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The development and testing of Australian prehospital care quality indicators: study protocol

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3 1 **The development and testing of Australian prehospital care quality indicators:**
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5 2 **study protocol**
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3 **27 Abstract**
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5 **28 Introduction** Historically, ambulance services were established to provide rapid transport
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7 of patients to hospital. Contemporary prehospital care involves provision of sophisticated
8
9 'mobile healthcare' to patients across the lifespan presenting with a range of injuries or
10
11 illnesses of varying acuity. Because of its young age, the paramedicine profession has until
12
13 recently experienced a lack of research capacity which has led to paucity of a discipline-
14
15 specific, scientific evidence-base. Therefore, the performance and quality of ambulance
16
17 services has traditionally been measured using simple, evidence-poor indicators forming a
18
19 deficient reflection of the true quality of care and providing little direction for quality
20
21 improvement efforts. This paper reports the study protocol for the development and testing
22
23 of quality indicators for the Australian prehospital care setting.
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25

26 **38 Methods and analysis** This project has three phases. In the first phase, preliminary work
27
28 in the form of a scoping review was conducted which provided an initial list of quality
29
30 indicators. In the subsequent phase, these quality indicators will be developed by
31
32 aggregating them and by performing related rapid reviews. The summarised evidence will be
33
34 used to support an expert consensus process aimed at optimising the clarity and evaluating
35
36 the validity of proposed quality indicators. Finally, in the third phase those quality indicators
37
38 deemed valid will be tested for acceptability, feasibility and reliability using mixed research
39
40 methods. Evidence-based indicators can facilitate meaningful measurement of the quality of
41
42 care provided. This forms the first step to identify unwarranted variation and direction for
43
44 improvement work. This project will develop and test of quality indicators for the Australian
45
46 prehospital care setting.
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49 **49 Ethics and dissemination** This project has been approved by the University of Adelaide
50
51 Human Research Ethics Committee. Findings will be communicated using a comprehensive
52
53 dissemination strategy.
54
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57

58 **53 Keywords:** Emergency medical services; healthcare quality assessment; prehospital care;
59
60 quality indicators

55 **Strengths and limitations of the study**

- 56 • A preliminary list of prehospital care quality indicators was established using
57 systematic scoping review methods.
- 58 • A rapid review and evidence summary approach will be used to inform a modified
59 RAND/UCLA Appropriateness Method.
- 60 • Australian prehospital care experts will evaluate the validity proposed quality
61 indicators.
- 62 • Candidate quality indicators will be tested for acceptability, feasibility and reliability.
- 63 • The evidence supporting many of the quality indicators is expected to be weak.

65 **Introduction**

66 The quality and safety of health care is on the agenda in any modern health care
67 organisation, including ambulance services. Strategies to continuously improve the quality of
68 service should primarily be based on information about the level of quality produced by the
69 health care organisation.¹ Indicators of desirable structures, processes and outcomes allow
70 the quality of care and services to be measured. This assessment can be facilitated by
71 systematically developing quality indicators that describe the performance that should occur,
72 and then measuring and monitoring whether a service's operations and patient care are
73 consistent with these indicators.²

74
75 For the purpose of this project, the context of prehospital care is limited to the health care
76 services provided by ambulance services. Historically, the function of ambulance services
77 was primarily one of transport; paramedics would provide only stabilising care to patients
78 with high-acuity presentations before transporting to an emergency department. However,
79 ambulance service models of care have evolved considerably. Contemporary prehospital
80 care involves provision of often complex 'mobile healthcare' to patients across the lifespan
81 presenting with injury or illness across the spectrum of acuity. An increasingly aged

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3 82 population and an increased incidence of chronic disease have led to a substantial increase
4
5 83 in non-emergency, or 'low acuity' presentations for whom the traditional emergency
6
7 84 department disposition may not be most appropriate.^{3,4} Ambulance services now play a key
8
9 85 role in integrated health care frameworks, with transport to an emergency department being
10
11 86 one of many disposition outcomes following care from paramedics alongside referral into
12
13 87 primary and community-based healthcare. On the other verge of the patient spectrum,
14
15 88 ambulance services continue to provide critical care and transport for those suffering life-
16
17 89 threatening illness or injury.^{4,5} Therefore, this project adopts the definition of prehospital
18
19 90 care previously developed which encompasses this range of patients seen by ambulance
20
21 91 services: Prehospital care is the care that ambulance services provide for patients with real
22
23 92 or perceived emergency or urgent care needs from the time point of emergency telephone
24
25 93 access until care is concluded or until arrival and transfer of care to a hospital or other health
26
27 94 care facility.^{6,7}
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33 96 An indicator is an explicitly defined and measurable element of health care services.⁸ A
34
35 97 *quality* indicator (QI) is an indicator for which there is evidence or consensus that it can be
36
37 98 used to assess the quality, and hence measure changes in quality over time.⁹ Essential for
38
39 99 the development of QIs is a definition of quality. Proceeding to develop indicators for the
40
41 100 measurement of quality without understanding and consensus on what the concept of quality
42
43 101 entails is unlikely to result in meaningful assessment of quality.¹⁰ Indicators can be
44
45 102 developed using non-systematic and systematic methods.⁸ Non-systematic methods are
46
47 103 relatively quick; however, they tend not to incorporate all available evidence during their
48
49 104 development. Systematically developed QIs are ideally based on high-level scientific
50
51 105 evidence or they are derived from evidence-informed guidelines.^{8,11} In areas or disciplines
52
53 106 with limited scientific evidence, such as paramedicine, it may be necessary to combine the
54
55 107 available evidence with expert consensus.¹²
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3 109 As far as possible, QIs should possess the fundamental characteristics clarity, validity,
4
5 110 acceptability, feasibility and reliability.⁸ A good quality indicator has clear meaning which
6
7 111 enables what is being assessed to be precisely attributable to that indicator.^{8,13} In other
8
9 112 words, a clear QI is one which is free of ambiguity, inaccuracy or imprecision. Validity is
10
11 113 arguably the most important property of a quality indicator. In science, validity refers to the
12
13 114 degree to which evidence and theory support the interpretation of the scores entailed by
14
15 115 proposed uses of the instrument.¹⁴ Thus, in the quality measurement context, validity refers
16
17 116 to the degree to which evidence and theory support the expected interpretation of measured
18
19 117 elements of practice performance related to the quality indicators. In more simple terms,
20
21 118 validity refers to the extent to which the given statement represents high-quality care and
22
23 119 would therefore be an endorsed indicator of quality. When assessing the validity of QIs,
24
25 120 careful consideration of the intended context is important.^{15–17} Whilst there are considerable
26
27 121 benefits in using work from other locations, QIs cannot simply be transferred directly
28
29 122 between different settings without an intermediate process to allow for variation in
30
31 123 professional culture and clinical practice.¹⁸ Rating the validity of QIs, therefore, entails as
32
33 124 much assessment of whether they represent high-quality care as it does of how contextually
34
35 125 applicable they are. Acceptability refers to the quality of being satisfactory or agreeable in
36
37 126 terms of professional standards and values. If the aim of measurement is to provide direction
38
39 127 for quality improvement, then the quality indicators need to be interpretable and meaningful
40
41 128 to the audience, i.e. clinicians and managers. However, the benefit of assessing quality
42
43 129 indicators for acceptability extends beyond their development and testing. Measurement
44
45 130 provides information to direct improvement efforts and is thus central to quality
46
47 131 improvement.^{8,19–23} Involvement of clinicians and managers in the development of indicators
48
49 132 is likely to improve their uptake and contributes to sustainability in quality improvement.²⁴
50
51 133 Measurement of the quality of care may also serve as or contribute to performance appraisal
52
53 134 systems. In this instance, user acceptance of such systems may be a critical criterion to
54
55 135 ensure the successful implementation.²⁴ Feasibility and reliability relate to the measurability
56
57 136 of a QI. Testing QIs for these attributes is critical and ensures that implementation and
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3 137 sustained measurement is successful. Feasibility relates to the availability or attainability of
4
5 138 accurate data and whether this data is realistically collectable.¹³ Feasibility thus
6
7 139 encompasses technical and non-technical aspects of data collection and analysis. A feasible
8
9 140 QI also facilitates measurement which is applicable to quality improvement, sensitive to
10
11 141 improvement over time and useful for decision-making.²⁵ Reliability, in this instance, is
12
13 142 closely related to precision and refers to the consistency of scores across replications of a
14
15 143 testing procedure.²⁶ Testing reliability intends to assess whether the QIs are non-
16
17 144 erroneously reproducible and for any errors to be identified.¹³ A reliable QI facilitates
18
19 145 measurement which has low inter- or intra-rater variation and suitable for statistical
20
21 146 analyses.²⁵
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26 148 Similarly to many other countries, Australia has measures in its national performance
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28 149 indicator framework for ambulance services that track the quality of care delivered to its
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30 150 residents across the various jurisdictions.²⁷ However, the scope of current measurement is
31
32 151 limited. With increasing research activity and the recent commencement of national
33
34 152 registration of paramedics in Australia, a timely need to expand the nationally utilised
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36 153 indicators of prehospital care quality exists. Both, an expanding evidence-base and
37
38 154 regulations which primarily ensure patient and community safety, ultimately aim to protect
39
40 155 and continuously improve the quality of prehospital care. Meaningful measurement based on
41
42 156 systematically developed QIs not only produces data to ensure the maintenance of quality, it
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44 157 also provides information on whether or not change is effective in achieving improvement.
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49 159 This paper reports the context and methods for a project on development and testing of
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51 160 prehospital care QIs. The primary aim of the project is to develop and test QIs for the
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53 161 Australian prehospital care setting. To achieve this, the project addresses the following
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55 162 objectives:
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3 163 1. To map the attributes or dimensions of 'quality' in the context of prehospital care and
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5 164 explore indicators that have been developed internationally to measure prehospital
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7 165 care quality.
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9 166 2. To develop prehospital care QIs for the Australian setting and to evaluate their
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11 167 validity.
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13 168 3. To test selected candidate prehospital care QIs for acceptability, feasibility and
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15 169 reliability.
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172 **Methods and analysis**

173 This project consists of three phases (figure 1): An initial scoping review addressing
174 objective 1; Evidence-informed development of prehospital care QIs and an evaluation of
175 their validity using an expert consensus process (modified RAND/UCLA Appropriateness
176 Method) to address objective 2; And finally a mixed methods approach (explanatory
177 sequential design) to test the QIs as detailed in objective 3.

