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Streamlining acute stroke and cardiac treatments using the PulsaraTM multi-disciplinary digital communication app: a pragmatic feasibility study.

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Streamlining acute stroke and cardiac treatments using the Pulsara™ multi-disciplinary digital communication app: a pragmatic feasibility study.

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Ethics

Approval for this research was obtained from Human Research Ethics Committees from participating hospitals (Bendigo Health HREC approval: LRN/16/BHCG/5, 22 March 2016; Ballarat Health Services HREC approval LRN/17/BHSSJOG/13, 28 April 2017) and the Ambulance Victoria Research and Governance Committee (R16-005, 3 May 2016).

Competing Interests
None of the authors have a financial interest in the Pulsara™ app or Pulsara Communicare Technology Inc. KLB and DAC received a travel grant paid to their institution from Pulsara Communicare Technology Inc. This grant was a contribution to defray the costs of attending an international conference to present the final results. The peer reviewed abstract submission was accepted prior to receiving the travel grant. The company had no input to the content of the abstracts or the presentations (nor this manuscript).

**Data sharing**

The authors confirm that the data supporting the findings of this study are available within the article [and/or] its supplementary materials. Patient-level raw data are subject to third party restrictions and are not publicly available due to the possibility that the privacy of research participants could be compromised.
Abstract

Background: Fast treatment delivery for acute stroke and ST-Elevation Myocardial Infarction (STEMI) is associated with better patient outcomes but requires efficient interdisciplinary communication. Multiple systems require repeating patient details, contributing to delays. We aimed to determine if a digital communication app improves care timelines for patients with suspected acute stroke/STEMI.

Methods: Real-world feasibility study, 12-month (May 2017-April 2018) quasi-experimental design. The Pulsara™ communication app was implemented pre-hospital (25 Ambulance Victoria branches) and within-hospital (2 hospitals) in regional Victoria, Australia. Pulsara provides secure, two-way, real-time communication. Paramedics or Emergency Department (ED) clinicians identified patients with suspected acute stroke (onset <4.5 hours) or STEMI. Assessment/treatment times were recorded, with timelines compared between ‘Pulsara initiated’ (Pulsara) and ‘not initiated’ (no Pulsara). Primary outcome was door-to-treatment (needle for stroke, balloon for STEMI) with other ambulance and hospital processes secondary outcomes.

Results: Stroke (no Pulsara n=215, Pulsara n=389) and STEMI (no Pulsara n=76, Pulsara n=171) groups were of similar age and sex (stroke: 76 vs 75 years; both groups 50% male; STEMI: 66 vs 63 years; 68% and 72% male). When Pulsara was used, patients were off ambulance stretcher faster for stroke (11[7,17] vs 19[11,29]; p=.0001) and STEMI (14[7,23] vs 19[10,32]; p=0.0014). ED door-to-first medical review was faster (6[2,14] vs 23[8,67]; p=0.0001) for stroke but only by 1 minute for STEMI (3[0,7] vs 4[0,14]; p=0.25). Door-to-CT times were 44 minutes faster (27[18,44] vs 71[43,147]; p=0.0001) for stroke, and percutaneous intervention (PCI) door-to-balloon times improved by 17 minutes, but non-significant (56[34,88] vs 73[49,110]; p=0.41) for STEMI. There were improvements in the
proportions of patients treated within 60 minutes for stroke (12% to 26%, p=0.15) and 90 minutes for STEMI (50% to 78%, p=0.20).

**Conclusion:** In this Australian-first study, uptake of the digital communication app was strong, patient-centred care timelines improved, although door-to-treatment times remained similar.

**Strengths and limitations of this study**

- Implementation of a single digital communication system pre-hospital and within-hospital
- Multiple health services and different clinician groups involved
- Two major acute medical conditions examined
- Pragmatic, non-randomised controlled design
- Relatively small sample size, not powered for long term clinical outcomes

**Author contributions**

CFB conceived and supervised all aspects of the research; KLB designed the evaluation and wrote the protocol; TC and DP collected the data; KLB and JK completed analyses; CFB and KLB prepared the initial manuscript; DAC contributed to the study design, supervision and provided critical revision of the article; all authors reviewed results, provided input and approved the final version of the manuscript.


Introduction

Cardiovascular disease is the leading cause of death and disability in Australia, with over 75,000 patients experiencing a stroke or STEMI (ST-Elevation Myocardial Infarction) cardiac event each year.¹ A key element to achieving better outcomes is rapid patient assessment and treatment.²,³ International guidelines detail evidence-based emergency treatment for both stroke and STEMI, including medications (i.e., aspirin and thrombolysis) and interventional procedures (e.g., revascularisation) to reopen blocked blood vessels in the brain and heart (collectively referred to as ‘reperfusion therapies’). For STEMI the benefits of reperfusion therapy are maximised when administered within the first 90 minutes following symptom onset, including less myocardial damage, fewer complications, and better short and long-term outcomes.⁴⁻⁷ Similarly, for stroke “time is brain”: every minute saved in delivering thrombolysis (<4.5 hours) equates to an extra day of disability free survival,⁸ every 20 minutes saved in delivering endovascular thrombectomy (EVT) equates to an extra 3 months of disability free survival.⁹

Timely treatment delivery for acute ischaemic stroke and STEMI requires a co-ordinated, interdisciplinary approach across multiple settings. In addition, advances in time-critical reperfusion therapies have brought the need for better integration of pre- and intra-hospital systems of care into sharp focus. Preliminary assessment, diagnosis and sometimes treatment is undertaken by paramedics in the community (pre-hospital) setting, and subsequently by clinicians in the emergency department (ED), as well as either hospital stroke (neurology and radiology) or cardiology clinicians (catheterisation laboratory [cath lab]). Pre-hospital notification of incoming patient details by paramedics provides advance notice and time for these multiple, interdisciplinary hospital teams to mobilise, prepare, and prioritise patient cases leading to faster onset-to-treatment times.¹⁰ For example, Australian registry data shows a 50% increase in the proportion of patients receiving primary percutaneous intervention
(PCI) within guideline timeframes when pre-hospital notification is undertaken (within 90 minutes: 61.3% without pre-hospital notification vs 89.3% with pre-hospital notification).\textsuperscript{11}

Pre-hospital notification to the hospital team about an incoming patient is a key time saving procedure for improving patient treatment times.\textsuperscript{12} Interdisciplinary pre-hospital communication is however often fragmented with clinicians dispersed geographically, across health services and reliant upon multiple separate communication systems, such as radio, phone and paging systems, for the one patient. This disjointed system leads to repetition of documenting clinical details, transmission of incorrect or out of date clinical information and subsequent treatment delays. New digital applications allow end-to-end communication so that patients’ clinical details such as symptoms, assessments, treatment or contraindications, and subsequent time metrics are transparent to all clinicians involved, from within the community and into the hospital setting. These types of end-to-end communication tools have not been trialled within the Australian context for pre-hospital and hospital emergency care management for acute cardiovascular and cerebrovascular conditions. To date, very few reports from other countries of HIPAA compliant options have been published\textsuperscript{13-15} with no single system being used from first-responders to hospital treatment.

Our aim was to undertake a real-world, pilot feasibility study and determine if a secure, digital communication app (Pulsara\textsuperscript{TM}), operating both between and within health services, could improve the timelines for the different stages involved in the inter-disciplinary processes of care for patients with suspected acute stroke or STEMI.

\textbf{Methods}

\textit{Design}

A quasi-experimental, pragmatic design was used with the control group defined as those patients not receiving the intervention within the study period, compared to those who did.
Differences between the two hospitals precluded a pre-post design; specifically, the cardiac PCI lab at one site only commenced soon after the intervention began. Following a 6-month feasibility pilot at hospital 1 (August 2016 to February 2017), a 12-month evaluation was conducted in Hospitals 1 and 2 (May 2017 to April 2018) simultaneously.

**Setting**

This real-world pilot feasibility study for application within the Australian context was undertaken within two large regional hospitals in Victoria, Australia, (Hospital 1=534 beds, Hospital 2=361 beds) and 25 Ambulance Victoria (AV) branches (Emergency Medical Service; EMS). A single EMS agency (AV) covers the state of Victoria. In 2017-2018, the two hospital EDs received 111,322 ED presentations per annum, 58,048 (52%) triaged as Category 1-3 (i.e., requiring attention within 30 minutes). Both hospitals treat patients with acute ischaemic stroke or STEMI, including access to cardiac PCI and support from the Victorian Stroke Telemedicine (VST) service. Patients requiring endovascular thrombectomy for cerebral large vessel occlusion are urgently transferred to hospitals in metropolitan Melbourne.

**Digital Health Technology**

The Pulsara™ smartphone/tablet app (Pulsara; [www.pulsara.com](http://www.pulsara.com)) is designed for secure (HIPPA compliant) sharing of patient details, symptoms, arrival time, plus tracking of treatment time metrics (e.g. arrival at ED, CT brain imaging, PCI cath lab, stroke/STEMI reperfusion times) and possible contra-indications for treatment (Figure 1). Images are securely sent to expedite hospital triage/patient identification (e.g., patient’s driver’s licence, utility accounts), or facilitate patient care (e.g., medication lists, ambulance vitals, or ECG results). Patient details and team member status (e.g., which clinicians have acknowledged the incoming case) are available to case-relevant users. Pulsara has condition-specific
modules (i.e., stroke, STEMI, trauma, sepsis, mental health) with disease-specific data fields (e.g., last known well time for stroke). Minimum data fields allow rapid input and sharing, with clinical updates pushed simultaneously to all users on a case. Upon conclusion, a case summary is provided to all those involved, and data extractions (e.g., for monitoring and feedback) can be made immediately or cumulatively.

