effect of the intervention will be presented as the OR of receiving any lumbar imaging and its 95% confidence interval (CI). In case of convergence issues caused by the inclusion of two random effects, we will remove the random clinician effect and keep the random cluster effect.

2.6.2 Treatment of missing data

Given the ED dataset only records lumbar images that occurred, we will assume that a missing data point indicates that the corresponding procedure did not occur. The primary outcome (i.e. lumbar imaging) will therefore not contain any missing data. However, manual data extraction from patient's medical records were conducted for some secondary outcomes (i.e. opioid medication), since some EDs did not have electronic medication system (eMEDS) available. No imputation of secondary or patient reported outcomes will be performed.

2.6.3 Subgroup analyses

The following subgroup analyses will be carried out for the primary outcome only:

- Age (<65 *versus* ≥65 years)
- Socioeconomic status (measured by patient's postcode - SEIFA)
- Australasian Triage Scale (ATS) category (ATS 1 to 5)
- SNOMED diagnosis codes (non-specific low back pain *versus* radicular low back pain)
- ED mode of arrival

The analysis for each subgroup analysis will be performed by adding the subgroup variable as well as its interaction with the intervention as fixed effects to the logistic regression model used for the primary analysis (see Section 2.6.1). Within each subgroup, summary measures will include raw counts and percentages within each treatment arm, as well as the OR for treatment effect with 95% CI. The results will be displayed on a forest plot including the P value for heterogeneity corresponding to the interaction term between the intervention and the subgroup variable.

2.7 Sensitivity analyses of the primary outcome

2.7.1 Adjusted analyses

The logistic regression model described in Section 2.6.1 will be re-run after adjustment for the following covariates: gender, age (continuous), ED diagnosis, day of ED presentation, ED mode of arrival and ATS category.

2.7.2 Analysis including the intervention period

A secondary exploratory analysis will be performed including the implementation period into the intervention group (see definition in Section 1.1). This analysis will be performed both unadjusted and adjusted; however, no subgroup analysis will be applied.

2.8 Analysis of secondary outcomes

2.8.1 Binary outcomes

All binary secondary outcomes will be analysed using the same strategy as the one applied to the primary outcome, that is using both an unadjusted and adjusted logistic regression model and both by excluding and including the intervention period, thus giving four models. Subgroup analyses will not be conducted on secondary outcomes.

2.8.2 Continuous outcomes

Continuous outcomes such as time in ED, will be analysed using the same strategy as the binary outcomes; however, logistic regression will be replaced with linear regression (normal distribution and an identity link function) and the effect of the intervention will be estimated as the modelled mean difference and its 95% CI.

2.8.3 Patient reported outcomes

All patient reported outcomes will be treated as continuous outcomes and therefore analysed following the strategy described in Section 2.8.2.

3 References

1. Machado GC, Richards B, Needs C for the SHaPED trial Investigators, et al Implementation of an evidence-based model of care for low back pain in emergency departments: protocol for the Sydney Health Partners Emergency Department (SHaPED) trial BMJ Open 2018;8:e019052.
2. Hussey MA, Hughes JP. Design and analysis of stepped wedge cluster randomized trials. Contemp Clin Trials 2007;28:182–91.

Appendix 1 Proposed main tables and figures

[Purple notes in square brackets like this one act as a guide for the statistician/programmer, they will not appear in the final output]

Figure 1. Flowchart showing number of eligible presentations per time period and per ED

Month	ED 1	ED 2	ED 3	ED 4
1	xxx	xxx	xxx	xxx
2	xxx	xxx	xxx	xxx
3	xxx	xxx	xxx	xxx
4	xxx	xxx	xxx	xxx
5	xxx	xxx	xxx	xxx
6	xxx	xxx	xxx	xxx
7	xxx	xxx	xxx	xxx
8	xxx	xxx	xxx	xxx
9	xxx	xxx	xxx	xxx
10	xxx	xxx	xxx	xxx
11	xxx	xxx	xxx	xxx
12	xxx	xxx	xxx	xxx
13	xxx	xxx	xxx	xxx
14	xxx	xxx	xxx	xxx
15	xxx	xxx	xxx	xxx
16	xxx	xxx	xxx	xxx
17	xxx	xxx	xxx	xxx
18	xxx	xxx	xxx	xxx
19	xxx	xxx	xxx	xxx
20	xxx	xxx	xxx	xxx

