Australasian Journal of Paramedicine

Research

Protocol for development of a consensus-based reporting guideline extension for pre-hospital case reports (PREHOSPITAL-CARE)

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https://doi.org/10.33151/ajp.18.885

Abstract

Introduction
Case reports make important contributions to evidence-based practice. As with research of any methodological design, the quality and completeness in how the evidence is reported influences the strength of the evidence. Quality in reporting is best achieved through the use of a consensus-based reporting guideline. 'Case Reports' (CARE) is a 13-item reporting guideline for case reports. To make CARE more applicable, several discipline specific 'extensions' have been developed. Pre-hospital care is an emerging clinical discipline rich in its own specific context and character. Therefore, the aim of this project is to develop and disseminate a pre-hospital extension of the CARE reporting guideline (PREHOSPITAL-CARE).

Methods
This project will consist of four phases and will be undertaken in accordance with the Enhancing the Quality and Transparency of Health Research (EQUATOR) Network's guidance for developers of health research reporting guidelines. Phase 1 will comprise a systematic review aimed at identifying features commonly reported in pre-hospital case reports. In phase 2, two consensus-based processes will be conducted, including a Delphi method and an interactive consensus meeting, to produce a list of items that will form the draft guideline items for PREHOSPITAL-CARE. Phase 3 will see this draft being piloted among a selected group of pre-hospital clinicians, academics and students. In the fourth and final phase, an extensive dissemination strategy will be executed, including publication of the PREHOSPITAL-CARE reporting guideline and an 'elaboration and explanation' (E&E) companion paper to advocate for the standardised, high-quality reporting of pre-hospital case reports.

Outcomes
The final outcome will be the publication of the PREHOSPITAL-CARE reporting guideline with an associated E&E paper.

Discussion
The reporting of health research, including pre-hospital case reports, has been criticised for a lack of completeness and consistency. The development of PREHOSPITAL-CARE will enable the improvement and standardised reporting of pre-hospital case reports.

Keywords:
pre-hospital care; case report; case study; EQUATOR Network; health research reporting guidelines

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Introduction

Case reports make important contributions to evidence-based practice. Defined as a detailed narrative that describes – for medical, scientific or educational purposes – a medical problem experienced by one or several patients (1), case reports have been described as the 'eyewitness reports' of health care (2). Case reports have been instrumental in the early discovery and exploration of major health issues including congenital abnormalities associated with thalidomide use in pregnancy (3), HIV/AIDS (4), pulmonary illness from e-cigarette use (5) and early reports of COVID-19 (6). While limited in their generalisability and unable to establish any cause-effect relationship (7), case reports are useful in documenting and describing novel presentations or approaches to care (8). They can provide new ideas in health care (9) and, importantly, are a feasible contribution to scholarship for busy clinicians (10). As with research of any methodological design, the quality and completeness in how the evidence is reported influences the strength of the evidence drawn from a case report and the subsequent translational impact.

Quality in reporting of evidence has garnered increasing attention, driven, in part, through the work of the Enhancing Quality and Transparency of Health Research (EQUATOR) Network (11). Quality reporting of research enhances the capacity of readers to understand, interpret, assess and apply evidence, and reduces 'waste research' (12). Quality in reporting is best achieved through the use of a consensus-based reporting guideline, defined as a '… checklist, flow diagram, or structured text to guide authors in reporting a specific type of research, developed using explicit methodology' (13). Reporting guidelines exist for many research designs including the widely adopted PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) for systematic reviews (14) and CONSORT (Consolidated Standards of Reporting Trials) for randomised controlled trials (15).