Pulsara can be activated by ambulance paramedics to pre-notify patient’s arrival to the hospital ED, or the hospital can initiate a case for “walk-ins” or hospital inpatients, as relevant. The ED can then simultaneously alert and synchronise care across multiple hospital departments as relevant (e.g., Cath Lab, Radiology, Cardiac team, Stroke team), prior to the ambulance arriving at the ED with a patient. The Pulsara app was downloaded onto paramedics’ and clinicians’ personal and/or dedicated work smartphones with dedicated iPads situated in ED, Cardiology and Radiology. At the time of implementation in 2016, only the stroke and STEMI modules were available (Pulsara version 4.6). Pulsara version 11 (November 2020) is currently used.

Procedure

Eligible patients were those with suspected acute stroke (with symptom onset < 4.5 hours or unknown onset) or STEMI, as identified by AV or hospital personnel. For AV paramedics, if cases required pre-notification, then Pulsara was to be activated. As this was a research study, usual paramedic communication systems were a medicolegal requirement throughout the evaluation period; that is, activating Pulsara was an additional procedure required of paramedics and hospital personnel. At the time of the trial, usual pre-notification communication systems involved patient information exchanged via multiple systems, with some variations across different hospitals. Communication flow generally involved paramedics radioing to an AV Clinician who forwarded information via phone to the ED.

Where relevant, the ED then activated a ‘stroke alert’ or ‘cardiac alert’ by notifying
switchboard where pager messages were activated to those on the team. Fax was used between AV and the ED to share ECG results and between ED and Radiology to indicate CT required.

Pre-hospital and hospital assessment and treatment times were recorded, patient at triage, patient off AV stretcher, ambulance hospital departure time, with hospital times of patient arrival in ED (door time) and first medical review. For patients with suspected stroke, CT time available and thrombolysis time (where relevant), and for patient with suspected STEMI undergoing primary PCI, procedure start time and balloon time were collected systematically (case report forms) from sources independent from the project; that is, from AV and hospital data systems.

**Patient and Public Involvement**

Patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans of our research.

Approval for this research was obtained from Human Research Ethics Committees from participating hospitals (Bendigo Health HREC approval: LRN/16/BHCG/5, 22 March 2016; Ballarat Health Services HREC approval LRN/17/BHSSJOG/13, 28 April 2017) and the Ambulance Victoria Research and Governance Committee (R16-005, 3 May 2016).

**Statistical analyses**

To examine group differences between when Pulsara was or was not used, chi² tests for categorical, and Kruskal-Wallis tests for continuous variables, were conducted within STATA (v16). The primary outcome was door-to-treatment (needle for stroke and balloon for STEMI, with secondary outcomes for ambulance metrics as arrival at hospital to triage, arrival at hospital to off-stretcher and arrival at hospital to hospital departure times with
hospital metrics as door to first medical review, door to CT (stroke only), door to procedure (STEMI only). Author KB had full access to all the data in the study and takes responsibility for its integrity and the data analysis. Data quality checks were undertaken.

Results

There were 604 patients with suspected acute stroke and 247 with suspected STEMI identified by paramedics and hospital personnel (Table 1). Pulsara was activated for 64% of stroke cases and 69% of STEMI cases. When Pulsara was activated, the majority (57%) of stroke cases were initiated by paramedics. Hospital ED staff activated a Pulsara case on behalf of the paramedics in 16% of cases for STEMI, while 42% of cases were self-presenting. Patients were similar in age and gender for stroke and STEMI cohorts regardless of whether Pulsara was, or was not, activated (Table 2).

Stroke

For suspected stroke cases, the median times (IQRs) for paramedic metrics with (n=206) and without (n=272) Pulsara are reported in Table 3. Compared to cases where Pulsara was not initiated, use of Pulsara by paramedics resulted in triage 4 minutes faster (p=0.0001), off stretcher 8 minutes faster (p=0.0001), and paramedics departed hospital 5 minutes faster (p=0.0001).

Hospital based metrics for patients with suspected stroke are reported in Table 4. Compared to cases where Pulsara was not used, patient first medical review was 17 minutes faster (p=0.0001), and CT scan undertaken 44 minutes faster (p=0.0001) when Pulsara was used. As Pulsara was used in 96% (52/54) of patients receiving thrombolysis, door to needle times were compared with the equivalent pre-Pulsara period (same time period, 12 months earlier).
Door-to-needle time improved by 6 minutes \( (p=0.36) \) with a higher but non-significant proportion receiving treatment within 60 minutes \( (12\% \text{ pre-Pulsara vs } 25\% \text{ Pulsara}; p=0.15) \).

**STEMI**

For STEMI cases, median time (IQRs) for paramedic metrics with \( (n=73) \) and without \( (n=84) \) Pulsara are reported in Table 5. Compared to cases where Pulsara was not initiated, use of Pulsara resulted in triage 3 minutes faster \( (p=0.004) \), and off stretcher 5 minutes faster \( (p=0.014) \). Paramedics departed the hospital 14 minutes slower \( (p=0.031) \).

Hospital based metrics for STEMI cases are reported in Table 6. Time from patient arriving in ED and first medical review was similar \( (1 \text{ minute faster, } p=0.25) \), PCI procedure start time improved by 6 minutes \( (p=0.42) \), and door-to-balloon by 17 minutes although not significant \( (p=0.41) \). With Pulsara, there was increased proportion of PCI procedures (door-to-balloon time) started within 90 minutes \( (50\% \text{ no Pulsara to } 78\% \text{ Pulsara, } p=0.20) \).

**Discussion**

Our prospective, real-world feasibility study is the first to systematically examine the use of Pulsara for the treatment of stroke and STEMI across the entire patient care journey; that is, from patient assessment in the community to patient treatment in hospital. Health services’ agreement and subsequent participation in the trial indicates the feasibility of implementing a single communication system across multiple health services \( \text{(i.e., AV and two regional hospitals)} \). This agreement extended across clinicians within multiple disciplines \( \text{(e.g., ED, Radiology, Neurology, Cardiology)} \). There was excellent uptake in the use of Pulsara by clinicians with over 90% use in stroke cases receiving thrombolysis, and STEMI cases undergoing PCI. For all eligible cases however, Pulsara was not activated for approximately one third of both stroke and STEMI cases. During this research study, clinicians had to use
usual communication systems and Pulsara was an additional step, that was not undertaken in 100% of eligible cases. Our process evaluation data (unpublished data) suggests that cases where Pulsara was not used were largely due to issues of technology (e.g. forgot password/PIN), time constraints (e.g. added time) or human error (e.g., remembering to use the app) reasons. Implementation of the Pulsara digital communication application resulted in faster metrics of the patient arriving at hospital and being at triage when Pulsara was used, as well as patient off ambulance stretcher times for both stroke and STEMI cases. Hospital metrics for stroke cases also improved significantly with door-to-first medical review and door-to-CT completed more rapidly. Improvements in door-to- treatment times for suspected stroke (door-to-needle) and STEMI (door-to- procedure/balloon) did not reach significance, possibly due to small sample sizes, however they were in the expected direction.

Previous studies evaluating the use of Pulsara have not compared metrics across both pre-hospital and within hospital for treatment of stroke and STEMI. A single hospital comparison of tPA stroke cases (n=34 pre/n=34 post use of Pulsara) demonstrated a 28% significant improvement (77 to 56 minutes, p=.001) in door to needle time (DTNT), as well as greater proportion of cases achieving DTNT <60 minutes (32% to 82%, p=0.001) after Pulsara implementation.\(^\text{19}\) In a larger retrospective cohort study of stroke codes at 12 medical centres (n = 2589) using Pulsara, those cases activated by EMS were more likely to receive tPA than those with ED activation (20% vs 12%, p<.0001).\(^\text{20}\) Cases with EMS activation had shorter door to CT (6 minutes, 95% CI [-10.3, -2]) and shorter DTNT (12.8 minutes, 95% CI [-21, -4.6]).\(^\text{20}\) For treatment of STEMI, a pre (4 month) / post (6 month) retrospective hospital study that implemented Pulsara reported reduced door to balloon times (DTBT) by 22% (91 minutes to 71 minutes, p=.05), and greater numbers of DTBT cases <60 minutes (56% to 80%).\(^\text{13}\)
The importance of time to treatment is well-established. The mantra for urgency in the
treatment of STEMI and stroke has been that “time is muscle” and “time is brain”
respectively, with a focus on reperfusion achieved within 60 minutes (stroke), 30 minutes (for
STEMI thrombolysis) and 90 minutes (for STEMI-PCI). Treatment however can be
inconsistent. One in three STEMI patients in Australia did not receive any form of
reperfusion and of those who did, only one in three received it in an optimal time frame.21
Comparing STEMI populations from regional (predominantly receiving thrombolysis) and
metro hospitals (predominantly receiving PCI) indicated no difference in reperfusion rates,
and no difference in long term outcomes. This emphasises that time to reperfusion is more
important than modality of reperfusion.21 It is clear that reducing total system delay (from
first medical contact to reperfusion therapy) is more strongly associated with mortality than
patient delay in seeking care.22 In recent 2018 data from an Australian registry (Victorian
Cardiac Outcomes Registry; VCOR), it was found that 81% of PCI cases are treated within
90 minutes (median time to PCI 58 minutes [IQR: 39, 83]). This increased to 89% with pre-
hospital notification. However, in the 1/3 of cases where there was no pre-hospital
notification, only 61% were treated with PCI <90 minutes (median time to PCI 80 minutes;
IQR: 56, 112 ).11

Improvements in one aspect of healthcare may have implications in another areas. For
example, with the use of Pulsara for STEMI cases (with pre-hospital notification, sharing
ECGs etc.), the entire cardiac team was often fully mobilised before the patient arrived in the
ED triage area. Patients were transferred directly from triage to the cath lab on the ambulance
stretcher, rather than moving the patient to an ED stretcher. This streamlined care was
reflected in a longer time for paramedics to depart hospital (by 14 minutes; p=0.031). Recent
advances in stroke care now support the pre-hospital delivery of thrombolysis via the Mobile
Stroke Unit (i.e., a specialised ambulance with a CT scanner and stroke team).23 Immediate
and accurate sharing of patient clinical and treatment information with the receiving hospital
is essential. A single communication system such as Pulsara that covers both the pre- and
within-hospital settings further supports the integration of treatment advances that span both
community and medical settings.