178
179 <insert Figure 1 here>

180 **Figure 1:** Flow diagram detailing the three phases of the project (QI: quality indicator)

181 182 **Phase 1: Scoping Review**

183 This phase has been completed and involved preparatory work in the form of a scoping
184 review.²⁸ The purpose of the review was to map the attributes of 'quality' in the context of
185 prehospital care and to chart existing international prehospital care QIs. The review
186 employed the Joanna Briggs Institute (JBI) methodology for conducting scoping reviews.²⁹
187 The objectives, inclusion and exclusion criteria, and methods were specified in advance and
188 documented in a protocol.³⁰

189

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3 190 The review's systematic search confirmed paucity in literature that defines prehospital care
4
5 191 quality or examines which dimensions of generic health care quality definitions are important
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7 192 in prehospital care. However, synthesis of included articles suggested that timely access to
8
9 193 appropriate, safe and effective care which is responsive to a patient's needs and efficient
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11 194 and equitable to populations is reflective of high-quality prehospital care. There is growing
12
13 195 interest in developing QIs to evaluate prehospital care. In total, the review charted 526 QIs
14
15 196 addressing clinical and non-clinical aspects of ambulance services providing prehospital
16
17 197 care. The scoping review highlighted the need for validation of existing prehospital care QIs
18
19 198 and *de novo* QI development.
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24 200 ***Phase 2: Evidence-Informed Expert Consensus Process***

26 201 Phase 2 will comprise an evidence-informed expert consensus process to optimise the
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28 202 clarity of QIs and evaluate which are valid for the measurement of prehospital care quality in
29
30 203 Australia. Preparative work will involve aggregating the dimensions of prehospital care
31
32 204 quality and the prehospital care QIs charted in phase 1, as well as performing evidence
33
34 205 summaries to inform the expert panel. There are practical advantages, including the critical
35
36 206 appraisal of QIs, in aggregating multiple dimensions of quality into a smaller number of
37
38 207 principal dimensions.³¹ Campbell and colleagues (2000)³¹ argue that there are two
39
40 208 overarching dimensions of quality of care; access and effectiveness. Aggregation of
41
42 209 attributes of prehospital care quality into these two key dimensions has previously been
43
44 210 performed by Owen (2010).⁷
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49 212 The development of the evidence summaries will be guided by the JBI approach for rapid
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51 213 reviews and evidence summaries.³² Figure 2 provides a diagrammatic outline of the rapid
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53 214 review and evidence summary process.
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57 217

218 <insert Figure 2 here>

219 **Figure 2:** The evidence summary development process (adopted from Munn, Lockwood &
220 Moola, 2015³²)

221

222 Literature searches will be undertaken in the following databases: PubMed, CINAHL, the JBI
223 Database of Systematic Reviews and Implementation Reports and the Cochrane Library.

224 Table 1 details an example of search terms used. Generally, terms related to prehospital
225 care will be combined with QI specific terms. Development of the terms related to
226 prehospital care will be guided by search filters created by Olausson, et al.³³ Only English
227 language papers will be included for pragmatic reasons. Searches will not be limited by date.
228 The search will also include backtracking of references. In line with JBI's approach to
229 evidence summaries,^{32,34} the best available evidence will be incorporated in each summary.
230 This means that lower-level evidence will be included only when no systematic reviews are
231 located. The JBI levels of evidence are detailed in Table 2.

232

233 **Table 1** Example of search terms/filters used in PubMed

Concept	[1] Prehospital Care	[2] QI
Search terms	Ambulances[mh] OR Emergency Medical Technicians[mh] OR Air Ambulances[mh] OR paramedic*[tiab] OR ems[tiab] OR emt[tiab] OR prehospital[tiab] OR pre-hospital[tiab] OR first responder*[tiab] OR emergency medical technician*[tiab] OR emergency services[tiab] OR ambulance*[tiab]	(QI related search terms)
Search Filter	[1] AND [2], English only; Systematic Reviews and Meta-Analyses/Meta-Synthesis only (Change to '[1] AND [2], English only' if no or poor-quality Systematic Reviews and Meta-Analyses/Meta-Synthesis are identified)	

234

235 Following the search, titles and abstracts will be screened. If potentially eligible, the full text
236 of the papers will be read to determine whether the article should be included in the
237 applicable evidence summary. Full-text reading will involve an assessment of internal validity
238 utilising an abridged critical appraisal tool (Table 3). The rapid reviews and evidence
239 summaries that will be developed for this study will have several limitations. The more a

240 rapid review adheres to the methodological rigor of systematic reviews, the longer it will take
 241 to complete.^{32,35,36} Therefore, the less time is taken to complete a rapid review the less
 242 thorough it will be. The JBI approach to evidence summaries aims for a rapid development
 243 cycle.³² This method is considered suitable for the purpose of this project considering the
 244 limited resources and time available. These restrictions also mean that there will be only one
 245 researcher to screen, select, appraise and summarise the evidence and no peer review will
 246 be undertaken which may inevitable introduce increased risk of bias and error.

247

248 **Table 2** JBI Levels of Evidence for Effectiveness, Diagnosis and Meaningfulness³⁴ (JBI:
 249 Joanna Briggs Institute)

Level of Evidence	Study Designs		
	Effectiveness	Diagnosis	Meaningfulness
1	Experimental Designs including: a. Systematic review of Randomized Controlled Trials (RCTs) b. Systematic review of RCTs and other study designs c. RCTs d. Pseudo-RCTs	Studies of test accuracy among consecutive patients: a. Systematic review of studies of test accuracy among consecutive patients b. Study of test accuracy among consecutive patients	Qualitative or mixed-methods systematic review
2	Quasi-Experimental Designs including: a. Systematic review of quasi-experimental studies b. Systematic review of quasi-experimental and other lower study designs c. Quasi-experimental prospectively controlled study d. Pre-test post-test or historic/retrospective control group study	Studies of Test Accuracy among non-consecutive patients: a. Systematic review of studies of test accuracy among non-consecutive patients b. Study of test accuracy among non-consecutive patients	Qualitative or mixed-methods synthesis
3	Observational – Analytic Designs including: a. Systematic review of comparable cohort studies b. Systematic review of comparable cohort and other lower study designs c. Cohort study with control group d. Case-controlled study e. Observational study without a control group	Diagnostic Case control studies: a. Systematic review of diagnostic case control studies b. Diagnostic case-control study	Single qualitative study
4	Observational – Descriptive Designs including: a. Systematic review of descriptive studies b. Cross-sectional study c. Case series d. Case study	Diagnostic yield studies: a. Systematic review of diagnostic yield studies b. Individual diagnostic yield study	Systematic review of expert opinion
5	Expert Opinion and Bench Research including:	Expert Opinion and Bench Research:	Expert opinion

	a. Systematic review of expert opinion b. Expert consensus c. Bench research/single expert opinion	a. Systematic review of expert opinion b. Expert consensus c. Bench research/ single expert opinion	
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252 **Table 3** Abridged Quality Appraisal Criteria for JBI Evidence Summaries³² (JBI: Joanna
253 Briggs Institute)

Type of Study/Evidence	Quality Appraisal Criteria
Systematic Review	<ul style="list-style-type: none"> • Is the review question clearly and explicitly stated? • Was the search strategy appropriate? • Were the inclusion criteria appropriate for the review question? • Were the criteria for appraising studies appropriate? • Was critical appraisal by two or more independent reviewers? • Were there methods used to minimize error in data extraction? • Were the methods used to combine studies appropriate?
Quantitative Evidence	<ul style="list-style-type: none"> • Was there appropriate randomization? • Was allocation concealed? • Was blinding to allocation maintained? • Was incompleteness of data addressed? • Were outcomes reported accurately?
Qualitative Evidence	<ul style="list-style-type: none"> • Was the research design appropriate for the research? • Was the recruitment strategy appropriate for the research? • Were data collected in a way that addressed the research issue? • Has the relationship between researcher and participants been considered? • Was the data analysis sufficiently rigorous?

254

255

256 Several consensus processes have been used for the development of QIs. The
257 RAND/UCLA Appropriateness Method (RAM) is a formal panel judgement process which
258 systematically and quantitatively combines available scientific evidence with expert opinion
259 by asking panel members to rate, discuss and then re-rate the items of interest.³⁷ The
260 original RAM was developed in the mid-1980s by the RAND Corporation in collaboration
261 with the University of California Los Angeles (UCLA) as an instrument to facilitate the
262 measurement of medical and surgical intervention appropriateness.³⁸ RAM has been used
263 extensively as a method of QI development,^{8,13,39,40} including QIs to evaluate prehospital
264 care.⁷ In accordance with guidelines for conducting RAM,³⁸ an Australian prehospital care
265 expert panel of seven to 15 members will be recruited. Panellists must have perspectives
266 and areas of expertise in Australian paramedicine, prehospital care, ambulance service

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3 267 leadership and management, quality improvement, performance/quality measurement and
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5 268 patient perspective. There are eight State/Territory-based ambulance services, one
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7 269 paramedicine professional associations and eighteen universities offering paramedicine
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9 270 programs. These institutions will be contacted and asked to nominate experts for
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11 271 participation in the study. The nomination process will require the nominator making a
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13 272 project information and nomination form available to the nominee for perusal and signature.
14
15 273 Self-nomination will be allowed. The completed forms and attached curriculum vitae (CV) will
16
17 274 be emailed to the lead investigator. The research team will select expert panel members
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19 275 based on information provided in the forms and attached CV. This is a confidential process
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21 276 and only the researchers will peruse the completed forms and CV. The main selection
22
23 277 criteria to be considered will be acknowledged leadership in paramedicine, absence of
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25 278 conflicts of interest and geographic diversity (ideally at least one panellist from each
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27 279 State/Territory). For the purpose of this project, the RAM will be modified in the following
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30 280 ways:

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- 34
35 282 • **Evidence summaries instead of systematic reviews:** As described in the RAM
36
37 283 user's manual³⁸, the critical review of the literature summarising the best available
38
39 284 scientific evidence is a fundamental initial step to inform panel members and as a
40
41 285 resource to facilitate resolving any disagreements. The manual suggests that a
42
43 286 systematic review is a good way to conduct a RAM literature review.³⁸ Due to the
44
45 287 rigorous methods applied when conducting a full systematic review, however, they
46
47 288 can take an extensive amount of time to complete.⁴¹ It is anticipated that it will not be
48
49 289 feasible to conduct systematic reviews for all QIs within the time and resources
50
51 290 available for this project. Instead, to assist panel members in rating the validity of the
52
53 291 QIs, evidence summaries will be compiled as described above for those QIs where
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55 292 published research evidence exists.
 - 56
57 293 • **Opportunity for expert panel members to suggest additional QIs:** In addition to
58
59 294 rating the proposed QIs, panel members will also be invited to suggest additional

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3 295 QIs. This is optional but considered important, especially if expert panel members
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5 296 feel that the proposed QIs do not sufficiently address vital aspects of prehospital care
6
7 297 essential for quality measurement in the Australian context.