Less well known is 'Case Reports' (CARE), a 13-item reporting guideline for case reports published in 2013 (1). Despite being produced in accordance with the EQUATOR Network's recommended guidance for the development of reporting guidelines (13), the CARE guideline has not been as widely accepted and applied as a few more high profile reporting guidelines. A barrier to adoption has been the perceived inability of CARE to accommodate the unique characteristics of each clinical discipline. This has resulted in the development of discipline specific 'extensions' to the original CARE guideline. This includes the PRICE 2020 extension for endodontic case reports (16), SCARE for surgical case reports (17), HOM-CASE for homeopathic case reports (18), and TMB for case reports in therapeutic massage and bodywork (19). An extension is based on the original reporting guideline and may include modified or additional reporting elements specific to a particular discipline or methodology.

Pre-hospital care is an emerging clinical discipline rich in its own specific context and character. Pre-hospital clinicians provide unscheduled out-of-hospital and community-based care to patients across the lifespan presenting with illness or injury across the spectrum of acuity. Through preliminary research, it was identified that adherence to the CARE reporting guideline in published pre-hospital case reports is uncommon and that the development of a pre-hospital specific extension to CARE is warranted. Using a Google Scholar search, it was found that of 735 published case reports citing the CARE guideline since the publication of CARE in 2013, only three were focussed on pre-hospital care (20). Of these three, only two appeared to closely follow the CARE reporting guideline. It is unclear why there has been poor adoption of CARE in the pre-hospital literature. Reasons could include a lack of awareness of the existence of the CARE reporting guideline; failure of journals publishing in the discipline of pre-hospital care to require adherence to the reporting guideline during manuscript submission; or a perception among authors that the existing CARE guideline is not suitable nor tailored to the unique requirements of pre-hospital care case reporting.

Against this background, the aim of this project will be to develop and disseminate a pre-hospital extension of the CARE reporting guideline, to be known as PREHOSPITAL-CARE.

Methods

This project will be undertaken in accordance with the EQUATOR Network's guidance for developers of health research reporting guidelines (13). As this is a reporting guideline extension, the project will commence with the original CARE reporting guideline as a framework. CARE was produced using a consensus process consisting of a literature review and interviews, a face-to-face consensus meeting and post-meeting feedback, review and pilot testing, followed by finalisation (1).

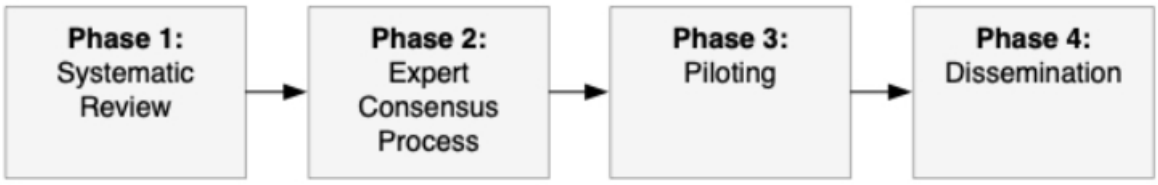

Figure 1. Phases of the PREHOSPITAL-CARE project

This proposed guideline extension project will be conducted in four phases (Figure 1):

1. A systematic review of existing published pre-hospital focussed case reports
2. An expert consensus process including Delphi method and interactive meeting to produce the items for the reporting guideline
3. Production and piloting of the draft guideline
4. Publication and dissemination of the final PREHOSPITAL-CARE reporting guideline.

Phase 1: Systematic review

Phase 1 of the project will be reported according to the PRISMA reporting guideline (14) with appropriate modifications where required. A systematic search of Medline, Embase, Emcare, CINAHL Complete and Scopus will be conducted from 1 January 2014 to August 2020. The search strategy for Medline is detailed in Table 1. A hand-search of journals of high relevance to pre-hospital care will also be undertaken. As this systematic review has no patient-based outcomes, it is excluded from prospective registration on the International Prospective Register of Systematic Reviews (PROSPERO). An alternative approach to prospective registration was taken, involving registration of the protocol with the Open Science Framework (OSF). The objectives and expected outcomes of the systematic review are reproduced here for context, with the registered protocol including the full methodology available in detail on the OSF at https://osf.io/b9j5g.