Our study has a number of strengths, including evaluation with two acute medical conditions
involving different clinician groups, across multiple health services. A number of limitations,
however, need to be considered when reviewing results. First, the study design was pragmatic
and a non-randomised controlled design that was not powered for clinical effectiveness. This
limitation includes no control for case mix. For STEMI PCI cases, the sites were not
equivalent prior to the Pulsara implementation period (i.e., no cath lab at one site during the
pre-Pulsara period but opened the same week that the Pulsara intervention period
commenced); comparisons were therefore between cases that used and did not use Pulsara.
This approach accounted for changes across time, such as other improvements within the
hospital/s. Pulsara was also used in a very high proportion of cases receiving stroke
thrombolysis (96%), illustrating clinicians’ willingness to use Pulsara for their acute cases.
However, this uptake necessitated a pre-post comparison for DTNT times (comparison times
were sourced from the same period in the previous year at each hospital). Second, although
the overall small number of tPA/PCI cases in these regional hospitals were low and precluded
achieving statistical significance, the consistent clinically significant time improvements
suggest improved patient outcomes are likely. Finally, it is also important to note that for
medicolegal surety, the usual communication systems were retained throughout the study
period; that is, the use of Pulsara was in addition to usual communications. We would
therefore anticipate even faster timelines when Pulsara is not an additional step, but the only
communication system utilised. Despite this, the ease of use and benefits of time saved for
paramedics and ED clinicians in removal of repetition of information was readily apparent
with clinicians electing to use Pulsara in addition to usual systems.

In conclusion, the use of Pulsara led to shorter timelines in the care of patients with suspected
stroke and STEMI. While stroke thrombolysis/PCI numbers were perhaps small, the gains
were similarly apparent, with increased numbers within defined treatment time windows
(<60/<90 minutes). Strong uptake suggests the clinical utility of such a communication
system. Patient-centred care needs a patient-centred communication system incorporating
patients identified in the community by first responders, then assessed and treated by multiple
clinicians within the community and hospital setting. Our research provides evidence that
Pulsara can be used as a single digital communication system to enhance the emergency
management of patients across multiple conditions. Identifying significant improvements in
the timelines for other acute conditions such as trauma, sepsis and mental health warrants
further research.
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Table 1: Activation of Pulsara

| Activation status, and location | Stroke (N=604) | STEMI (N=247) |
|---------------------------------|---------------|---------------|
| Not activated                   | 215 (36%)     | 76 (31%)      |
| Activated cases                 | 389 (64%)     | 171 (69%)     |
| Ambulance Victoria (AV)         | 223 (57%)     | 71 (42%)      |
| Emergency Department on behalf of AV | 41 (11%) | 28 (16%) |
| Emergency Department (walk-in, inpatient) | 125 (32%) | 72 (42%) |
Table 2: Demographics of participants for stroke and STEMI

| Demographic | Stroke Without Pulsara N=215 | Stroke With Pulsara N=389 | STEMI Without Pulsara N=76 | STEMI With Pulsara N=171 |
|-------------|------------------------------|---------------------------|----------------------------|----------------------------|
| Sex, male   | 107 (50%) p=0.69 195 (50%) | 52 (68%) p=0.51 123 (72%) |
| Age, years  | 76 (63, 84) p=0.25 75 (62, 82) | 66 (57, 79) p=0.35 63 (55, 74) |
Table 3: Ambulance metrics for suspected stroke

| AV Metric                                | Without Pulsara | With Pulsara | Time difference | (p value) |
|------------------------------------------|----------------|--------------|-----------------|-----------|
| Median minutes (IQR)                     | N=206          | N=272        |                 |           |
| Arrive Hospital and Triage time          | N=204          | N=272        | -4 mins         | p=0.0001  |
|                                          | 7 (3, 11)      | 3 (2, 7)     |                 |           |
| Arrive Hospital and Off-stretcher time   | N=203          | N=272        | -8 mins ^       | p=0.0001  |
|                                          | 19 (11, 29)    | 11 (7, 17)   |                 |           |
| Arrive Hospital and Depart Hospital time | N=206          | N=272        | -5 mins ^       | p=0.14    |
|                                          | 50 (36, 58)    | 45 (35, 57)  |                 |           |

Note: ^These results are if Pulsara was initiated by AV or hospital. N varies due to missing data.
Table 4: Hospital metrics for suspected stroke

| Hospital Metric                  | Median minutes (IQR) | Without Pulsara | With Pulsara | Time difference (p value) |
|---------------------------------|----------------------|-----------------|--------------|--------------------------|
| Door to first medical review    | N=155                | N=319           | -17 mins     | p=0.0001                 |
|                                 | 23 (8, 67)           | 6 (2, 14)       |              |                          |
| Door to CT completed            | N=130                | N=300           | -44 mins     | p=0.0001                 |
|                                 | 71 (43, 147)         | 27 (18, 44)     |              |                          |

Note: *Pulsara used on 96% (52/54) tPA cases, so with and without Pulsara comparisons cannot be made. Comparisons made between with and pre-Pulsara period (equivalent months in prior year). N varies between first medical review and CT as not all cases received a CT scan.
| AV Metric                                      | Without Pulsara | With Pulsara | Time difference (p value) |
|-----------------------------------------------|-----------------|--------------|--------------------------|
| **Median minutes (IQR)**                      |                 |              |                          |
| **N=73**                                      |                 |              |                          |
| Arrive Hospital and Triage time               | 6 (3, 10)       | 3 (2, 6)     | -3 mins                  |
| && p=0.004                                    |                 |              |                          |
| Arrive Hospital and Off-stretcher             | 19 (10, 32)     | 14 (7, 23)   | -5 mins                  |
| time                                          |                 |              | && p=0.014                |
| Arrive Hospital and Depart Hospital time for all suspected STEMI cases | 56 (40, 84)     | 70 (50, 90)  | +14 mins**               |
| && p=0.031                                    |                 |              |                          |
| Arrive Hospital and Depart Hospital time for Primary PCI cases only | N=8             | N=31         | +16 mins**               |
| && p=0.008                                    |                 |              |                          |
| Arrive Hospital and Depart Hospital time for non-Primary PCI cases only | N=39            | N=29         | +2 mins**                |
| && p=0.59                                     |                 |              |                          |

**Note:** #includes if AV or ED activate App. ## Extended time with patients being transferred on ambulance stretchers to Cath Lab and paramedics staying to watch PCI procedure (new Cath Lab). N varies due to missing data.
### Table 6: Hospital metrics for suspected STEMI

| Hospital Metric                        | Without | With | Time difference |
|----------------------------------------|---------|------|-----------------|
|                                        | Median minutes (IQR) | Pulsara | Pulsara | (p value) |
|                                        | N=52 | N=142 |                  | -1 min   |
| Door to first medical review           | 4 (0, 14) | 3 (0, 7) |                  | p=0.25   |
|                                        | N=6 | N=61 |                  | -6 mins  |
| Door to Procedure start time for Primary PCI # | 41 (27, 87) | 35 (19, 59) |                  | p=0.42   |
| Door to Procedure start time for Primary PCI <90 minutes | 5/6 | 55/61 |                  | p=0.60   |
| Door to Balloon time                   | N=4 | N=46 |                  | -17 mins |
|                                        | 73 (49, 110) | 56 (34, 88) |                  | p=0.41   |
| Door to Balloon < 90 minutes           | 2/4 | 36/46 |                  | p=0.20   |
|                                        | 50% | 78% |                  |           |

Note: # includes if AV or ED activate App. Procedure time reported as balloon time may have delays within operation and balloon time not captured for all cases. Direct admits precluded door times for 8 patients. N varies as not all cases had a procedure/balloon and there were missing data for some balloon times.
Legend

Figure 1: Screen shots Pulsara™ STOP Stroke/STEMI (version 4.6 originally implemented June 2016, version 11 in use November 2020): a) select patient condition, b) enter patient symptoms, c) adding images (e.g., driver’s licence) or messages, d) alert Emergency Department. See www.Pulsara.com for video.
Figure 1: Screen shots Pulsara™ STOP Stroke/STEMI (version 4.6 originally implemented June 2016, version 11 in use November 2020): a) select patient condition, b) enter patient symptoms, c) adding images (e.g., driver’s licence) or messages, d) alert Emergency Department. See www.Pulsara.com for video.
Completed for the submitted manuscript titled

Streamlining acute stroke and cardiac treatments using the Pulsara™ multi-disciplinary digital communication app: a pragmatic feasibility study.

Revised Standards for Quality Improvement Reporting Excellence (SQUIRE 2.0)  
September 15, 2015  
Text Section and Item Name  
Notes to authors  
□ The SQUIRE guidelines provide a framework for reporting new knowledge about how to improve healthcare  
□ The SQUIRE guidelines are intended for reports that describe system level work to improve the quality, safety, and value of healthcare, and used methods to establish that observed outcomes were due to the intervention(s).  
□ A range of approaches exists for improving healthcare. SQUIRE may be adapted for reporting any of these.  
□ Authors should consider every SQUIRE item, but it may be inappropriate or unnecessary to include every SQUIRE element in a particular manuscript.  
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□ Please cite SQUIRE when it is used to write a manuscript.