Light grey: 12-month retrospective + prospective baseline control periods

Middle grey: 4-week implementation period

Dark grey: post-implementation + follow-up periods

ED, emergency department

Table 1. Baseline characteristics per ED aggregated over periods 1-12

	ED 1	ED 2	ED 3	ED 4
Age	n=xxx	n=xxx	n=xxx	n=xxx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, Q2, Q3	xx, xx, xx	xx, xx, xx	xx, xx, xx	xx, xx, xx
Min, max	xx, xx	xx, xx	xx, xx	xx, xx
<30 (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
30-<49	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
50-<69	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
70+	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Gender	n=xxx	n=xxx	n=xxx	n=xxx
Female (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Male (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Socioeconomic status	n=xxx	n=xxx	n=xxx	n=xxx
SEIFA Decile 1 (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
SEIFA Decile 2 (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Etc.	etc.	etc.	etc.	etc.
ED Diagnosis <i>[see Table 2]</i>	n=xxx	n=xxx	n=xxx	n=xxx
Non-specific low back pain (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Low back-pain with radicular symptoms (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day of ED presentation	n=xxx	n=xxx	n=xxx	n=xxx
Monday	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Tuesday	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Etc.	etc.	etc.	etc.	etc.
ED presentation hour	n=xxx	n=xxx	n=xxx	n=xxx
Working hours	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
After hours	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
ED mode of arrival	n=xxx	n=xxx	n=xxx	n=xxx
Private car (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
State ambulance vehicle (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
ATS category	n=xxx	n=xxx	n=xxx	n=xxx
ATS 1 (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
ATS 2 (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
ATS 3 (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
ATS 4 (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
ATS 5 (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Length of ED stay (hours)	n=xxx	n=xxx	n=xxx	n=xxx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, Q2, Q3	xx, xx, xx	xx, xx, xx	xx, xx, xx	xx, xx, xx
Min, max	xx, xx	xx, xx	xx, xx	xx, xx

ED, emergency department. ATS, Australasian Triage Scale

Table 2. Baseline characteristics per group (periods 11-20)

	Pre-intervention	Post-intervention	P-value ¹
Age	n=xxx	n=xxx	0.xxx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	
Q1, Q2, Q3	xx, xx, xx	xx, xx, xx	
Min, max	xx, xx	xx, xx	
<30 (%)	xx (xx.x%)	xx (xx.x%)	
30-<49	xx (xx.x%)	xx (xx.x%)	
50-<69	xx (xx.x%)	xx (xx.x%)	
70+	xx (xx.x%)	xx (xx.x%)	
Gender	n=xxx	n=xxx	0.xxx
Female (%)	xx (xx.x%)	xx (xx.x%)	
Male (%)	xx (xx.x%)	xx (xx.x%)	
Socioeconomic status	n=xxx	n=xxx	0.xxx
SEIFA Decile 1 (%)	xx (xx.x%)	xx (xx.x%)	
SEIFA Decile 2 (%)	xx (xx.x%)	xx (xx.x%)	
Etc.	etc.	etc.	
ED Diagnosis <i>[see Table 2]</i>	n=xxx	n=xxx	0.xxx
Non-specific low back pain (%)	xx (xx.x%)	xx (xx.x%)	
Low back-pain with radicular symptoms (%)	xx (xx.x%)	xx (xx.x%)	
Day of ED presentation	n=xxx	n=xxx	0.xxx
Monday	xx (xx.x%)	xx (xx.x%)	
Tuesday	xx (xx.x%)	xx (xx.x%)	
Etc.	etc.	etc.	
ED presentation hour	n=xxx	n=xxx	0.xxx
Working hours	xx (xx.x%)	xx (xx.x%)	
After hours	xx (xx.x%)	xx (xx.x%)	
ED mode of arrival	n=xxx	n=xxx	0.xxx
Private car (%)	xx (xx.x%)	xx (xx.x%)	
State ambulance vehicle (%)	xx (xx.x%)	xx (xx.x%)	
Other (%)	xx (xx.x%)	xx (xx.x%)	
ATS category	n=xxx	n=xxx	0.xxx
ATS 1 (%)	xx (xx.x%)	xx (xx.x%)	
ATS 2 (%)	xx (xx.x%)	xx (xx.x%)	
ATS 3 (%)	xx (xx.x%)	xx (xx.x%)	
ATS 4 (%)	xx (xx.x%)	xx (xx.x%)	
ATS 5 (%)	xx (xx.x%)	xx (xx.x%)	
Length of ED stay (hours)	n=xxx	n=xxx	0.xxx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	
Q1, Q2, Q3	xx, xx, xx	xx, xx, xx	
Min, max	xx, xx	xx, xx	

¹ P-value from linear model or multinomial logistic model adjusted for clustering. ED, emergency department. ATS, Australasian Triage Scale *[repeat for periods 1-20]*