- 9 298 • **Online rating and discussions instead of a postal rating sheet and face-to-face**
10
11 299 **meeting:** In anticipation of geographically distant locations of potential expert panel
12
13 300 members in Australia, the second round will be conducted online. This has been
14
15 301 found feasible in other studies using the method amongst geographically distributed
16
17 302 participants.⁴²

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22 304 The consensus method will be a two-round online process. The online process will be
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24 305 designed on Qualtrics (Qualtrics, Provo, UT, USA). In round one, panellists will be asked to
25
26 306 separately rate the clarity and validity of each QI on scales from 1 to 9. To improve clarity,
27
28 307 panellist will have the opportunity to make suggestions on changing the wording of the QIs.
29
30 308 Panellists will also have an opportunity to suggest additional QIs, ideally supported by best
31
32 309 available evidence. For the assessment of the QIs' validity, panellist will be asked to
33
34 310 consider the summarised evidence as well as their own knowledge and experience. In round
35
36 311 two, panellists will join an asynchronous online discussion platform (Kialo Inc. Brooklyn, NY
37
38 312 USA) moderated by one of the researchers. Discussions will be informed by individualised
39
40 313 and anonymised results from the first round consisting of each panellist's own rating
41
42 314 compared to the frequency distribution for the ratings, the overall panel median and the
43
44 315 mean absolute deviation from the median. Panellists will have an opportunity to discuss
45
46 316 each QI before re-rating its validity.

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50 318 Data analysis will be performed using Microsoft Excel for Mac 2019 (Microsoft Corp.,
51
52 319 Richmond, WA, USA) and in accordance with the RAM.³⁸ To proceed to the third and final
53
54 320 phase of the project, there needs to be consensus that the QI is valid in the Australian
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56 321 prehospital care context. Validity will be signalled by a final panel median score of greater

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3 322 than or equal to seven with no disagreement. The definition of disagreement will depend on
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5 323 the number of panellists.
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11 326 ***Phase 3: Mixed Methods***

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13 327 Taking a social science theory perspective informed by reviews and frameworks of
14
15 328 acceptability as a criterion for evaluating performance measures,^{24,43,44} phase 3 will involve
16
17 329 the successional collection of quantitative and qualitative data to facilitate integrated
18
19 330 interpretations and conclusions about the acceptability of the candidate QIs. Feasibility and
20
21 331 reliability will be investigated in the same fashion. Thus, this phase will see the utilisation of
22
23 332 explanatory sequential designs as illustrated in figure 3.
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27
28 334 *<insert Figure 3 here>*

29
30 335 **Figure 3:** Explanatory sequential design of phase 3 (AS: ambulance service)

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32 336

33
34 337 Target participants for part 1 will be Australian paramedics and ambulance service
35
36 338 managers. Based on the Australian registered paramedic population of approximately
37
38 339 17,000,⁴⁵ and using a sample size estimation with a confidence interval of 95% and margin
39
40 340 of error of 8%, an ideal sample size of 149 will be required for the survey (part 1A). The
41
42 341 survey will be disseminated through Australian paramedicine professional associations and
43
44 342 social media. Participants will be asked to complete an anonymous online non-validated
45
46 343 survey instrument purpose-built for this project (designed on Qualtrics; Qualtrics, Prova, UT,
47
48 344 USA). The survey will collect basic demographic data such as gender, age, paramedic
49
50 345 qualification, years of experience in paramedicine, employment location, and role.
51
52 346 Depending on the number of candidate QIs stemming from phase 2 of the project, the
53
54 347 survey will consist of all or a random sample of the QIs. Using a 5-point Likert scale,
55
56 348 participants will be asked to rate the acceptability of each QI ranging from very unacceptable
57
58 349 to very acceptable. At the end of the survey, participants will be asked if they would like to

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2
3 350 volunteer to partake in the subsequent semi-structured interviews (part 1B). It will be made
4
5 351 clear that by participating in part 1B anonymity cannot be maintained. However, information
6
7 352 gathered in this part will be kept confidential. If the cohort of self-selected interview
8
9 353 participants lacks demographic diversity, purposeful recruitment within the researchers'
10
11 354 professional networks will be used in conjunction. Quantitative data analysis will be
12
13 355 performed using Microsoft Excel for Mac 2019 (Microsoft Corp., Richmond, WA, USA).
14
15 356 Nonparametric procedures, based on the median, as well as distribution free methods such
16
17 357 as tabulations, frequencies, contingency tables and chi-squared statistics will be used for
18
19 358 analysing these data.^{46,47} Analysed data from part 1A will inform the development of a semi-
20
21 359 structured interview guide for part 1B. The interview guide will also contain some a priori
22
23 360 questions. Questions will be open-ended and aimed at facilitating the explanation of what
24
25 361 makes QIs acceptable or unacceptable and how the candidate QIs align to professional
26
27 362 standards and values. To ensure diversity in the participants, maximum variation sampling
28
29 363 will be used in part 1B.^{48,49} This will be achieved by combining self-selected participants with
30
31 364 purposeful recruitment of individuals meeting demographic criteria poorly accounted for in
32
33 365 the self-selected cohort. Targeted recruitment will be done through the professional
34
35 366 networks of the researchers. Interviews will be conducted and qualitative data will be
36
37 367 collected until saturation is achieved.⁵⁰ Qualitative descriptive analysis will be performed
38
39 368 using Nvivo 12 (QRS International, Doncaster, Australia).^{51,52}
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43 369
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45 370 For part 2, voluntary participation of Australian State/Territory ambulance services and their
46
47 371 quality managers will be sought. The research team will make direct contact with the
48
49 372 ambulance services to enquire about interest in participating. There are eight jurisdictional
50
51 373 ambulance services in Australia and participation of as many as possible will be pursued.
52
53 374 Depending on the number of candidate QIs stemming from phase 2 of the project,
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55 375 participating ambulance services will be asked to pilot all or a random sample of the QIs
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57 376 (part 2A). A questionnaire will collect service-describing data on variables such as size, call
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59 377 volume, data-sets and quality measurement/management/improvement practices, and elicit
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3 378 details about the feasibility and reliability of measuring ambulance service performance
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5 379 using the candidate QIs. Quantitative data analysis will be performed using Microsoft Excel
6
7 380 for Mac 2019 (Microsoft Corp., Richmond, WA, USA). Summarised results from part 2A will
8
9 381 inform the development of a semi-structured interview guide for part 2B. This guide will also
10
11 382 contain some a priori questions. Questions will be open-ended and aimed at facilitating the
12
13 383 explanation of what makes QIs feasible or unfeasible, especially from a non-technical
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15 384 perspective. Qualitative data will be analysed using NVivo 12 (QRS International, Doncaster,
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18 385 Australia).

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21 22 387 **Patient and public involvement**

23
24 388 Neither patients nor the public have been involved in the design of this project. The findings
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26 389 of the project will be made available to patients and the general public as part of the
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28 390 dissemination strategy. Future research may evaluate patient and public perceptions of the
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30 391 quality indicators.

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33 34 393 **Discussion**

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37 394 Not only is there growing demand for ambulance services but also increasing requirements
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39 395 to improve, maintain and evidence quality of care. QIs are often selected arbitrarily.^{19,53} A
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41 396 good QI needs to possess certain attributes which will assure that it can be used to make an
42
43 397 accurate and fair judgement about quality. QIs should be valid, acceptable, feasible and
44
45 398 reliable and must therefore be assessed or tested for these attributes before implementation.
46
47 399 There is growing interest in the measurement of prehospital care quality of ambulance
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49 400 services.²⁸ Measurement of intelligent and meaningful QIs over time is key to understanding
50
51 401 variation and ultimately where and how to conduct improvement efforts.⁵⁴ The QIs which will
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53 402 be developed in this project provide a mechanism to appraise Australian ambulance
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55 403 services' performance and a framework to direct, monitor and demonstrate quality
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57 404 improvement efforts.