Title and Abstract  
1. Title  
Indicate that the manuscript concerns an initiative to improve healthcare (broadly defined to include the quality, safety, effectiveness, patient-centeredness, timeliness, cost, efficiency, and equity of healthcare)  
Yes, p1
2. Abstract
   a. Provide adequate information to aid in searching and indexing
   b. Summarize all key information from various sections of the text using the abstract format of the intended publication or a structured summary such as: background, local problem, methods, interventions, results, conclusions
   Yes, p5

Introduction
   Why did you start?
   Nature and significance of the local problem
   Yes pp 7-8

3. Problem Description
   Summary of what is currently known about the problem, including relevant previous studies
   Yes p 8

4. Available knowledge
   Informal or formal frameworks, models, concepts, and/or theories used to explain the problem, any reasons or assumptions that were used to develop the intervention(s), and reasons why the intervention(s) was expected to work
   Yes p 8

5. Rationale
   Purpose of the project and of this report
   Yes p 8

6. Specific aims

Methods
   What did you do?
   Contextual elements considered important at the outset of introducing the intervention(s)
   Yes, p 9 Setting
   And p 10 Procedure

7. Context

8. Intervention(s)
   a. Description of the intervention(s) in sufficient detail that others could reproduce it
   b. Specifics of the team involved in the work
   Yes, p 9 Intervention and Figure 1, p 6 contribution of authors and p2 acknowledgements

9. Study of the Intervention(s)
   a. Approach chosen for assessing the impact of the intervention(s)
   b. Approach used to establish whether the observed outcomes were due to the intervention(s)
   Yes pp 8-9 Design,

10. Measures
   a. Measures chosen for studying processes and outcomes of the intervention(s), including rationale for choosing them, their operational definitions, and their validity and reliability
   Yes p 11 and 12, Statistical analyses, primary and secondary outcomes; data
b. Description of the approach to the ongoing assessment of contextual elements that contributed to the success, failure, efficiency, and cost

c. Methods employed for assessing completeness and accuracy of data

11. Analysis

a. Qualitative and quantitative methods used to draw inferences from the data
b. Methods for understanding variation within the data, including the effects of time as a variable

12. Ethical Considerations

Ethical aspects of implementing and studying the intervention(s) and how they were addressed, including, but not limited to, formal ethics review and potential conflict(s) of interest

Results

What did you find?

13. Results

a. Initial steps of the intervention(s) and their evolution over time (e.g., time line diagram, flow chart, or table), including modifications made to the intervention during the project
b. Details of the process measures and outcome
c. Contextual elements that interacted with the intervention(s)
d. Observed associations between outcomes, interventions, and relevant contextual elements
e. Unintended consequences such as unexpected benefits, problems, failures, or costs associated with the intervention(s).
f. Details about missing data

Discussion

What does it mean?

14. Summary

a. Key findings, including relevance to the rationale and specific aims
b. Particular strengths of the project

15. Interpretation

a. Nature of the association between the intervention(s) and the outcomes
b. Comparison of results with findings from other publications
c. Impact of the project on people and systems
d. Reasons for any differences between observed and anticipated outcomes, including the influence of context
e. Costs and strategic trade-offs, including opportunity costs

16. Limitations
   a. Limits to the generalizability of the work
   b. Factors that might have limited internal validity such as confounding, bias, or imprecision in the design, methods, measurement, or analysis
   c. Efforts made to minimize and adjust for limitations

17. Conclusions
   a. Usefulness of the work
   b. Sustainability
   c. Potential for spread to other contexts
   d. Implications for practice and for further study in the field
   e. Suggested next steps

Yes p 16 and p17

Other information

18. Funding
   Sources of funding that supported this work. Role, if any, of the funding organization in the design, implementation, interpretation, and reporting

Yes p 3 Sources of funding; funders had no role in any aspect of the conducting or reporting on the study
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Streamlining acute stroke and cardiac treatments using the Pulsara™ multi-disciplinary digital communication app: a pragmatic feasibility study.

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Ethics

Approval for this research was obtained from Human Research Ethics Committees from
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Competing Interests
None of the authors have a financial interest in the Pulsara™ app or Pulsara Communicare Technology Inc. KLB and DAC received a travel grant paid to their institution from Pulsara Communicare Technology Inc. This grant was a contribution to defray the costs of attending an international conference to present the final results. The peer reviewed abstract submission was accepted prior to receiving the travel grant. The company had no input to the content of the abstracts or the presentations (nor this manuscript).

**Data sharing**

The authors confirm that the data supporting the findings of this study are available within the article [and/or] its supplementary materials. Patient-level raw data are subject to third party restrictions and are not publicly available due to the possibility that the privacy of research participants could be compromised.
Abstract

Background: Fast treatment delivery for acute stroke and ST-Elevation Myocardial Infarction (STEMI) is associated with better patient outcomes but requires efficient interdisciplinary communication. Multiple systems require repeating patient details, contributing to delays. We aimed to determine if a digital communication app improves care timelines for patients with suspected acute stroke/STEMI.

Methods: Real-world feasibility study, 12-month (May 2017-April 2018) quasi-experimental design. The Pulsara™ communication app was implemented pre-hospital (25 Ambulance Victoria branches) and within-hospital (2 hospitals) in regional Victoria, Australia. Pulsara provides secure, two-way, real-time communication. Paramedics or Emergency Department (ED) clinicians identified patients with suspected acute stroke (onset <4.5 hours) or STEMI. Assessment/treatment times were recorded, with timelines compared between ‘Pulsara initiated’ (Pulsara) and ‘not initiated’ (no Pulsara). Primary outcome was door-to-treatment (needle for stroke, balloon for STEMI) with other ambulance and hospital processes secondary outcomes.

Results: Stroke (no Pulsara n=215, Pulsara n=389) and STEMI (no Pulsara n=76, Pulsara n=171) groups were of similar age and sex (stroke: 76 vs 75 years; both groups 50% male; STEMI: 66 vs 63 years; 68% and 72% male). When Pulsara was used, patients were off ambulance stretcher faster for stroke (11[7,17] vs 19[11,29]; p=.0001) and STEMI (14[7,23] vs 19[10,32]; p=0.0014). ED door-to-first medical review was faster (6[2,14] vs 23[8,67]; p=0.0001) for stroke but only by 1 minute for STEMI (3[0,7] vs 4[0,14]; p=0.25). Door-to-CT times were 44 minutes faster (27[18,44] vs 71[43,147]; p=0.0001) for stroke, and percutaneous intervention (PCI) door-to-balloon times improved by 17 minutes, but non-significant (56[34,88] vs 73[49,110]; p=0.41) for STEMI. There were improvements in the
proportions of patients treated within 60 minutes for stroke (12% to 26%, p=0.15) and 90 minutes for STEMI (50% to 78%, p=0.20).

**Conclusion:** In this Australian-first study, uptake of the digital communication app was strong, patient-centred care timelines improved, although door-to-treatment times remained similar.

**Strengths and limitations of this study**

- Implementation of a single digital communication system pre-hospital and within-hospital
- Multiple health services and different clinician groups involved
- Two major acute medical conditions examined
- Pragmatic, non-randomised controlled design
- Relatively small sample size, not powered for long term clinical outcomes

**Author contributions**

CFB conceived and supervised all aspects of the research; KLB designed the evaluation and wrote the protocol; TC and DP collected the data; KLB and JK completed analyses; CFB and KLB prepared the initial manuscript; DAC contributed to the study design, supervision and provided critical revision of the manuscript; MV, JK, SB, KS, GH, TC, DP, DV, MB, VN, WP, HH, BK, AS, PC, EO, RS, TK, CH, DS reviewed results, provided input and all authors approved the final version of the manuscript.

**Data availability**

The authors confirm that the data supporting the findings of this study are available within the article [and/or] its supplementary materials. Patient-level raw data are subject to third
party restrictions and are not publicly available due to the possibility that the privacy of research participants could be compromised.
Introduction

Cardiovascular disease is the leading cause of death and disability in Australia, with over 75,000 patients experiencing a stroke or STEMI (ST-Elevation Myocardial Infarction) cardiac event) each year.\(^1\) A key element to achieving better outcomes is rapid patient assessment and treatment.\(^2,3\) International guidelines detail evidence-based emergency treatment for both stroke and STEMI, including medications (i.e., aspirin and thrombolysis) and interventional procedures (e.g., revascularisation) to reopen blocked blood vessels in the brain and heart (collectively referred to as ‘reperfusion therapies’). For STEMI the benefits of reperfusion therapy are maximised when administered within the first 90 minutes following symptom onset, including less myocardial damage, fewer complications, and better short and long-term outcomes.\(^4-7\) Similarly, for stroke “time is brain”: every minute saved in delivering thrombolysis (<4.5 hours) equates to an extra day of disability free survival,\(^8\) every 20 minutes saved in delivering endovascular thrombectomy (EVT) equates to an extra 3 months of disability free survival.\(^9\)

Timely treatment delivery for acute ischaemic stroke and STEMI requires a co-ordinated, interdisciplinary approach across multiple settings. In addition, advances in time-critical reperfusion therapies have brought the need for better integration of pre- and intra-hospital systems of care into sharp focus. Preliminary assessment, diagnosis and sometimes treatment is undertaken by paramedics in the community (pre-hospital) setting, and subsequently by clinicians in the emergency department (ED), as well as either hospital stroke (neurology and radiology) or cardiology clinicians (catheterisation laboratory [cath lab]). Pre-hospital notification of incoming patient details by paramedics provides advance notice and time for these multiple, interdisciplinary hospital teams to mobilise, prepare, and prioritise patient cases leading to faster onset-to-treatment times.\(^10\) For example, Australian registry data shows a 50% increase in the proportion of patients receiving primary percutaneous intervention
(PCI) within guideline timeframes when pre-hospital notification is undertaken (within 90 minutes: 61.3% without pre-hospital notification vs 89.3% with pre-hospital notification).\textsuperscript{11}

Pre-hospital notification to the hospital team about an incoming patient is a key time saving procedure for improving patient treatment times.\textsuperscript{12} Interdisciplinary pre-hospital communication is however often fragmented with clinicians dispersed geographically, across health services and reliant upon multiple separate communication systems, such as radio, phone and paging systems, for the one patient. This disjointed system leads to repetition of documenting clinical details, transmission of incorrect or out of date clinical information and subsequent treatment delays. New digital applications allow end-to-end communication so that patients’ clinical details such as symptoms, assessments, treatment or contraindications, and subsequent time metrics are transparent to all clinicians involved, from within the community and into the hospital setting. These types of end-to-end communication tools have not been trialled within the Australian context for pre-hospital and hospital emergency care management for acute cardiovascular and cerebrovascular conditions. To date, very few reports from other countries of HIPAA compliant options have been published\textsuperscript{13-15} with no single system being used from first-responders to hospital treatment.