Systematic review objectives

A systematic review will be undertaken to determine:

1. The total number of case reports which primarily focus on and describe the pre-hospital care of one patient or incident in the published literature.
2. From the identified case reports, the proportion that refer to the original CARE reporting guideline, determined by either:
   - citation of the CARE guideline and/or exploration and elaboration papers, or;
   - mention of either CARE paper in the manuscript, or;
   - significant adherence to the CARE reporting guideline items/structure (without citation or reference to either CARE paper).
3. Completeness of reporting (COR) of the included case reports according to the CARE reporting guideline items.
4. Characteristics of included content and pre-hospital specific information of the included case reports.

Systematic review expected outcomes

The outcomes from this systematic review process will be:

1. A published manuscript reporting on the review objectives; and,
2. A list of pre-hospital care specific elements reported in case reports that will be used to inform the subsequent consensus process leading to creation of the PREHOSPITAL-CARE guideline extension.

Table 1. Search strategy for Medline (Ovid interface)

#	Searches	Results
1	Ambulances/	6107
2	Emergency medical Technicians/	5707
3	Air Ambulances/	2794
4	emergency medical services/	42858
5	paramedic*.tw.	7905
6	ems.tw.	12220
7	emt.tw.	22162
8	prehospital.tw.	12101
9	pre-hospital.tw.	4390
10	first responder*.tw.	2170
11	emergency medical technician*.tw.	1051
12	emergency medical services.tw.	6637
13	Ambulance*.tw.	10489
14	HEMS.tw.	703
15	field triage.tw.	265
16	“out of hospital”.tw.	10564
17	or/1-16	103971
18	Case reports.pt.	2119353
19	Case report*.tw.	371587
20	Case stud*.tw.	96853
21	(case* adj4 (report* or descri*)).ab.	568589
22	or/18-21	2378637
23	and/17,22	5521
24	(“0197-2510” or “2159-3078” or “2158-7833” or “1946-4967” or “1946-9365” or “1081-4507”).is,il.	5265
25	23 not 24	5236
26	limit 25 to (English language and yr=”2014 -Current”)	1517

Phase 2: Expert consensus process

Phase 2 of the project consists of two consensus-based processes including an online three-round Delphi method, followed by an interactive consensus meeting, as recommended by the EQUATOR Network (13).

The Delphi process

A standard Delphi process will be conducted according to published recommendations (21,22). The process will be informed by the pre-hospital care specific reporting elements identified from systematic review conducted in Phase 1. The objective of the Delphi process is to develop and refine the content for the PREHOSPITAL-CARE reporting guideline extension and in doing so, generate a list of items for consideration at the subsequent interactive meeting. Ethics approval to conduct this stage of the project will be sought from an appropriate lead Human Research Ethics Committee.

Recruitment and selection of expert consensus participants
A multipronged approach will be utilised to identify potential participants. Potential participants may include authors of published pre-hospital case reports identified in the systematic review; editors of journals that have published pre-hospital case reports as identified in the systematic review; editors of journals that focus on pre-hospital care; clinicians and/or academics with expertise in pre-hospital care; or experts in reporting guideline development. Those identified as potentially suitable to serve as a panellist will be contacted via email, which will contain approved participant information and consent forms. Those who do not respond to the initial invitation will be emailed seven and 14 days after the initial invitation. International geographical and pre-hospital care structure diversity will be sought in the formation of the expert panel.

Potential panellists who express interest in participating will then be screened to determine eligibility according to the following criteria:

1. Agree to commit to participating in the entire consensus process, and;
2. Have no declared conflicts of interest, and;
3. Demonstrated academic experience including a track record of peer-reviewed research publications, or;
4. Demonstrated authorship of at least one pre-hospital case report in a peer-reviewed journal, or;
5. Demonstrated experience with more than 5 years of practice as a pre-hospital clinician and/or academic.

Size and composition of the expert panel
While there is no clear standard on what constitutes an appropriate number of panellists to ensure validity of results in a Delphi method, a minimum panel size of 15 will be sought in line with previous reporting guideline consensus processes (23). A larger panel size has however been associated with more reliable results, so no upper limit will be applied should a high number of potential panellists express interest (24).