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3 406 There are a number of anticipated real and potential limitations. Firstly, the preliminary
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5 407 scoping review bears inherent and specific limitations. Scoping reviews methods do not
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7 408 include an appraisal of quality or risk of bias when selecting studies for inclusion. The
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9 409 scoping review conducted for this project included articles written in English only and
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11 410 therefore the search performed may not have been exhaustive. Secondly and similarly, rapid
12
13 411 reviews also have intrinsic limitations concerning their scope, comprehensiveness and rigor.
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15 412 However, considering the large number of QIs for which evidence needs to be identified and
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17 413 the time it would take to conduct systematic reviews, the rapid review and evidence
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19 414 summary approach is most appropriate. Thirdly, whilst there are clear advantages of
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21 415 conducting online expert panels (e.g. more efficient use of the experts' time and make online
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23 416 discussions anonymous and thus reduce possible biases based on participant status or
24
25 417 personality),^{42,55} this approach may also potentially present limitations. Unfamiliarity,
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27 418 technical issues or general dislike of online tools could decrease levels of engagement and
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29 419 interactions amongst the expert panel. This may undermine the expert panel members'
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31 420 willingness to participate and affect the quality of discussions and outputs.⁵⁶ Lastly, it is
32
33 421 unlikely that all Australian State/Territory Ambulance Services will be able or willing to
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35 422 participate in the final phase of the project. These Services have significant differences in
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37 423 aspects such as size, clinical practice, data management, etc., and thus the smaller the
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39 424 number of participating services the less generalisable the results.
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427 **Ethics and dissemination**

428 The project will be conducted in accordance with the National Health and Medical Research
429 Council National Statement on Ethical Conduct in Human Research, as well as the approved
430 research proposal. This project has been approved by the University of Adelaide Human
431 Research Ethics Committee (Approval Number H-2017-157). It is supported through an

1
2
3 432 Australian Government Research Training Program Scholarship and in part by a research
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5 433 grant from the Australian and New Zealand College of Paramedicine (ANZCP).
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7 434
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9 435 The scoping review has been published. Further findings of the project will be communicated
10
11 436 using a comprehensive dissemination strategy. This strategy includes several different forms
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13 437 of dissemination to reach out to individuals and stakeholder groups at the national and
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15 438 international level. More specifically, this will involve publishing in peer-reviewed journals
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17 439 and presenting at national and international conference presentations, posting on social
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19 440 media sites such as Twitter, making announcements on the project's website
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21 441 (www.aspireproject.net), and e-mailing study findings to participants and appropriate
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23 442 stakeholders.
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600 applications of the Delphi technique in clinical informatics research. Proc AMIA Symp.
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For peer review only

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2
3 628 **List of abbreviations**
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5 629 AS: Ambulance Service; CINAHL: Cumulative Index to Nursing and Allied Health Literature;

6
7 630 CV: Curriculum Vitae; JBI: Joanna Briggs Institute; QI: Quality Indicator; RAM: RAND/UCLA

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9 631 Appropriateness Method; RAND Corporation: Research and Development Corporation;

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11 632 UCLA: University of California Los Angeles
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16 634 **Authors' contributions**
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18 635 RP is the guarantor. RP incepted the project and prepared the manuscript. CL, MS and PS

19
20 636 reviewed drafts to help refine the manuscript. All authors have read and approved the final

21
22 637 draft.
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27 639 **Funding statement**
28

29 640 This project is supported by an Australian Government Research Training Program

30
31 641 Scholarship. This project is in part supported by a research grant from the Australian and

32
33 642 New Zealand College of Paramedicine (ANZCP).
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37 644 **Competing interests**
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39 645 The authors declare that they have no competing interests.
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44 647 **Word Count**
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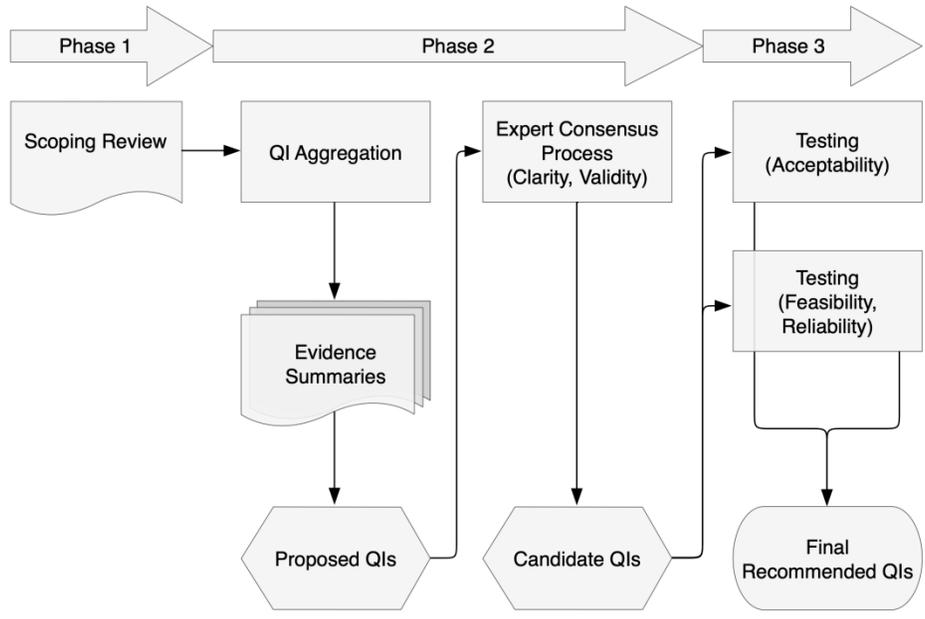


Figure 1: Flow diagram detailing the three phases of the project (QI: quality indicator)

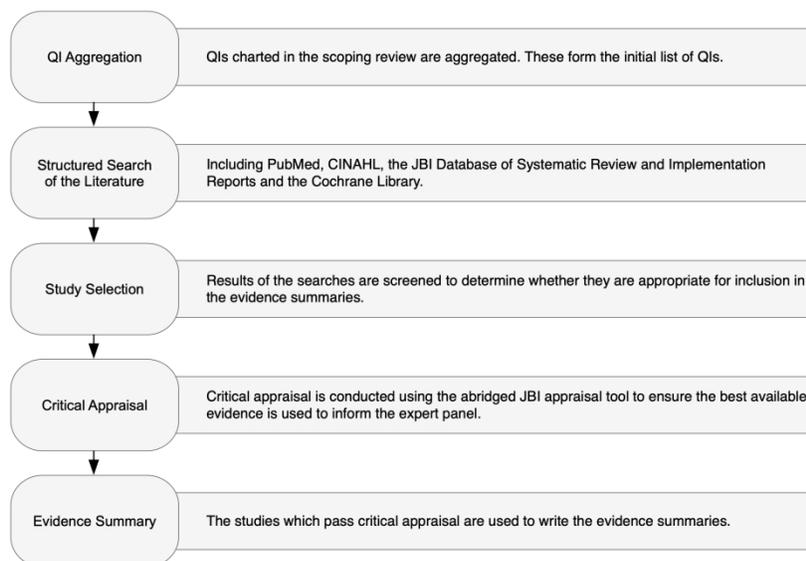


Figure 2: The evidence summary development process (adopted from Munn, Lockwood & Moola, 201532)

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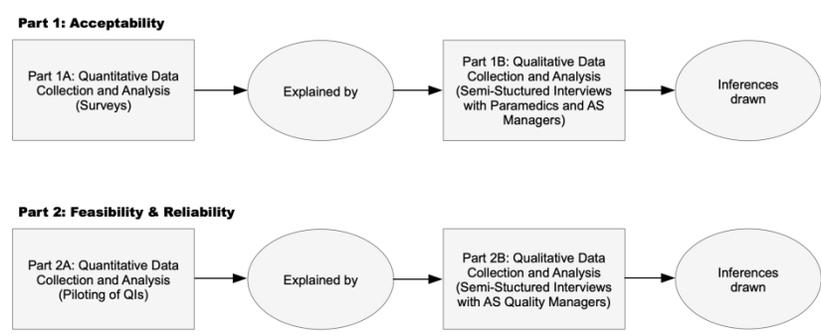


Figure 3: Explanatory sequential design of phase 3 (AS: ambulance service)

BMJ Open

The development and testing of Australian prehospital care quality indicators: study protocol

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2020-038310.R1
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Date Submitted by the Author:	28-Apr-2020
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Primary Subject Heading:	Health services research
Secondary Subject Heading:	Emergency medicine
Keywords:	ACCIDENT & EMERGENCY MEDICINE, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, HEALTH SERVICES ADMINISTRATION & MANAGEMENT

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3 1 **The development and testing of Australian prehospital care quality indicators:**
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5 2 **study protocol**
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3 **27 Abstract**
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5 **28 Introduction** Historically, ambulance services were established to provide rapid transport
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7 of patients to hospital. Contemporary prehospital care involves provision of sophisticated
8
9 'mobile healthcare' to patients across the lifespan presenting with a range of injuries or
10
11 illnesses of varying acuity. Because of its young age, the paramedicine profession has until
12
13 recently experienced a lack of research capacity which has led to paucity of a discipline-
14
15 specific, scientific evidence-base. Therefore, the performance and quality of ambulance
16
17 services has traditionally been measured using simple, evidence-poor indicators forming a
18
19 deficient reflection of the true quality of care and providing little direction for quality
20
21 improvement efforts. This paper reports the study protocol for the development and testing
22
23 of quality indicators for the Australian prehospital care setting.
24
25

26 **38 Methods and analysis** This project has three phases. In the first phase, preliminary work
27
28 in the form of a scoping review was conducted which provided an initial list of quality
29
30 indicators. In the subsequent phase, these quality indicators will be developed by
31
32 aggregating them and by performing related rapid reviews. The summarised evidence will be
33
34 used to support an expert consensus process aimed at optimising the clarity and evaluating
35
36 the validity of proposed quality indicators. Finally, in the third phase those quality indicators
37
38 deemed valid will be tested for acceptability, feasibility and reliability using mixed research
39
40 methods. Evidence-based indicators can facilitate meaningful measurement of the quality of
41
42 care provided. This forms the first step to identify unwarranted variation and direction for
43
44 improvement work. This project will develop and test quality indicators for the Australian
45
46 prehospital care setting.
47
48

49 **49 Ethics and dissemination** This project has been approved by the University of Adelaide
50
51 Human Research Ethics Committee. Findings will be disseminated by publications in peer-
52
53 reviewed journals, presentations at appropriate scientific conferences, as well as posts on
54
55 social media and on the project's website.
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3 54 **Keywords:** Emergency medical services; healthcare quality assessment; prehospital care;
4
5 55 quality indicators
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7 56