Our aim was to undertake a real-world, pilot feasibility study and determine if a secure, digital communication app (Pulsara\textsuperscript{TM}), operating both between and within health services, could improve the timelines for the different stages involved in the inter-disciplinary processes of care for patients with suspected acute stroke or STEMI.

\textbf{Methods}

\textit{Design}

A quasi-experimental, pragmatic design was used with the control group defined as those patients not receiving the intervention within the study period, compared to those who did.
Differences between the two hospitals precluded a pre-post design; specifically, the cardiac PCI lab at one site only commenced soon after the intervention began. Following a 6-month feasibility pilot at hospital 1 (August 2016 to February 2017), a 12-month evaluation was conducted in Hospitals 1 and 2 (May 2017 to April 2018) simultaneously.

Setting

This real-world pilot feasibility study for application within the Australian context was undertaken within two large regional hospitals in Victoria, Australia, (Hospital 1=534 beds, Hospital 2=361 beds) and 25 Ambulance Victoria (AV) branches (Emergency Medical Service; EMS). A single EMS agency (AV) covers the state of Victoria. In 2017-2018, the two hospital EDs received 111,322 ED presentations per annum, 58,048 (52%) triaged as Category 1-3 (i.e., requiring attention within 30 minutes). Both hospitals treat patients with acute ischaemic stroke or STEMI, including access to cardiac PCI and support from the Victorian Stroke Telemedicine (VST) service. Patients requiring endovascular thrombectomy for cerebral large vessel occlusion are urgently transferred to hospitals in metropolitan Melbourne.

Digital Health Technology

The Pulsara™ smartphone/tablet app (Pulsara; www.pulsara.com) is designed for secure (HIPAA compliant) sharing of patient details, symptoms, arrival time, plus tracking of treatment time metrics (e.g. arrival at ED, CT brain imaging, PCI cath lab, stroke/STEMI reperfusion times) and possible contra-indications for treatment (Figure 1). Images are securely sent to expedite hospital triage/patient identification (e.g., patient’s driver’s licence, utility accounts), or facilitate patient care (e.g., medication lists, ambulance vitals, or ECG results). Patient details and team member status (e.g., which clinicians have acknowledged the incoming case) are available to case-relevant users. Pulsara has condition-specific
modules (i.e., stroke, STEMI, trauma, sepsis, mental health) with disease-specific data fields (e.g., last known well time for stroke). Minimum data fields allow rapid input and sharing, with clinical updates pushed simultaneously to all users on a case. Upon conclusion, a case summary is provided to all those involved, and data extractions (e.g., for monitoring and feedback) can be made immediately or cumulatively.

Pulsara can be activated by ambulance paramedics to pre-notify patient’s arrival to the hospital ED, or the hospital can initiate a case for “walk-ins” or hospital inpatients, as relevant. The ED can then simultaneously alert and synchronise care across multiple hospital departments as relevant (e.g., Cath Lab, Radiology, Cardiac team, Stroke team), prior to the ambulance arriving at the ED with a patient. The Pulsara app was downloaded onto paramedics’ and clinicians’ personal and/or dedicated work smartphones with dedicated iPads situated in ED, Cardiology and Radiology. At the time of implementation in 2016, only the stroke and STEMI modules were available (Pulsara version 4.6). Pulsara version 11 (November 2020) is currently used.

Procedure

Eligible patients were those with suspected acute stroke (with symptom onset < 4.5 hours or unknown onset) or STEMI, as identified by AV or hospital personnel. For AV paramedics, if cases required pre-notification, then Pulsara was to be activated. As this was a research study, usual paramedic communication systems were a medicolegal requirement throughout the evaluation period; that is, activating Pulsara was an additional procedure required of paramedics and hospital personnel. At the time of the trial, usual pre-notification communication systems involved patient information exchanged via multiple systems, with some variations across different hospitals. Communication flow generally involved paramedics radioing to an AV Clinician who forwarded information via phone to the ED.

Where relevant, the ED then activated a ‘stroke alert’ or ‘cardiac alert’ by notifying
switchboard where pager messages were activated to those on the team. Fax was used 
between AV and the ED to share ECG results and between ED and Radiology to indicate CT 
required.

Pre-hospital and hospital assessment and treatment times were recorded, patient at triage, 
patient off AV stretcher, ambulance hospital departure time, with hospital times of patient 
arrival in ED (door time) and first medical review. For patients with suspected stroke, CT 
time available and thrombolysis time (where relevant), and for patient with suspected STEMI 
undergoing primary PCI, procedure start time and balloon time were collected systematically 
(case report forms) from sources independent from the project; that is, from AV and hospital 
data systems.

Patient and Public Involvement

Patients or the public were not involved in the design, or conduct, or reporting, or 
dissemination plans of our research.

Approval for this research was obtained from Human Research Ethics Committees from 
participating hospitals (Bendigo Health HREC approval: LRN/16/BHC5/5, 22 March 2016; 
Ballarat Health Services HREC approval LRN/17/BHSSJOG/13, 28 April 2017) and the 
Ambulance Victoria Research and Governance Committee (R16-005, 3 May 2016).

Statistical analyses

To examine group differences between when Pulsara was or was not used, chi² tests for 
categorical, and Kruskal-Wallis tests for continuous variables, were conducted within 
STATA (v16). The primary outcome was door-to-treatment (needle for stroke and balloon for 
STEMI, with secondary outcomes for ambulance metrics as arrival at hospital to triage, 
arrival at hospital to off-stretcher and arrival at hospital to hospital departure times with
hospital metrics as door to first medical review, door to CT (stroke only), door to procedure (STEMI only). Author KB had full access to all the data in the study and takes responsibility for its integrity and the data analysis. Data quality checks were undertaken.

Results

There were 604 patients with suspected acute stroke and 247 with suspected STEMI identified by paramedics and hospital personnel (Table 1). Pulsara was activated for 64% of stroke cases and 69% of STEMI cases. When Pulsara was activated, the majority (57%) of stroke cases were initiated by paramedics. Hospital ED staff activated a Pulsara case on behalf of the paramedics in 16% of cases for STEMI, while 42% of cases were self-presenting. Patients were similar in age and gender for stroke and STEMI cohorts regardless of whether Pulsara was, or was not, activated (Table 2).

Stroke

For suspected stroke cases, the median times (IQRs) for paramedic metrics with (n=206) and without (n=272) Pulsara are reported in Table 3. Compared to cases where Pulsara was not initiated, use of Pulsara by paramedics resulted in triage 4 minutes faster (p=0.0001), off stretcher 8 minutes faster (p=0.0001), and paramedics departed hospital 5 minutes faster (p=0.0001). Overall, the time between patient ambulance loaded and hospital arrival for stroke was 5mins faster if Pulsara was used (18mins vs 13mins P<0.0009). On arrival at hospital, 92% of stroke patients with Pulsara were triaged as Emergency (category 1&2), compared to 47% without Pulsara (p=0.000).

Hospital-based time metrics for patients with suspected stroke are reported in Table 4. Compared to cases where Pulsara was not used, patient first medical review was 17 minutes faster (p=0.0001), and CT scan undertaken 44 minutes faster (p=0.0001) when Pulsara was
used. As Pulsara was used in 96% (52/54) of patients receiving thrombolysis, door to needle
times were compared with the equivalent pre-Pulsara period (same time period, 12 months
earlier). Door-to-needle time improved by 6 minutes (p=0.36) with a higher but non-
significant proportion receiving treatment within 60 minutes (12% pre-Pulsara vs 25%
Pulsara; p=0.15).

**STEMI**

For STEMI cases, median time (IQRs) for paramedic metrics with (n=73) and without (n=84)
Pulsara are reported in Table 5. Compared to cases where Pulsara was not initiated, use of
Pulsara resulted in triage 3 minutes faster (p=0.004), and off stretcher 5 minutes faster
(p=0.014). Paramedics departed the hospital 14 minutes slower (p=0.031). Overall, the time
between patient ambulance loaded and hospital arrival for STEMI was 23 minutes faster if
Pulsara was used (45 minutes vs 22 minutes p<0.006). On arrival at hospital, 100% of
STEMI patients with Pulsara were triaged as Emergency (categories 1 & 2), compared to
86% without Pulsara (p=0.19).

Hospital based metrics for STEMI cases are reported in Table 6. Time from patient arriving
in ED and first medical review was similar (1 minute faster, p=0.25), PCI procedure start
time improved by 6 minutes (p=0.42), and door-to-balloon by 17 minutes although not
significant (p=0.41). With Pulsara, there was increased proportion of PCI procedures (door-
to-balloon time) started within 90 minutes (50% no Pulsara to 78% Pulsara, p=0.20).

**Discussion**

Our prospective, real-world feasibility study is the first to systematically examine the use of
Pulsara for the treatment of stroke and STEMI across the entire patient care journey; that is,
from patient assessment in the community to patient treatment in hospital. Health services’
agreement and subsequent participation in the trial indicates the feasibility of implementing a single communication system across multiple health services (i.e., AV and two regional hospitals). This agreement extended across clinicians within multiple disciplines (e.g., ED, Radiology, Neurology, Cardiology). There was excellent uptake in the use of Pulsara by clinicians with over 90% use in stroke cases receiving thrombolysis, and STEMI cases undergoing PCI. For all eligible cases however, Pulsara was not activated for approximately one third of both stroke and STEMI cases. During this research study, clinicians had to use usual communication systems and Pulsara was an additional step, that was not undertaken in 100% of eligible cases. Our process evaluation data (unpublished data) suggests that paramedics report that cases where Pulsara was not used were largely due to issues of technology (e.g., forgot password/PIN), time constraints (e.g., added time) or human error (e.g., remembering to use the app) reasons. Implementation of the Pulsara digital communication application resulted in faster metrics of the patient arriving at hospital and being at triage when Pulsara was used, as well as patient off ambulance stretcher times for both stroke and STEMI cases. Hospital metrics for stroke cases also improved significantly with door-to-first medical review and door-to-CT completed more rapidly. Improvements in door-to-treatment times for suspected stroke (door-to-needle) and STEMI (door-to-procedure/balloon) did not reach significance, possibly due to small sample sizes, however they were in the expected direction.