Figure 2. Proportion of patients with primary outcome

y-axis: % receiving lumbar imaging

x-axis: period (1 to 20)

4 curves: one per ED

For example:

Source: Wu Y, Li S, Patel A, et al. Effect of a Quality of Care Improvement Initiative in Patients With Acute Coronary Syndrome in Resource-Constrained Hospitals in China: A Randomized Clinical Trial. JAMA Cardiol. doi:10.1001/jamacardio.2019.0897

[Notes:

Change symbols and/or colours/grading (e.g. light to dark) to distinguish the intervention periods:

- 1) Pre-intervention (control) e.g. light colour*
- 2) During intervention e.g. medium colour or hashed*
- 3) Post intervention e.g. dark colour*

Etc... do similar figures for all secondary outcomes + PROMs]

Table 3. Main results

		Numerator/denominator (%) or N, mean (SD)		Primary analysis		Adjusted analysis	
Outcome	ICC	Post- intervention (n=xxx)	Pre- intervention (n=xxx)	Odds ratio or mean difference (95% CI)	p- value	OR or mean difference (95% CI)	p- value
Any lumbar imaging ¹	0.xx	xxx/xxxx (%)	xxx/xxxx (%)	xx.xx (xx.x; xx.x)	0.xxx	xx.xx (xx.x; xx.x)	0.xxx
Advanced imaging	0.xx	xxx/xxxx (%)	xxx/xxxx (%)	xx.xx (xx.x; xx.x)	0.xxx	xx.xx (xx.x; xx.x)	0.xxx
Strong opioid medication	0.xx	xxx/xxxx (%)	xxx/xxxx (%)	xx.xx (xx.x; xx.x)	0.xxx	xx.xx (xx.x; xx.x)	0.xxx
Any opioid medication	0.xx	xxx/xxxx (%)	xxx/xxxx (%)	xx.xx (xx.x; xx.x)	0.xxx	xx.xx (xx.x; xx.x)	0.xxx
Other analgesic medication	0.xx	xxx/xxxx (%)	xxx/xxxx (%)	xx.xx (xx.x; xx.x)	0.xxx	xx.xx (xx.x; xx.x)	0.xxx
Admission as an inpatient	0.xx	xxx/xxxx (%)	xxx/xxxx (%)	xx.xx (xx.x; xx.x)	0.xxx	xx.xx (xx.x; xx.x)	0.xxx
Admission to EMU or EDSSU	0.xx	xxx/xxxx (%)	xxx/xxxx (%)	xx.xx (xx.x; xx.x)	0.xxx	xx.xx (xx.x; xx.x)	0.xxx
Consultation in ED	0.xx	xxx/xxxx (%)	xxx/xxxx (%)	xx.xx (xx.x; xx.x)	0.xxx	xx.xx (xx.x; xx.x)	0.xxx
Represented to ED ²	0.xx	xxx/xxxx (%)	xxx/xxxx (%)	xx.xx (xx.x; xx.x)	0.xxx	xx.xx (xx.x; xx.x)	0.xxx
Time in ED (hours)	0.xx	N, mean (SD)	N, mean (SD)	xx.xx (xx.x; xx.x)	0.xxx	xx.xx (xx.x; xx.x)	0.xxx
Time in hospital ward (days)	0.xx	N, mean (SD)	N, mean (SD)	xx.xx (xx.x; xx.x)	0.xxx	xx.xx (xx.x; xx.x)	0.xxx
Pain intensity	0.xx	N, mean (SD)	N, mean (SD)	xx.xx (xx.x; xx.x)	0.xxx	xx.xx (xx.x; xx.x)	0.xxx
Physical function	0.xx	N, mean (SD)	N, mean (SD)	xx.xx (xx.x; xx.x)	0.xxx	xx.xx (xx.x; xx.x)	0.xxx
Quality of life	0.xx	N, mean (SD)	N, mean (SD)	xx.xx (xx.x; xx.x)	0.xxx	xx.xx (xx.x; xx.x)	0.xxx
Satisfaction	0.xx	N, mean (SD)	N, mean (SD)	xx.xx (xx.x; xx.x)	0.xxx	xx.xx (xx.x; xx.x)	0.xxx

¹ Primary outcome; ² Representation within 48 hours to same facility; ED: Emergency Department; EMU: Emergency Medical Unit; EDSSU: ED Short Stay Unit

[Repeat after including intervention period performed including the implementation period into the intervention group – to be included in Supplement]

Figure 3. Subgroup analysis (forest plot)