8
9 57 **Strengths and limitations of the study**

- 10
11 58 • The scoping review, which was used to establish a preliminary list of prehospital care
12
13 quality indicators, utilised systematic methods.
14 59
15
16 60 • By incorporating systematically synthesised literature into the expert consensus
17
18 61 process, it will be evidence informed.
19
20 62 • Selection of an Australian prehospital care expert panel will ensure that validity of
21
22 63 proposed quality indicators is evaluated with contextual considerations.
23
24 64 • Testing of candidate quality indicators will involve the participation of paramedics and
25
26 65 ambulance services.
27
28 66 • Considering the relatively young age of the paramedicine discipline, the evidence
29
30 67 supporting many of the quality indicators is expected to be weak.
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80 Introduction

81 The quality and safety of health care is on the agenda in any modern health care
82 organisation, including ambulance services. Strategies to continuously improve the quality of
83 service should primarily be based on information about the level of quality produced by the
84 health care organisation.¹ Indicators of desirable structures, processes and outcomes allow
85 the quality of care and services to be measured. This assessment can be facilitated by
86 systematically developing quality indicators that describe the performance that should occur,
87 and then measuring and monitoring whether a service's operations and patient care are
88 consistent with these indicators.² Thus, an indicator may be defined as an explicitly defined
89 and measurable element of health care services and, as far as possible, should possess the
90 fundamental characteristics of clarity, validity, acceptability, feasibility and reliability.³ A
91 *quality* indicator (QI) is an indicator for which there is evidence or consensus that it can be
92 used to assess the quality, and hence measure changes in quality over time.⁴

93
94 For the purpose of this project, the context of prehospital care is limited to the health care
95 services provided by ambulance services. Historically, the function of ambulance services
96 was primarily one of transport; paramedics would provide only stabilising care to patients
97 with high-acuity presentations before transporting to an emergency department. However,
98 ambulance service models of care have evolved considerably. Contemporary prehospital
99 care involves provision of often complex 'mobile healthcare' to patients across the lifespan
100 presenting with injury or illness across the spectrum of acuity. An increasingly aged
101 population and an increased incidence of chronic disease have led to a substantial increase
102 in non-emergency, or 'low acuity' presentations for whom the traditional emergency
103 department disposition may not be most appropriate.^{5,6} Ambulance services now play a key
104 role in integrated health care frameworks, with transport to an emergency department being
105 one of many disposition outcomes following care from paramedics alongside referral into
106 primary and community-based health care. On the other verge of the patient spectrum,
107 ambulance services continue to provide critical care and transport for those suffering life-

1
2
3 108 threatening illness or injury.^{6,7} Therefore, this project adopts the definition of prehospital
4
5 109 care previously developed which encompasses this range of patients seen by ambulance
6
7 110 services: Prehospital care is the care that ambulance services provide for patients with real
8
9 111 or perceived emergency or urgent care needs from the time point of emergency telephone
10
11 112 access until care is concluded or until arrival and transfer of care to a hospital or other health
12
13 113 care facility.^{8,9}
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16 114

17
18 115 Similarly to many other countries, Australia has measures in its national performance
19
20 116 indicator framework for ambulance services that track the quality of care delivered to its
21
22 117 residents across the various jurisdictions.¹⁰ However, the scope of current measurement is
23
24 118 limited. For example, a short response time interval may be an important indicator in certain,
25
26 119 time-critical patient cohorts,^{11–13} however, its validity as a holistic prehospital care quality
27
28 120 indicator is questionable.^{14,15} Response times and other, similarly simple quality indicators
29
30 121 have predominated in ambulance services' performance reports since they are easily
31
32 122 measured and readily understood by the public and policymakers alike.¹⁶ With increasing
33
34 123 research activity and the recent commencement of national registration of paramedics in
35
36 124 Australia, a timely need to expand the nationally utilised indicators of prehospital care quality
37
38 125 exists. Both, an expanding evidence-base and regulations which primarily ensure patient
39
40 126 and community safety, ultimately aim to protect and continuously improve the quality of
41
42 127 prehospital care. Meaningful measurement based on systematically developed QIs not only
43
44 128 produces data to ensure the maintenance of quality, it also provides information on whether
45
46 129 or not change is effective in achieving improvement.
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51 131 This paper reports the context and methods for a project on development and testing of
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53 132 prehospital care QIs. The primary aim of the project is to develop and test QIs for the
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55 133 Australian prehospital care setting. To achieve this, the project addresses the following
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57 134 objectives:
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3 135 1. To map the attributes or dimensions of 'quality' in the context of prehospital care and
4
5 136 explore indicators that have been developed internationally to measure prehospital
6
7 137 care quality.
8
9 138 2. To develop prehospital care QIs for the Australian setting and to evaluate their
10
11 139 validity.
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13 140 3. To test selected candidate prehospital care QIs for acceptability, feasibility and
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15 141 reliability.
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144 **Methods and analysis**

145 This project consists of three phases (figure 1): An initial scoping review addressing
146 objective 1; Evidence-informed development of prehospital care QIs and an evaluation of
147 their validity using an expert consensus process (modified RAND/UCLA Appropriateness
148 Method) to address objective 2; And finally a mixed methods approach (explanatory
149 sequential design) to test the QIs as detailed in objective 3.

150
151 <insert Figure 1 here>

152 **Figure 1:** Flow diagram detailing the three phases of the project (QI: quality indicator)

154 **Phase 1: Scoping Review**

155 This phase has been completed and involved preparatory work in the form of a scoping
156 review.¹⁷ The purpose of the review was to map the attributes of 'quality' in the context of
157 prehospital care and to chart existing international prehospital care QIs. The review
158 employed the Joanna Briggs Institute (JBI) methodology for conducting scoping reviews.¹⁸
159 The objectives, inclusion and exclusion criteria, and methods were specified in advance and
160 documented in a protocol.¹⁹

161

1
2
3 162 The review's systematic search confirmed paucity in literature that defines prehospital care
4
5 163 quality or examines which dimensions of generic health care quality definitions are important
6
7 164 in prehospital care. However, synthesis of included articles suggested that timely access to
8
9 165 appropriate, safe and effective care which is responsive to a patient's needs and efficient
10
11 166 and equitable to populations is reflective of high-quality prehospital care. There is growing
12
13 167 interest in developing QIs to evaluate prehospital care. In total, the review charted 526 QIs
14
15 168 addressing clinical and non-clinical aspects of ambulance services providing prehospital
16
17 169 care. The scoping review highlighted the need for validation of existing prehospital care QIs
18
19 170 and *de novo* QI development.
20
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22 171

23 24 172 ***Phase 2: Evidence-Informed Expert Consensus Process***

25
26 173 Phase 2 will comprise an evidence-informed expert consensus process to optimise the
27
28 174 clarity of QIs and evaluate which are valid for the measurement of prehospital care quality in
29
30 175 Australia. Preparative work will involve aggregating the dimensions of prehospital care
31
32 176 quality and the prehospital care QIs charted in phase 1, as well as performing evidence
33
34 177 summaries to inform the expert panel. There are practical advantages, including the critical
35
36 178 appraisal of QIs, in aggregating multiple dimensions of quality into a smaller number of
37
38 179 principal dimensions.²⁰ Campbell and colleagues (2000)²⁰ argue that there are two
39
40 180 overarching dimensions of quality of care; access and effectiveness. Aggregation of
41
42 181 attributes of prehospital care quality into these two key dimensions has previously been
43
44 182 performed by Owen (2010).⁹
45
46

47 183

48
49 184 The development of the evidence summaries to inform the expert panel of best available
50
51 185 evidence for each QI will be guided by the JBI approach for rapid reviews and evidence
52
53 186 summaries.²¹ Figure 2 provides a diagrammatic outline of the rapid review and evidence
54
55 187 summary process.
56
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3 190 <insert Figure 2 here>
4

5 191 **Figure 2:** The evidence summary development process (adopted from Munn, Lockwood &
6
7 192 Moola, 2015²¹)
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10
11 194 Literature searches will be undertaken in the following databases: PubMed, CINAHL, the JBI
12
13 195 Database of Systematic Reviews and Implementation Reports and the Cochrane Library.

14
15 196 Table 1 details an example of search terms used. Generally, terms related to prehospital
16
17 197 care will be combined with QI specific terms. Development of the terms related to
18
19 198 prehospital care will be guided by search filters created by Olausson, et al.²² Only English
20
21 199 language papers will be included for pragmatic reasons. Searches will not be limited by date.
22
23 200 The search will also include backtracking of references. In line with JBI's approach to
24
25 201 evidence summaries,^{21,23} the best available evidence will be incorporated in each summary.
26
27 202 This means that lower-level evidence will be included only when no systematic reviews are
28
29 203 located. The JBI levels of evidence are detailed in Table 2.
30
31

32 204

33
34
35 205 **Table 1** Example of search terms/filters used in PubMed

Concept	[1] Prehospital Care	[2] QI
Search terms	Ambulances[mh] OR Emergency Medical Technicians[mh] OR Air Ambulances[mh] OR paramedic*[tiab] OR ems[tiab] OR emt[tiab] OR prehospital[tiab] OR pre-hospital[tiab] OR first responder*[tiab] OR emergency medical technician*[tiab] OR emergency services[tiab] OR ambulance*[tiab]	(QI related search terms)
Search Filter	[1] AND [2], English only; Systematic Reviews and Meta-Analyses/Meta-Synthesis only (Change to '[1] AND [2], English only' if no or poor-quality Systematic Reviews and Meta-Analyses/Meta-Synthesis are identified)	

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50 207 Following the search, titles and abstracts will be screened. If potentially eligible, the full text
51
52 208 of the papers will be read to determine whether the article should be included in the
53
54 209 applicable evidence summary. Full-text reading will involve an assessment of internal validity
55
56 210 utilising an abridged critical appraisal tool (Table 3). The rapid reviews and evidence
57
58 211 summaries that will be developed for this study will have several limitations. The more a
59
60

212 rapid review adheres to the methodological rigor of systematic reviews, the longer it will take
 213 to complete.^{21,24,25} Therefore, the less time is taken to complete a rapid review the less
 214 thorough it will be. The JBI approach to evidence summaries aims for a rapid development
 215 cycle.²¹ This method is considered suitable for the purpose of this project considering the
 216 limited resources and time available. These restrictions also mean that there will be only one
 217 researcher to screen, select, appraise and summarise the evidence and no peer review will
 218 be undertaken which may inevitable introduce increased risk of bias and error.