Previous studies evaluating the use of Pulsara have not compared metrics across both pre-hospital and within hospital for treatment of stroke and STEMI. A single hospital comparison of tPA stroke cases (n=34 pre/n=34 post use of Pulsara) demonstrated a 28% significant improvement (77 to 56 minutes, p=.001) in door to needle time (DTNT), as well as greater proportion of cases achieving DTNT <60 minutes (32% to 82%, p=0.001) after Pulsara implementation. In a larger retrospective cohort study of stroke codes at 12 medical centres
(n = 2589) using Pulsara, those cases activated by EMS were more likely to receive tPA than those with ED activation (20% vs 12%, p<.0001).\textsuperscript{20} Cases with EMS activation had shorter door to CT (6 minutes, 95% CI [−10.3, −2]) and shorter DTNT (12.8 minutes, 95% CI [−21, -4.6]).\textsuperscript{20} For treatment of STEMI, a pre (4 month) / post (6 month) retrospective hospital study that implemented Pulsara reported reduced door to balloon times (DTBT) by 22% (91 minutes to 71 minutes, p=.05), and greater numbers of DTBT cases <60 minutes (56% to 80%).\textsuperscript{13}

The importance of time to treatment is well-established. The mantra for urgency in the treatment of STEMI and stroke has been that “time is muscle” and “time is brain” respectively, with a focus on reperfusion achieved within 60 minutes (stroke), 30 minutes (for STEMI thrombolysis) and 90 minutes (for STEMI-PCI). Treatment however can be inconsistent. One in three STEMI patients in Australia did not receive any form of reperfusion and of those who did, only one in three received it in an optimal time frame.\textsuperscript{21} Comparing STEMI populations from regional (predominantly receiving thrombolysis) and metro hospitals (predominantly receiving PCI) indicated no difference in reperfusion rates, and no difference in long term outcomes. This emphasises that \textit{time to reperfusion} is more important than \textit{modality of reperfusion}.\textsuperscript{21} It is clear that reducing total system delay (from first medical contact to reperfusion therapy) is more strongly associated with mortality than patient delay in seeking care.\textsuperscript{22} In recent 2018 data from an Australian registry (Victorian Cardiac Outcomes Registry; VCOR), it was found that 81% of PCI cases are treated within 90 minutes (median time to PCI 58 minutes [IQR: 39, 83]). This increased to 89% with pre-hospital notification. However, in the 1/3 of cases where there was no pre-hospital notification, only 61% were treated with PCI <90 minutes (median time to PCI 80 minutes; IQR: 56, 112 ).\textsuperscript{11}
Improvements in one aspect of healthcare may have implications in another areas. For example, with the use of Pulsara for STEMI cases (with pre-hospital notification, sharing ECGs etc.), the entire cardiac team was often fully mobilised before the patient arrived in the ED triage area. Patients were transferred directly from triage to the cath lab on the ambulance stretcher, rather than moving the patient to an ED stretcher. This streamlined care was reflected in a longer time for paramedics to depart hospital (by 14 minutes; p=0.031). Recent advances in stroke care now support the pre-hospital delivery of thrombolysis via the Mobile Stroke Unit (i.e., a specialised ambulance with a CT scanner and stroke team). Immediate and accurate sharing of patient clinical and treatment information with the receiving hospital is essential. A single communication system such as Pulsara that covers both the pre- and within-hospital settings further supports the integration of treatment advances that span both community and medical settings.

Our study has a number of strengths, including evaluation with two acute medical conditions involving different clinician groups, across multiple health services. A number of limitations, however, need to be considered when reviewing results. First, the design of this feasibility study was pragmatic with a non-randomised controlled design that was not powered for clinical effectiveness or patient outcomes (e.g., morbidity/mortality). This limitation includes no control for case mix. As Pulsara was an additional communication system, it was up to individual paramedic and hospital clinicians to decide to activate the app for eligible cases, which did not consistently occur. It is possible that, in some cases, paramedics may have not activated Pulsara if it was felt that the patient symptoms were perhaps too mild. For example, 92% of stroke cases with Pulsara vs 47% (p<0.000) without Pulsara were categorised as Emergency care (ED triage categories 1 & 2). This difference was less evident for STEMI cases. However, this reflects practice in the real world where paramedic clinical judgment is focused on the optimal rapid treatment of patients, particularly if they feel the symptoms are
severe. Another consideration is that for STEMI PCI cases, the sites were not equivalent prior to the Pulsara implementation period (i.e., no cath lab at one site during the pre-Pulsara period but opened the same week that the Pulsara intervention period commenced); comparisons were therefore between cases that used and did not use Pulsara. This approach accounted for changes across time, such as other improvements within the hospital/s. Pulsara was also used in a very high proportion of cases receiving stroke thrombolysis (96%), illustrating clinicians’ willingness to use Pulsara for their acute cases. However, this uptake necessitated a pre-post comparison for DTNT times (comparison times were sourced from the same period in the previous year at each hospital). Second, although the overall small number of tPA/PCI cases in these regional hospitals were low and precluded achieving statistical significance, the consistent clinically significant time improvements suggest improved patient outcomes are likely. Our inclusion of both ambulance and walk-in (no time for medical team to mobilise prior to patient arrival) cases suggests our reported time saving are conservative. Finally, it is also important to note that for medicolegal surety, the usual communication systems were retained throughout the study period; that is, the use of Pulsara was in addition to usual communications. We would therefore anticipate even faster timelines when Pulsara is not an additional step, but the only communication system utilised. Despite this, the ease of use and benefits of time saved for paramedics and ED clinicians in removal of repetition of information was readily apparent with clinicians electing to use Pulsara in addition to usual systems.

In conclusion, the use of Pulsara led to shorter timelines in the care of patients with suspected stroke and STEMI. While stroke thrombolysis/PCI numbers were perhaps small, the gains were similarly apparent, with increased numbers within defined treatment time windows (<60/<90 minutes). Strong uptake suggests the clinical utility of such a communication system. Patient-centred care needs a patient-centred communication system incorporating
patients identified in the community by first responders, then assessed and treated by multiple clinicians within the community and hospital setting. Our research provides evidence that Pulsara can be used as a single digital communication system to enhance the emergency management of patients across multiple conditions. Identifying significant improvements in the time lines for other acute conditions such as trauma, sepsis and mental health warrants further research.
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Table 1: Activation of Pulsara

| Activation status, and location                      | Stroke N=604 | STEMI N=247 |
|------------------------------------------------------|--------------|-------------|
| Not activated                                        | 215 (36%)    | 76 (31%)    |
| Activated cases                                      | 389 (64%)    | 171 (69%)   |
| Ambulance Victoria (AV)                              | 223 (57%)    | 71 (42%)    |
| Emergency Department on behalf of AV                  | 41 (11%)     | 28 (16%)    |
| Emergency Department (walk-in, inpatient)            | 125 (32%)    | 72 (42%)    |
Table 2: Demographics of participants for stroke and STEMI

| Demographic     | Stroke       | STEMI        | p value | STEMI       | p value |
|-----------------|--------------|--------------|---------|--------------|---------|
|                 | N=604        | N=247        |         |              |         |
|                 | Without Pulsara | With Pulsara |         | Without Pulsara | With Pulsara | |
|                 | N=215        | N=389        |         | N=76         | N=171   | |
| Sex, male n (%) | 107 (50%)    | 195 (50%)    | p=0.69  | 52 (68%)     | 123 (72%)| p=0.51 |
| Age, years median (IQR) | 76 (63, 84) | 75 (62, 82) | p=0.25  | 66 (57, 79)  | 63 (55, 74)| p=0.35 |
Table 3: Ambulance metrics for suspected stroke

| AV Metric                          | Without Pulsara | With Pulsara | Time difference (p value) |
|------------------------------------|-----------------|--------------|--------------------------|
| Median minutes (IQR)               | N=206           | N=272        |                          |
| Arrive Hospital and Triage time    | N=204           | N=272        | -4 mins                  |
| (p value)                          |                 |              | p=0.0001                 |
| Arrive Hospital and Off-stretcher  | N=203           | N=272        | -8 mins ^                |
| time                               | 19 (11, 29)     | 11 (7, 17)   | p=0.0001                 |
| Arrive Hospital and Depart Hospital| N=206           | N=272        | -5 mins ^                |
| time                               | 50 (36, 58)     | 45 (35, 57)  | p=0.14                   |

Note: ^These results are if Pulsara was initiated by AV or hospital. N varies due to missing data.
Table 4: Hospital metrics for suspected stroke

| Hospital Metric               | Without Pulsara | With Pulsara | Time difference | p value |
|------------------------------|-----------------|--------------|----------------|---------|
| Door to first medical review | N=155           | N=319        | -17 mins       | p=0.0001|
|                              | 23 (8, 67)      | 6 (2, 14)    |                |         |
| Door to CT completed         | N=130           | N=300        | -44 mins       | p=0.0001|
|                              | 71 (43, 147)    | 27 (18, 44)  |                |         |

Note: *Pulsara used on 96% (52/54) tPA cases, so with and without Pulsara comparisons cannot be made. Comparisons made between with and pre-Pulsara period (equivalent months in prior year). N varies between first medical review and CT as not all cases received a CT scan.
Table 5: Ambulance metrics for suspected STEMI

| AV Metric                              | Without Pulsara | With Pulsara | Time difference | (p value) |
|----------------------------------------|-----------------|--------------|----------------|-----------|
| Median minutes (IQR)                   | N=73            | N=84         |                |           |
| Arrive Hospital and Triage time        | 6 (3, 10)       | 3 (2, 6)     | -3 mins        | p=0.004   |
| Arrive Hospital and Off-stretcher time | 19 (10, 32)     | 14 (7, 23)   | -5 mins        | p=0.014   |
| Arrive Hospital and Depart Hospital time for all suspected STEMI cases | 56 (40, 84) | 70 (50, 90) | +14 mins** | p=0.031   |
| Arrive Hospital and Depart Hospital time for Primary PCI cases only | N=8 | N=31 | +16 mins*** | p=0.008 |
|                                      | 50 (33, 67)     | 76 (58, 97)  |                |           |
| Arrive Hospital and Depart Hospital time for non-Primary PCI cases only | N=39 | N=29 | +2 mins** | p=0.59 |
|                                      | 64 (47, 84)     | 66 (48, 86)  |                |           |