Survey, rounds and definition of consensus
The Delphi method will be quasi-anonymous, in that whilst anonymity between panellists will be maintained, individuals will be known to the research team. This will be made clear to potential participants in the initial information provided. Participants will be invited to be acknowledged as a member of the expert consensus panel in presentations and publications if they wish to be.

On constitution of the final panel, each panellist will receive an invite for each round of voting regardless of participation in the previous round unless they indicate withdrawal. The Delphi process will then comprise a series of three rounds of questions, responses and feedback.

- Round 1: The first round will start with the 13-item CARE checklist and the summarised results of the systematic review (Phase 1: Objective 4), with the ability to provide free-text responses. Participants will be invited to recommend adaptations to the current items and generate a list of potential new items believed to be required in order to create the PREHOSPITAL-CARE extension of the original tool. The expected outcome for Round 1 will be a list of potential new items to add to or modify the original CARE items.
- Round 2: The second round will see the panellists rate the importance of reporting each item arising from Round 1 on a 5-point Likert-style 'level of agreement' scale. The expected outcome for Round 2 will be an analysis of item rankings, followed by creation of feedback for the panel ahead of the third round. No new items will be added in Rounds 2 or 3.
- Round 3: This is the final round. Panellists will receive anonymised summarised feedback from Round 2 that will comprise each panellist's own rating compared to the frequency distribution for the ratings, the mean rating and the standard deviation (SD) of the entire panel. Panellists will be asked to consider the provided feedback when re-rating the items in this third and final round. Agreement on inclusion of an item will be deemed to have been achieved when an absolute agreement (ie. 'agree' plus 'strongly agree') of at least 80% is gained.

The expected outcome of the Delphi process is a list of reporting items that achieved at least 80% absolute agreement that will be subjected to discussion in the consensus meeting.

Expert panel meeting to gain final consensus
In line with published guidance for developers of health research reporting guidelines, an interactive meeting will be held (13). Traditional methods describe a face-to-face meeting, however convening of a hybrid face-to-face plus streamed online meeting, or online only meeting will likely be required due to the COVID-19 global pandemic. Those who participated in Round 2 will be invited to attend and form the final consensus panel. The purpose of this final interactive meeting will be to consider the agreed items generated from the Delphi method and reach final consensus on inclusion/exclusion. The meeting will provide an opportunity to discuss and document rationale for including items in the checklist, develop a flow diagram to guide future reporting, and discuss the strategy for document production and knowledge translation and dissemination (13). In the meeting, participants will receive presentations on the EQUATOR Network, advantages of using robust reporting guidelines for health research, the CARE guideline and CARE extensions for other disciplines. An open forum will be held to discuss each item of the daft checklist during which clarifications, opinions, justifications, operational definitions, and new ideas can be expressed. The expected outcome will be a final list of items that will form the draft guideline items for PREHOSPITAL-CARE.

Phase 3: Production and piloting
Drafting and piloting the guideline
Following completion of the interactive meeting, the executive group will collaborate on the preparation of the draft guideline statement that will contain the PREHOSPITAL-CARE checklist

of reporting guideline items. The draft checklist will be piloted among a selected group of pre-hospital clinicians and academics and paramedic students. Feedback from those stakeholders will then be incorporated into the final guideline ahead of submission for publication.

Drafting the 'Elaboration and Explanation' document
Concurrent to the drafting of the guideline statement, an 'elaboration and explanation' companion paper (E&E) will be prepared. An E&E publication provides detailed elaboration and explanation of how to apply the reporting guideline, and is an essential step in ensuring correct use and interpretation by future authors, editors and manuscript reviewers (13).