219

220 **Table 2** JBI Levels of Evidence for Effectiveness, Diagnosis and Meaningfulness²³ (JBI:
 221 Joanna Briggs Institute)

Level of Evidence	Study Designs		
	Effectiveness	Diagnosis	Meaningfulness
1	Experimental Designs including: a. Systematic review of Randomized Controlled Trials (RCTs) b. Systematic review of RCTs and other study designs c. RCTs d. Pseudo-RCTs	Studies of test accuracy among consecutive patients: a. Systematic review of studies of test accuracy among consecutive patients b. Study of test accuracy among consecutive patients	Qualitative or mixed-methods systematic review
2	Quasi-Experimental Designs including: a. Systematic review of quasi-experimental studies b. Systematic review of quasi-experimental and other lower study designs c. Quasi-experimental prospectively controlled study d. Pre-test post-test or historic/retrospective control group study	Studies of Test Accuracy among non-consecutive patients: a. Systematic review of studies of test accuracy among non-consecutive patients b. Study of test accuracy among non-consecutive patients	Qualitative or mixed-methods synthesis
3	Observational – Analytic Designs including: a. Systematic review of comparable cohort studies b. Systematic review of comparable cohort and other lower study designs c. Cohort study with control group d. Case-controlled study e. Observational study without a control group	Diagnostic Case control studies: a. Systematic review of diagnostic case control studies b. Diagnostic case-control study	Single qualitative study
4	Observational – Descriptive Designs including: a. Systematic review of descriptive studies b. Cross-sectional study c. Case series d. Case study	Diagnostic yield studies: a. Systematic review of diagnostic yield studies b. Individual diagnostic yield study	Systematic review of expert opinion
5	Expert Opinion and Bench Research including:	Expert Opinion and Bench Research:	Expert opinion

	a. Systematic review of expert opinion b. Expert consensus c. Bench research/single expert opinion	a. Systematic review of expert opinion b. Expert consensus c. Bench research/ single expert opinion	
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224 **Table 3** Abridged Quality Appraisal Criteria for JBI Evidence Summaries²¹ (JBI: Joanna
225 Briggs Institute)

Type of Study/Evidence	Quality Appraisal Criteria
Systematic Review	<ul style="list-style-type: none"> • Is the review question clearly and explicitly stated? • Was the search strategy appropriate? • Were the inclusion criteria appropriate for the review question? • Were the criteria for appraising studies appropriate? • Was critical appraisal by two or more independent reviewers? • Were there methods used to minimize error in data extraction? • Were the methods used to combine studies appropriate?
Quantitative Evidence	<ul style="list-style-type: none"> • Was there appropriate randomization? • Was allocation concealed? • Was blinding to allocation maintained? • Was incompleteness of data addressed? • Were outcomes reported accurately?
Qualitative Evidence	<ul style="list-style-type: none"> • Was the research design appropriate for the research? • Was the recruitment strategy appropriate for the research? • Were data collected in a way that addressed the research issue? • Has the relationship between researcher and participants been considered? • Was the data analysis sufficiently rigorous?

226

227 An Australian prehospital care expert panel of seven to 15 members will be recruited.

228 Panellists must have perspectives and areas of expertise in Australian paramedicine,

229 prehospital care, ambulance service leadership and management, quality improvement,

230 performance/quality measurement and patient perspective. There are eight State/Territory-

231 based ambulance services, one paramedicine professional associations and eighteen

232 universities offering paramedicine programs. These institutions will be contacted and asked

233 to nominate experts for participation in the study. The nomination process will require the

234 nominator making a project information and nomination form available to the nominee for

235 perusal and signature. Self-nomination will be allowed. The completed forms and attached

236 curriculum vitae (CV) will be emailed to the lead investigator. The research team will select

237 expert panel members based on information provided in the forms and attached CV. This is

238 a confidential process and only the researchers will peruse the completed forms and CV.

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3 239 The main selection criteria to be considered will be acknowledged leadership in
4
5 240 paramedicine, absence of conflicts of interest and geographic diversity (ideally at least one
6
7 241 panellist from each State/Territory). A RAND/UCLA Appropriateness Method (RAM) will be
8
9 242 applied. RAM is a formal panel judgement process which systematically and quantitatively
10
11 243 combines available scientific evidence with expert opinion by asking panel members to rate,
12
13 244 discuss and then re-rate the items of interest.²⁶ For the purpose of this project the original
14
15 245 method will be modified in the following ways:
16
17

18 246

19
20 247 • **Evidence summaries instead of systematic reviews:** As described in the RAM
21
22 248 user's manual²⁷, the critical review of the literature summarising the best available
23
24 249 scientific evidence is a fundamental initial step to inform panel members and as a
25
26 250 resource to facilitate resolving any disagreements. The manual suggests that a
27
28 251 systematic review is a good way to conduct a RAM literature review.²⁷ Due to the
29
30 252 rigorous methods applied when conducting a full systematic review, however, they
31
32 253 can take an extensive amount of time to complete.²⁸ It is anticipated that it will not be
33
34 254 feasible to conduct systematic reviews for all QIs within the time and resources
35
36 255 available for this project. Instead, to assist panel members in rating the validity of the
37
38 256 QIs, evidence summaries will be compiled as described above for those QIs where
39
40 257 published research evidence exists.

41
42
43 258 • **Opportunity for expert panel members to suggest additional QIs:** In addition to
44
45 259 rating the proposed QIs, panel members will also be invited to suggest additional
46
47 260 QIs. This is optional but considered important, especially if expert panel members
48
49 261 feel that the proposed QIs do not sufficiently address vital aspects of prehospital care
50
51 262 essential for quality measurement in the Australian context.

52
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54 263 • **Online rating and discussions instead of a postal rating sheet and face-to-face**
55
56 264 **meeting:** In anticipation of geographically distant locations of potential expert panel
57
58 265 members in Australia, the second round will be conducted online. This has been
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3 266 found feasible in other studies using the method amongst geographically distributed
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5 267 participants.²⁹
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9 269 The consensus method will be a two-round online process. The online process will be
10
11 270 designed on Qualtrics (Qualtrics, Provo, UT, USA). In round one, panellists will be asked to
12
13 271 separately rate the clarity and validity of each QI on scales from 1 to 9. To improve clarity,
14
15 272 panellist will have the opportunity to make suggestions on changing the wording of the QIs.
16
17 273 Panellists will also have an opportunity to suggest additional QIs, ideally supported by best
18
19 274 available evidence. For the assessment of the QIs' validity, panellist will be asked to
20
21 275 consider the summarised evidence as well as their own knowledge and experience. In round
22
23 276 two, panellists will join an asynchronous online discussion platform (Kialo Inc. Brooklyn, NY
24
25 277 USA) moderated by one of the researchers. Discussions will be informed by individualised
26
27 278 and anonymised results from the first round consisting of each panellist's own rating
28
29 279 compared to the frequency distribution for the ratings, the overall panel median and the
30
31 280 mean absolute deviation from the median. Panellists will have an opportunity to discuss
32
33 281 each QI before re-rating its validity.
34
35

36 282
37
38

39 283 Data analysis will be performed using Microsoft Excel for Mac 2019 (Microsoft Corp.,
40
41 284 Richmond, WA, USA) and in accordance with the RAM.²⁷ To proceed to the third and final
42
43 285 phase of the project, there needs to be consensus that the QI is valid in the Australian
44
45 286 prehospital care context. Validity will be signalled by a final panel median score of greater
46
47 287 than or equal to seven with no disagreement. The definition of disagreement will depend on
48
49 288 the number of panellists.
50

51 289
52

53 290 **Phase 3: Mixed Methods**

54
55 291 In this final phase, focus will be shifted from evaluating which QIs are valid to assessing
56
57 292 which QIs are useful. As such, this phase is based on pragmatism as a philosophical
58
59 293 foundation.³⁰ Taking a social science theory perspective informed by reviews and
60

1
2
3 294 frameworks of acceptability as a criterion for evaluating performance measures,^{31–33} phase 3
4
5 295 will involve the successional collection of quantitative and qualitative data to facilitate
6
7 296 integrated interpretations and conclusions about the acceptability of the candidate QIs.
8
9 297 Feasibility and reliability will be investigated in the same fashion. Thus, this phase will see
10
11 298 the utilisation of explanatory sequential designs as illustrated in figure 3. The choice of
12
13 299 mixed methods is in line with broad consensus that the rationale for a mixed approach must
14
15 300 be a pragmatic one.³⁴
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19
20 302 <insert Figure 3 here>
21

22 303 **Figure 3:** Explanatory sequential design of phase 3 (AS: ambulance service)
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24 304

25
26 305 Target participants for part 1 will be Australian paramedics and ambulance service
27
28 306 managers, the individuals and representatives of services whose quality of prehospital care
29
30 307 would be measured after implementation of the QIs. Based on the Australian registered
31
32 308 paramedic population of approximately 17,000,³⁵ and using a sample size estimation with a
33
34 309 confidence interval of 95% and margin of error of 8%, an ideal sample size of 149 will be
35
36 310 required for the survey (part 1A). The survey will be disseminated through Australian
37
38 311 paramedicine professional associations and social media. Participants will be asked to
39
40 312 complete an anonymous online non-validated survey instrument purpose-built for this project
41
42 313 (designed on Qualtrics; Qualtrics, Prova, UT, USA). The survey will collect basic
43
44 314 demographic data such as gender, age, paramedic qualification, years of experience in
45
46 315 paramedicine, employment location, and role. Depending on the number of candidate QIs
47
48 316 stemming from phase 2 of the project, the survey will consist of all or a random sample of
49
50 317 the QIs. Using a 5-point Likert scale, participants will be asked to rate the acceptability of
51
52 318 each QI ranging from very unacceptable to very acceptable. At the end of the survey,
53
54 319 participants will be asked if they would like to volunteer to partake in the subsequent semi-
55
56 320 structured interviews (part 1B). It will be made clear that by participating in part 1B
57
58 321 anonymity cannot be maintained. However, information gathered in this part will be kept
59
60