Note: #includes if AV or ED activate App. ## Extended time with patients being transferred on ambulance stretchers to Cath Lab and paramedics staying to watch PCI procedure (new Cath Lab). N varies due to missing data.
Table 6: Hospital metrics for suspected STEMI

| Hospital Metric                           | Without Pulsara | With Pulsara | Time difference | (p value) |
|------------------------------------------|-----------------|--------------|-----------------|-----------|
| Median minutes (IQR)                     |                 |              |                 |           |
| Door to first medical review             | N=52            | N=142        | -1 min          | p=0.25    |
|                                          | 4 (0, 14)       | 3 (0, 7)     |                 |           |
| Door to Procedure start time             | N=6             | N=61         | -6 mins         | p=0.42    |
| for Primary PCI #                        | 41 (27, 87)     | 35 (19, 59)  |                 |           |
| Door to Procedure start time #           | 5/6             | 55/61        |                 | p=0.60    |
| for Primary PCI <90 minutes              | 83%             | 90%          |                 |           |
| Door to Balloon time                     | N=4             | N=46         | -17 mins        | p=0.41    |
|                                          | 73 (49, 110)    | 56 (34, 88)  |                 |           |
| Door to Balloon < 90 minutes             | 2/4             | 36/46        |                 | p=0.20    |
|                                          | 50%             | 78%          |                 |           |

Note: #includes if AV or ED activate App. #Procedure time reported as balloon time may have delays within operation and balloon time not captured for all cases. Direct admits precluded door times for 8 patients. N varies as not all cases had a procedure/balloon and there were missing data for some balloon times.
Legend

Figure 1: Screen shots Pulsara™ STOP Stroke/STEMI (version 4.6 originally implemented June 2016, version 11 in use November 2020): a) select patient condition, b) enter patient symptoms, c) adding images (e.g., driver’s licence) or messages, d) alert Emergency Department. See www.Pulsara.com for video.
Figure 1: Screen shots Pulsara™ STOP Stroke/STEMI (version 4.6 originally implemented June 2016, version 11 in use November 2020): a) select patient condition, b) enter patient symptoms, c) adding images (e.g., driver’s licence) or messages, d) alert Emergency Department. See www.Pulsara.com for video.
Completed for the submitted manuscript titled

Streamlining acute stroke and cardiac treatments using the Pulsara™ multi-disciplinary digital communication app: a pragmatic feasibility study.

Revised Standards for Quality Improvement Reporting Excellence (SQUIRE 2.0)

September 15, 2015

Text Section and Item Name |
Notes to authors

- The SQUIRE guidelines provide a framework for reporting new knowledge about how to improve healthcare
- The SQUIRE guidelines are intended for reports that describe system level work to improve the quality, safety, and value of healthcare, and used methods to establish that observed outcomes were due to the intervention(s).
- A range of approaches exists for improving healthcare. SQUIRE may be adapted for reporting any of these.
- Authors should consider every SQUIRE item, but it may be inappropriate or unnecessary to include every SQUIRE element in a particular manuscript.
- The SQUIRE Glossary contains definitions of many of the key words in SQUIRE.
- The Explanation and Elaboration document provides specific examples of well-written SQUIRE items, and an in-depth explanation of each item.
- Please cite SQUIRE when it is used to write a manuscript.

Title and Abstract

1. Title

Indicate that the manuscript concerns an initiative to improve healthcare (broadly defined to include the quality, safety, effectiveness, patient-centeredness, timeliness, cost, efficiency, and equity of healthcare)

Yes, p1
2. Abstract

a. Provide adequate information to aid in searching and indexing
b. Summarize all key information from various sections of the text using the abstract format of the intended publication or a structured summary such as: background, local problem, methods, interventions, results, conclusions

Introduction

Why did you start?
Nature and significance of the local problem

3. Problem Description

Summary of what is currently known about the problem, including relevant previous studies

4. Available knowledge

Informal or formal frameworks, models, concepts, and/or theories used to explain the problem, any reasons or assumptions that were used to develop the intervention(s), and reasons why the intervention(s) was expected to work

5. Rationale

Purpose of the project and of this report

6. Specific aims

Methods

Contextual elements considered important at the outset of introducing the intervention(s)

7. Context

What did you do?

8. Intervention(s)

a. Description of the intervention(s) in sufficient detail that others could reproduce it
b. Specifics of the team involved in the work

9. Study of the Intervention(s)

a. Approach chosen for assessing the impact of the intervention(s)
b. Approach used to establish whether the observed outcomes were due to the intervention(s)

10. Measures

a. Measures chosen for studying processes and outcomes of the intervention(s), including rationale for choosing them, their operational definitions, and their validity and reliability

Yes, p5
Yes pp 7-8
Yes p 8
Yes p 8
Yes, p 9 Setting
Yes, p 9
Yes pp 8-9 Design,
Yes p 11 and 12, Statistical analyses, primary and secondary outcomes; data
b. Description of the approach to the ongoing assessment of contextual elements that contributed to the success, failure, efficiency, and cost

c. Methods employed for assessing completeness and accuracy of data

11. Analysis

a. Qualitative and quantitative methods used to draw inferences from the data

b. Methods for understanding variation within the data, including the effects of time as a variable

12. Ethical Considerations

Ethical aspects of implementing and studying the intervention(s) and how they were addressed, including, but not limited to, formal ethics review and potential conflict(s) of interest

Results

What did you find?

13. Results

a. Initial steps of the intervention(s) and their evolution over time (e.g., time line diagram, flow chart, or table), including modifications made to the intervention during the project

b. Details of the process measures and outcome

c. Contextual elements that interacted with the intervention(s)

d. Observed associations between outcomes, interventions, and relevant contextual elements

e. Unintended consequences such as unexpected benefits, problems, failures, or costs associated with the intervention(s).

f. Details about missing data

Discussion

What does it mean?

14. Summary

a. Key findings, including relevance to the rationale and specific aims

b. Particular strengths of the project

15. Interpretation

a. Nature of the association between the intervention(s) and the outcomes

b. Comparison of results with findings from other publications
c. Impact of the project on people and systems
d. Reasons for any differences between observed and anticipated outcomes, including the influence of context
e. Costs and strategic trade-offs, including opportunity costs

16. Limitations
a. Limits to the generalizability of the work p.16
b. Factors that might have limited internal validity such as confounding, bias, or imprecision in the design, methods, measurement, or analysis
c. Efforts made to minimize and adjust for limitations

17. Conclusions
a. Usefulness of the work
b. Sustainability
  Yes p 16 and p17
c. Potential for spread to other contexts
d. Implications for practice and for further study in the field
e. Suggested next steps

Other information
Sources of funding that supported this work. Role, if any, of the funding organization in the design, implementation, interpretation, and reporting
  Yes p 3 Sources of funding; funders had no role in any aspect of the conducting or reporting on the study
A real-world, feasibility study to investigate the use of a multidisciplinary app (Pulsara™) to improve pre-hospital communication, and timelines for acute stroke/STEMI care.

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A real-world, feasibility study to investigate the use of a multidisciplinary app (Pulsara™) to improve pre-hospital communication, and timelines for acute stroke/STEMI care.

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**Ethics**

Approval for this research was obtained from Human Research Ethics Committees from participating hospitals (Bendigo Health HREC approval: LRN/16/BHCG/5, 22 March 2016; Ballarat Health Services HREC approval LRN/17/BHSSJOG/13, 28 April 2017) and the Ambulance Victoria Research and Governance Committee (R16-005, 3 May 2016). HRECs waived the requirement for informed consent from patients.
Competing Interests

None of the authors have a financial interest in the Pulsara™ app or Pulsara Communicare Technology Inc. KLB and DAC received a travel grant paid to their institution from Pulsara Communicare Technology Inc. This grant was a contribution to defray the costs of attending an international conference to present the final results. The peer reviewed abstract submission was accepted prior to receiving the travel grant. The company had no input to the content of the abstracts or the presentations (nor this manuscript).

Data sharing

The authors confirm that the data supporting the findings of this study are available within the article. Patient-level raw data are subject to third party restrictions and are not publicly available due to the possibility that the privacy of research participants could be compromised.
Abstract

Objectives: to determine if a digital communication app improves care timelines for patients with suspected acute stroke/STEMI.

Design: Real-world feasibility study, quasi-experimental design.

Setting: Pre-hospital (25 Ambulance Victoria branches) and within-hospital (2 hospitals) in regional Victoria, Australia.

Participants: Paramedics or Emergency Department (ED) clinicians identified patients with suspected acute stroke (onset <4.5 hours; n=604) or STEMI (n=247).

Intervention: The Pulsara™ communication app provides secure, two-way, real-time communication. Assessment and treatment times were recorded for 12 months (May 2017-April 2018), with timelines compared between ‘Pulsara initiated’ (Pulsara) and ‘not initiated’ (no Pulsara).

Primary outcome measure: door-to-treatment (needle for stroke, balloon for STEMI)

Secondary outcome measures: ambulance and hospital processes.

Results: Stroke (no Pulsara n=215, Pulsara n=389) and STEMI (no Pulsara n=76, Pulsara n=171) groups were of similar age and sex (stroke: 76 vs 75 years; both groups 50% male; STEMI: 66 vs 63 years; 68% and 72% male). When Pulsara was used, patients were off ambulance stretcher faster for stroke (11[7,17] vs 19[11,29]; p=.0001) and STEMI (14[7,23] vs 19[10,32]; p=0.0014). ED door-to-first medical review was faster (6[2,14] vs 23[8,67]; p=0.0001) for stroke but only by 1 minute for STEMI (3[0,7] vs 4[0,14]; p=0.25). Door-to-CT times were 44 minutes faster (27[18,44] vs 71[43,147]; p=0.0001) for stroke, and percutaneous intervention (PCI) door-to-balloon times improved by 17 minutes, but non-significant (56[34,88] vs 73[49,110]; p=0.41) for STEMI. There were improvements in the
proportions of patients treated within 60 minutes for stroke (12% to 26%, p=0.15) and 90
minutes for STEMI (50% to 78%, p=0.20).