Phase 4: Dissemination
Peer-reviewed publications
The following publications will be produced. As per the EQUATOR Network guidance, simultaneous publication in several journals will be sought for the guideline and E&E papers, which may be produced and published simultaneously as a single paper:

1. PREHOSPITAL-CARE project protocol paper (this paper)
2. PREHOSPITAL-CARE systematic review report paper
3. PREHOSPITAL-CARE reporting guideline statement paper
4. PREHOSPITAL-CARE elaboration and explanation paper.

Conference and workshop presentations
Conference presentations and workshops, including online and face-to-face, will be sought in multiple countries to facilitate the implementation of the PREHOSPITAL-CARE reporting guideline.

Internet presence
A website containing the reporting guideline checklist and further resources will be made available at www.prehospital-care.org.

Discussion

This protocol outlines a robust plan for a project aiming to produce a consensus-based reporting guideline extension to enhance the quality and transparency of reporting of case reports in pre-hospital care. A preliminary analysis of case report quality in pre-hospital care indicated engagement with the CARE reporting guideline to be less than optimal, so pursuit of a pre-hospital extension is warranted. Pre-hospital care is an emerging discipline in the context of research, with the past 5 years seeing rapid growth in the number of peer-reviewed, discipline specific journals. Establishment of discipline-specific reporting guideline extensions such as that proposed in this project will provide the emerging pre-hospital researcher with guidance to enhance the quality and transparency of pre-hospital care research and will increase likelihood that such research can have impact on practice and policy.

The research agenda described herein conforms with best-practice standards for reporting guideline development (13), however some modifications have been incorporated. The expert consensus process that will be used to develop the guideline will likely culminate with a meeting of panellists in an online forum rather than the traditional 'face to face' meeting. There are several reasons for the adoption of an online approach. First, the suite of research will be conducted throughout 2021–2022 when restrictions on travel and large gatherings will most likely be enforced secondary to the COVID-19 pandemic. This would make organisation of a face-to-face meeting unfeasible. Second, experiences during the COVID-19 pandemic suggest an increased palatability towards online forums, facilitated by enhanced online meeting tools and programs, indicating that an effective interactive consensus meeting could be held in the online format. Third, an online forum provides a pragmatic means to reduce funding requirements that would be substantial if group international panellists were to convene face-to-face. There is no evidence to indicate an online meeting would produce inferior outcomes to one held in a face-to-face format, so we believe this adaption is justified.

Beyond the scope of this guideline development project, an evaluation of the impact of the PREHOSPITAL-CARE reporting guideline represents an essential future avenue of research. It is expected that a longitudinal analysis of published pre-hospital case reports 5 years after publication of the PREHOSPITAL-CARE reporting guideline will be undertaken to explore its impact in peer-reviewed publications. Based on those data, a recalibration of the guideline itself and the dissemination strategy may be necessary if uptake has been less optimal. This is not a mandatory step in the best-practice framework, however it may yield important data that could lead to alternative approaches to dissemination.

Conclusion

The proposed project will lead to a pre-hospital discipline-specific extension of the CARE reporting guideline for case reports, to be known as PREHOSPITAL-CARE. This will contribute to the improvement of health research evidence by enhancing the quality and transparency of research reporting.

Ethics

Ethics approval to conduct this stage of the project will be sought from an appropriate lead Human Research Ethics Committee.

Competing interests

The authors declare no competing interests. Each author of this paper has completed the ICMJE conflict of interest statement.

Funding

The PREHOSPITAL-CARE executive group would like to

acknowledge the in-kind support for the PARAMEDICS-CARE project by Flinders University, Western Sydney University, the University of Ottawa and the University of Hertfordshire.

Author contributions

All authors have made substantive intellectual contributions to the development of the project and this manuscript. JP conceptualised the project and led the writing and editing of this manuscript. RP and PS contributed significantly to the writing and editing of the manuscript. DM and JW provided support and guidance for the project and were involved in editing this manuscript. All authors read and approved the final manuscript. JP is guarantor for the manuscript and project overall.

Acknowledgements

The authors would like to thank Nikki May of the SA Health Library Service for assistance in developing the search strategy.

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