1
2
3 322 confidential. If the cohort of self-selected interview participants lacks demographic diversity,
4
5 323 purposeful recruitment within the researchers' professional networks will be used in
6
7 324 conjunction. Quantitative data analysis will be performed using Microsoft Excel for Mac 2019
8
9 325 (Microsoft Corp., Richmond, WA, USA). Nonparametric procedures, based on the median,
10
11 326 as well as distribution free methods such as tabulations, frequencies, contingency tables and
12
13 327 chi-squared statistics will be used for analysing these data.^{36,37} Analysed data from part 1A
14
15 328 will inform the development of a semi-structured interview guide for part 1B. The interview
16
17 329 guide will also contain some *a priori* questions (Box 1). Questions will be open-ended and
18
19 330 aimed at facilitating the explanation of what makes QIs acceptable or unacceptable and how
20
21 331 the candidate QIs align to professional standards and values. To ensure diversity in the
22
23 332 participants and to optimise credibility of results, maximum variation sampling will be used in
24
25 333 part 1B.^{38,39} This will be achieved by combining self-selected participants with purposeful
26
27 334 recruitment of individuals meeting demographic criteria poorly accounted for in the self-
28
29 335 selected cohort. Targeted recruitment will be done through the professional networks of the
30
31 336 researchers. Interviews will be conducted in English by the principle investigator (RP) and
32
33 337 recorded for transcription. During and immediately after field notes will be taken. Qualitative
34
35 338 data will be collected until saturation is achieved,⁴⁰ and descriptive approaches will be taken
36
37 339 by conducting content analyses using Nvivo 12 (QRS International, Doncaster,
38
39 340 Australia).^{41,42} This will involve disassembling the data thorough coding, reassembling the
40
41 341 coded data by putting it into context with each other to create categories and ultimately
42
43 342 themes, and finally interpreting the data thereby drawing analytical conclusions.^{43,44} Several
44
45 343 techniques will be used to enhance trustworthiness; these will include prolonged
46
47 344 engagement, triangulation of recorded interviews, transcripts and field notes, and member
48
49 345 checking.⁴⁵
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56 347 **Box 1** Questions set *a priori* in the interview guide for phase 3, part 1B

58 **Opening:**

- 59 1. How long have you been involved in the ambulance service and what roles have you held?

60 **Transition:**

2. What makes a quality indicator acceptable or not acceptable?

Key:

3. How acceptable did you find the quality indicators in general?
4. How well do you think the quality indicators align to professional standards and values?
5. Clinician: Would you agree for your clinical practice to be measured and evaluated using these quality indicators?
Manager/Supervisor: Would you agree to measure and evaluate the clinical practice of the staff you are supervising by using these quality indicators?

Closing:

6. Is there anything you would like to add?
7. Do you have any questions about the interview or the research?

348

349

350 For part 2, voluntary participation of Australian State/Territory ambulance services and their
 351 quality managers will be sought. The research team will make direct contact with the
 352 ambulance services to enquire about interest in participating. There are eight jurisdictional
 353 ambulance services in Australia and participation of as many as possible will be pursued.
 354 Depending on the number of candidate QIs stemming from phase 2 of the project,
 355 participating ambulance services will be asked to pilot all or a random sample of the QIs
 356 (part 2A). A questionnaire will collect service-describing data on variables such as size, call
 357 volume, data-sets and quality measurement/management/improvement practices, and elicit
 358 details about the feasibility and reliability of measuring ambulance service performance
 359 using the candidate QIs. Quantitative data analysis will be performed using Microsoft Excel
 360 for Mac 2019 (Microsoft Corp., Richmond, WA, USA). Similar to part 1, summarised results
 361 from part 2A will inform the development of a semi-structured interview guide for part 2B.
 362 This guide will also contain some a priori questions (Box 2). Questions will be open-ended
 363 and aimed at facilitating the explanation of what makes QIs feasible or unfeasible, especially
 364 from a non-technical perspective. Data collection during the interviews and subsequent
 365 processing and analysis will be conducted using the same approach described for part 1
 366 above.

367

368 **Box 2** Questions set *a priori* in the interview guide for phase 3, part 2B

In relation to specific QIs:

1. Do you think the target population is well described?
2. Is the numerator and denominator sufficiently defined?
3. Are the exclusions clear?
4. [In the pilot results form, it was indicated that IT/software is insufficient. What would need to be done to upgrade the system/software? Are there any barriers to this?]

5. [In the pilot results form, it was indicated that data is not available from existing sources. What would need to be done to obtain the required data? Are there any barriers to this?]
6. Is the data consistent with repeated measurements?
7. Do you think the indicator measures an aspect of your Service that occurs often enough to detect clinically (or other) important changes?
8. [In the pilot results form, it was indicated that piloting the indicator was not successful in producing an accurate reflection of (Ambulance Service name) performance. What made the results unreliable/imprecise? What would need to be changed to make it reliable/precise?]
9. Are the results understandable?
10. Do you believe using this indicator as a quality improvement tool induces risk of data manipulation?

Closing

1. Is there anything you would like to add?
2. Do you have any questions about the interview or the research?

369

370 Patient and public involvement

371 Neither patients nor the public have been involved in the design of this project. The findings
372 of the project will be made available to patients and the general public as part of the
373 dissemination strategy. Future research may evaluate patient and public perceptions of the
374 quality indicators.

375

376

377 Discussion

378 Not only is there rising demand for ambulance services but also increasing requirements to
379 improve, maintain and evidence quality of care. QIs are often selected arbitrarily,^{46,47}
380 however, there appears to be growing interest in finding better ways to measure the quality
381 of prehospital care provided by ambulance services.¹⁷ Measurement using intelligent and
382 meaningful QIs over time is key to understanding variation and ultimately where and how to
383 conduct improvement efforts.⁴⁸ The QIs which will be developed in this project provide a
384 mechanism to appraise Australian ambulance services' performance and a framework to
385 direct, monitor and demonstrate quality improvement efforts. Essential for the development
386 of QIs is a definition of quality. Proceeding to develop indicators for the measurement of
387 quality without understanding and consensus on what the concept of quality entails is
388 unlikely to result in meaningful assessment of quality.⁴⁹ Indicators can be developed using
389 non-systematic and systematic methods.³ Non-systematic methods are relatively quick;
390 however, they tend not to incorporate all available evidence during their development.

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3 391 Systematically developed QIs are ideally based on high-level scientific evidence or they are
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5 392 derived from evidence-informed guidelines.^{3,50} In areas or disciplines with limited scientific
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7 393 evidence, such as paramedicine, it may be necessary to combine the available evidence
8
9 394 with expert consensus.⁵¹
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11 395
12
13 396 A good QI needs to possess certain attributes which will assure that it can be used to make
14
15 397 an accurate and fair judgement about quality. QIs should be valid, acceptable, feasible and
16
17 398 reliable and must therefore be assessed or tested for these attributes before implementation.
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19 399 A good quality indicator also has clear meaning which enables what is being assessed to be
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21 400 precisely attributable to that indicator.^{3,52} In other words, a clear QI is one which is free of
22
23 401 ambiguity, inaccuracy or imprecision. Validity is arguably the most important property of a
24
25 402 quality indicator. In science, validity refers to the degree to which evidence and theory
26
27 403 support the interpretation of scores entailed by proposed uses of an instrument.⁵³ Thus, in
28
29 404 the quality measurement context, validity refers to the degree to which evidence and theory
30
31 405 support the expected interpretation of measured elements of practice performance related to
32
33 406 the quality indicators. In more simple terms, validity refers to the extent to which the given
34
35 407 statement represents high-quality care and would therefore be an endorsed indicator of
36
37 408 quality. When assessing the validity of QIs, careful consideration of the intended context is
38
39 409 important.^{54–56} Whilst there are considerable benefits in using work from other locations, QIs
40
41 410 cannot simply be transferred directly between different settings without an intermediate
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43 411 process to allow for variation in professional culture and clinical practice.⁵⁷ As such, rating
44
45 412 the validity of QIs entails as much assessment of whether they represent high-quality care
46
47 413 as it does of how contextually applicable they are. Therefore, a method of group consensus
48
49 414 using current scientific evidence in conjunction with Australian expert opinion to develop the
50
51 415 clarity and assess the contextual validity of proposed QIs is thus deemed to be the approach
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53 416 of choice for this particular phase of the project. Several consensus processes have been
54
55 417 used for the development of QIs. The original RAM was developed in the mid-1980s by the
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57 418 RAND Corporation in collaboration with the University of California Los Angeles (UCLA) as

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2
3 419 an instrument to facilitate the measurement of medical and surgical intervention
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5 420 appropriateness.²⁷ RAM has been used extensively as a method of QI development,^{3,52,58,59}
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7 421 including QIs to evaluate prehospital care.⁹
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11 423 Acceptability refers to the quality of being satisfactory or agreeable in terms of professional
12
13 424 standards and values. If the aim of measurement is to provide direction for quality
14
15 425 improvement, then the quality indicators need to be interpretable and meaningful to the
16
17 426 audience, i.e. clinicians and managers. However, the benefit of assessing quality indicators
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19 427 for acceptability extends beyond their development and testing. Measurement provides
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21 428 information to direct improvement efforts and is thus central to quality improvement.^{3,47,60–63}
22
23 429 Involvement of clinicians and managers in the development of indicators is likely to improve
24
25 430 their uptake and contributes to sustainability in quality improvement.³² Measurement of the
26
27 431 quality of care may also serve as or contribute to performance appraisal systems. In this
28
29 432 instance, user acceptance of such systems may be a critical criterion to ensure the
30
31 433 successful implementation.³² Feasibility and reliability relate to the measurability of a QI.
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33 434 Testing QIs for these attributes is critical and ensures that implementation and sustained
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35 435 measurement is successful. Feasibility relates to the availability or attainability of accurate
36
37 436 data and whether this data is realistically collectable.⁵² Feasibility thus encompasses
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39 437 technical and non-technical aspects of data collection and analysis. A feasible QI also
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41 438 facilitates measurement which is applicable to quality improvement, sensitive to
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43 439 improvement over time and useful for decision-making.⁶⁴ Reliability, in this instance, is
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45 440 closely related to precision and refers to the consistency of scores across replications of a
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47 441 testing procedure.⁶⁵ Testing reliability intends to assess whether the QIs are non-
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49 442 erroneously reproducible and for any errors to be identified.⁵² A reliable QI facilitates
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51 443 measurement which has low inter- or intra-rater variation and suitable for statistical
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53 444 analyses.⁶⁴
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3 446 To test if and to what extent the QIs are acceptable, feasible and reliable, a mixed methods
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5 447 approach will be used. The reason for mixing both types of data is that neither quantitative
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7 448 nor qualitative methods alone would suffice to adequately capture the complex issue of QI
8
9 449 acceptability, feasibility and reliability. Combined, quantitative and qualitative methods can
10
11 450 complement each other and thus provide a more comprehensive picture of a research
12
13 451 problem.⁶⁶ More specifically, by applying a sequential explanatory mixed methods design,
14
15 452 quantitative data and results will provide a general initial outline of how acceptable, feasible
16
17 453 and reliable the QIs are, while the subsequent qualitative data and its analysis will explain
18
19 454 those statistical results by exploring the participants' views regarding the QIs in more depth.
20
21 455 Although results of the quantitative and qualitative aspects will be integrated, priority will be
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23 456 given to the quantitative or the qualitative side during the analysis depending on which
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25 457 aspect is expected to require more emphasis.⁶⁷ Therefore, in part 1 (acceptability) more
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27 458 emphasis will be placed on the qualitative component to thoroughly understand why certain
28
29 459 QIs are deemed acceptable or not acceptable. Whilst part 2 (feasibility and reliability) will
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31 460 require more focus on the quantitative aspect, non-technical facilitators and barriers to
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33 461 feasibility will be explained through data analysis of the information obtained from
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35 462 participants.
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41 464 There are a number of anticipated real and potential limitations. Firstly, the preliminary
42
43 465 scoping review bears inherent and specific limitations. Scoping reviews methods do not
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45 466 include an appraisal of quality or risk of bias when selecting studies for inclusion. The
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47 467 scoping review conducted for this project included articles written in English only and
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49 468 therefore the search performed may not have been exhaustive. Secondly and similarly, rapid
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51 469 reviews also have intrinsic limitations concerning their scope, comprehensiveness and rigor.
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53 470 However, considering the large number of QIs for which evidence needs to be identified and
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55 471 the time it would take to conduct systematic reviews, the rapid review and evidence
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57 472 summary approach is most appropriate. Thirdly, whilst there are clear advantages of
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59 473 conducting online expert panels (e.g. more efficient use of the experts' time and make online
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3 474 discussions anonymous and thus reduce possible biases based on participant status or
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5 475 personality),^{29,68} this approach may also potentially present limitations. Unfamiliarity,
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7 476 technical issues or general dislike of online tools could decrease levels of engagement and
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9 477 interactions amongst the expert panel. This may undermine the expert panel members'
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11 478 willingness to participate and affect the quality of discussions and outputs.⁶⁹ Lastly, it is
12
13 479 unlikely that all Australian State/Territory Ambulance Services will be able or willing to
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15 480 participate in the final phase of the project. These Services have significant differences in
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17 481 aspects such as size, clinical practice, data management, etc., and thus the smaller the
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19 482 number of participating services the less generalisable the results.
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484 **Ethics and dissemination**

26 485 The project will be conducted in accordance with the National Health and Medical Research
27
28 486 Council National Statement on Ethical Conduct in Human Research, as well as the approved
29
30 487 research proposal. This project has been approved by the University of Adelaide Human
31
32 488 Research Ethics Committee (Approval Number H-2017-157). It is supported through an
33
34 489 Australian Government Research Training Program Scholarship and in part by a research
35
36 490 grant from the Australian and New Zealand College of Paramedicine (ANZCP).
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41 492 The scoping review has been published.¹⁷ Further findings of the project will be
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43 493 communicated using a comprehensive dissemination strategy. This strategy includes
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45 494 several different forms of dissemination to reach out to individuals and stakeholder groups at
46
47 495 the national and international level. More specifically, this will involve publishing in peer-
48
49 496 reviewed journals and presenting at national and international conference presentations,
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51 497 posting on social media sites such as Twitter, making announcements on the project's
52
53 498 website (www.aspireproject.net), and e-mailing study findings to participants and appropriate
54
55 499 stakeholders.
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3 501 **References**
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46 [services/2019/health/ambulance-services](https://www.pc.gov.au/research/ongoing/report-on-government-services/2019/health/ambulance-services)
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3 697 **List of abbreviations**
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5 698 AS: Ambulance Service; CINAHL: Cumulative Index to Nursing and Allied Health Literature;

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7 699 CV: Curriculum Vitae; JBI: Joanna Briggs Institute; QI: Quality Indicator; RAM: RAND/UCLA

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9 700 Appropriateness Method; RAND Corporation: Research and Development Corporation;

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11 701 UCLA: University of California Los Angeles
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16 703 **Authors' contributions**
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18 704 RP is the guarantor. RP incepted the project and prepared the manuscript. CL, MS and PS

19
20 705 reviewed drafts to help refine the manuscript. All authors have read and approved the final

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22 706 draft.
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28

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33 711 College of Paramedicine (ACP).
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38 713 **Competing interests**
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40 714 The authors declare that they have no competing interests.
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44 716 **Word Count**
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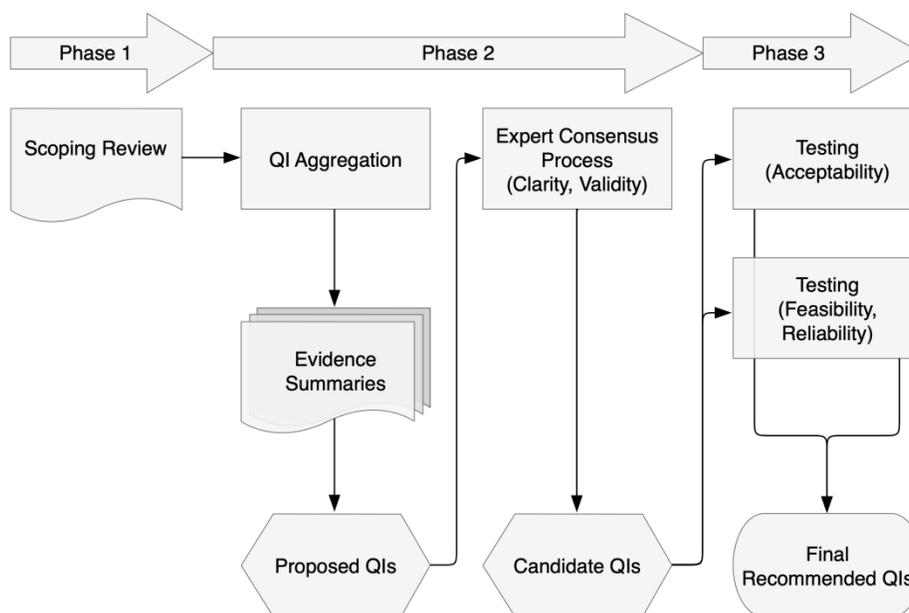


Figure 1: Flow diagram detailing the three phases of the project (QI: quality indicator)

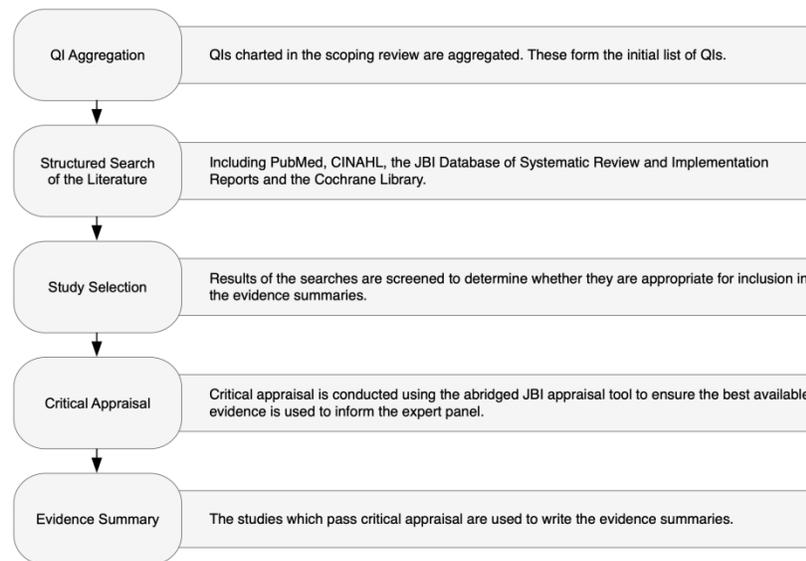


Figure 2: The evidence summary development process (adopted from Munn, Lockwood & Moola, 2015³²)

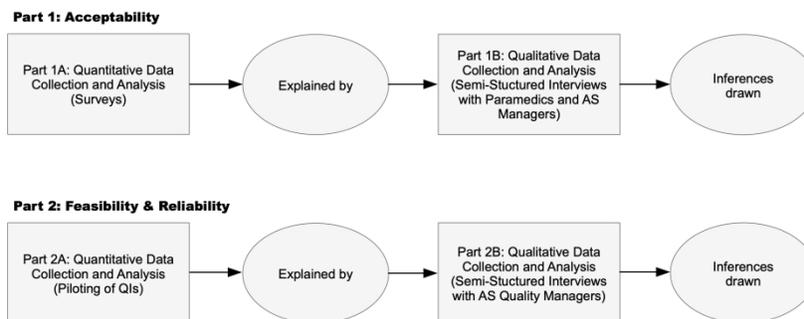


Figure 3: Explanatory sequential design of phase 3 (AS: ambulance service)