**Conclusions:** In this Australian-first study, uptake of the digital communication app was
strong, patient-centred care timelines improved, although door-to-treatment times remained
similar.

**Strengths and limitations of this study**

- In this Australian-first study, a single digital communication smartphone/tablet app
  was implemented in the pre-hospital and within-hospital setting.
- Multiple health services (25 ambulance branches, 2 hospitals) and different clinician
groups (paramedics; emergency, stroke/neurology, cath lab clinicians, radiologists)
  were involved.
- Participants were patients with suspected stroke (<4.5 hours) or suspected STEMI
  identified by paramedics or emergency clinicians.
- As a pragmatic feasibility study, limitations include the non-randomised controlled
design and a relatively small sample size, not powered for long term clinical
outcomes.

**Author contributions**

CFB conceived and supervised all aspects of the research; KLB designed the evaluation and
wrote the protocol; TC and DP collected the data; KLB and JK completed analyses; CFB and
KLB prepared the initial manuscript; DAC contributed to the study design, supervision and
provided critical revision of the manuscript; MV, JK, SB, KS, GH, TC, DP, DV, MB, VN,
WP, HH, BK, AS, PC, EO, RS, TK, CH, DS reviewed results, provided input and all authors
approved the final version of the manuscript.

**Data availability**
The authors confirm that the data supporting the findings of this study are available within the article. Patient-level raw data are subject to third party restrictions and are not publicly available due to the possibility that the privacy of research participants could be compromised.
Introduction

Cardiovascular disease is the leading cause of death and disability in Australia, with over 75,000 patients experiencing a stroke or STEMI (ST-Elevation Myocardial Infarction) cardiac event each year.\textsuperscript{1} A key element to achieving better outcomes is rapid patient assessment and treatment.\textsuperscript{2,3} International guidelines detail evidence-based emergency treatment for both stroke and STEMI, including medications (i.e., aspirin and thrombolysis) and interventional procedures (e.g., revascularisation) to reopen blocked blood vessels in the brain and heart (collectively referred to as ‘reperfusion therapies’). For STEMI the benefits of reperfusion therapy are maximised when administered within the first 90 minutes following symptom onset, including less myocardial damage, fewer complications, and better short and long-term outcomes.\textsuperscript{4-7} Similarly, for stroke “time is brain”: every minute saved in delivering thrombolysis (<4.5 hours) equates to an extra day of disability free survival,\textsuperscript{8} every 20 minutes saved in delivering endovascular thrombectomy (EVT) equates to an extra 3 months of disability free survival.\textsuperscript{9}

Timely treatment delivery for acute ischaemic stroke and STEMI requires a co-ordinated, interdisciplinary approach across multiple settings. In addition, advances in time-critical reperfusion therapies have brought the need for better integration of pre- and intra-hospital systems of care into sharp focus. Preliminary assessment, diagnosis and sometimes treatment is undertaken by paramedics in the community (pre-hospital) setting, and subsequently by clinicians in the emergency department (ED), as well as either hospital stroke (neurology and radiology) or cardiology clinicians (catheterisation laboratory [cath lab]). Pre-hospital notification of incoming patient details by paramedics provides advance notice and time for these multiple, interdisciplinary hospital teams to mobilise, prepare, and prioritise patient cases leading to faster onset-to-treatment times.\textsuperscript{10} For example, Australian registry data shows a 50% increase in the proportion of patients receiving primary percutaneous intervention
(PCI) within guideline timeframes when pre-hospital notification is undertaken (within 90 minutes: 61.3% without pre-hospital notification vs 89.3% with pre-hospital notification).

Pre-hospital notification to the hospital team about an incoming patient is a key time saving procedure for improving patient treatment times. Interdisciplinary pre-hospital communication is however often fragmented with clinicians dispersed geographically, across health services and reliant upon multiple separate communication systems, such as radio, phone and paging systems, for the one patient. This disjointed system leads to repetition of documenting clinical details, transmission of incorrect or out of date clinical information and subsequent treatment delays. New digital applications allow end-to-end communication so that patients’ clinical details such as symptoms, assessments, treatment or contraindications, and subsequent time metrics are transparent to all clinicians involved, from within the community and into the hospital setting. These types of end-to-end communication tools have not been trialled within the Australian context for pre-hospital and hospital emergency care management for acute cardiovascular and cerebrovascular conditions. To date, very few reports from other countries of HIPAA compliant options have been published with no single system being used from first-responders to hospital treatment.

Our aim was to undertake a real-world, pilot feasibility study and determine if a secure, digital communication app (Pulsara™), operating both between and within health services, could improve the timelines for the different stages involved in the inter-disciplinary processes of care for patients with suspected acute stroke or STEMI.

Methods

Design

A quasi-experimental, pragmatic design was used with the control group defined as those patients not receiving the intervention within the study period, compared to those who did.
Differences between the two hospitals precluded a pre-post design; specifically, the cardiac PCI lab at one site only commenced soon after the intervention began. Following a 6-month feasibility pilot at hospital 1 (August 2016 to February 2017), a 12-month evaluation was conducted in Hospitals 1 and 2 (May 2017 to April 2018) simultaneously.

**Setting**

This real-world pilot feasibility study for application within the Australian context was undertaken within two large regional hospitals in Victoria, Australia, (Hospital 1=534 beds, Hospital 2=361 beds) and 25 Ambulance Victoria (AV) branches (Emergency Medical Service; EMS). A single EMS agency (AV) covers the state of Victoria. In 2017-2018, the two hospital EDs received 111,322 ED presentations per annum, 58,048 (52%) triaged as Category 1-3 (i.e., requiring attention within 30 minutes). Both hospitals treat patients with acute ischaemic stroke or STEMI, including access to cardiac PCI and support from the Victorian Stroke Telemedicine (VST) service. Patients requiring endovascular thrombectomy for cerebral large vessel occlusion are urgently transferred to hospitals in metropolitan Melbourne.

**Digital Health Technology**

The Pulsara™ smartphone/tablet app (Pulsara; www.pulsara.com) is designed for secure (HIPAA compliant) sharing of patient details, symptoms, arrival time, plus tracking of treatment time metrics (e.g. arrival at ED, CT brain imaging, PCI cath lab, stroke/STEMI reperfusion times) and possible contra-indications for treatment (Figure 1). Images are securely sent to expedite hospital triage/patient identification (e.g., patient’s driver’s licence, utility accounts), or facilitate patient care (e.g., medication lists, ambulance vitals, or ECG results). Patient details and team member status (e.g., which clinicians have acknowledged the incoming case) are available to case-relevant users. Pulsara has condition-specific
modules (i.e., stroke, STEMI, trauma, sepsis, mental health) with disease-specific data fields (e.g., last known well time for stroke). Minimum data fields allow rapid input and sharing, with clinical updates pushed simultaneously to all users on a case. Upon conclusion, a case summary is provided to all those involved, and data extractions (e.g., for monitoring and feedback) can be made immediately or cumulatively.

Pulsara can be activated by ambulance paramedics to pre-notify patient’s arrival to the hospital ED, or the hospital can initiate a case for “walk-ins” or hospital inpatients, as relevant. The ED can then simultaneously alert and synchronise care across multiple hospital departments as relevant (e.g., Cath Lab, Radiology, Cardiac team, Stroke team), prior to the ambulance arriving at the ED with a patient. The Pulsara app was downloaded onto paramedics’ and clinicians’ personal and/or dedicated work smartphones with dedicated iPads situated in ED, Cardiology and Radiology. At the time of implementation in 2016, only the stroke and STEMI modules were available (Pulsara version 4.6). Pulsara version 11 (November 2020) is currently used.

Procedure

Eligible patients were those with suspected acute stroke (with symptom onset < 4.5 hours or unknown onset) or STEMI, as identified by AV or hospital personnel. For AV paramedics, if cases required pre-notification, then Pulsara was to be activated. As this was a research study, usual paramedic communication systems were a medicolegal requirement throughout the evaluation period; that is, activating Pulsara was an additional procedure required of paramedics and hospital personnel. At the time of the trial, usual pre-notification communication systems involved patient information exchanged via multiple systems, with some variations across different hospitals. Communication flow generally involved paramedics radioing to an AV Clinician who forwarded information via phone to the ED. Where relevant, the ED then activated a ‘stroke alert’ or ‘cardiac alert’ by notifying
switchboard where pager messages were activated to those on the team. Fax was used between AV and the ED to share ECG results and between ED and Radiology to indicate CT required.

Pre-hospital and hospital assessment and treatment times were recorded, patient at triage, patient off AV stretcher, ambulance hospital departure time, with hospital times of patient arrival in ED (door time) and first medical review. For patients with suspected stroke, CT time available and thrombolysis time (where relevant), and for patient with suspected STEMI undergoing primary PCI, procedure start time and balloon time were collected systematically (case report forms) from sources independent from the project; that is, from AV and hospital data systems.

**Patient and Public Involvement**

Patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans of our research.

Approval for this research was obtained from Human Research Ethics Committees from participating hospitals (Bendigo Health HREC approval: LRN/16/BHC/5, 22 March 2016; Ballarat Health Services HREC approval LRN/17/BHSSJOG/13, 28 April 2017) and the Ambulance Victoria Research and Governance Committee (R16-005, 3 May 2016).

**Statistical analyses**

To examine group differences between when Pulsara was or was not used, chi² tests for categorical, and Kruskal-Wallis tests for continuous variables, were conducted within STATA (v16). The primary outcome was door-to-treatment (needle for stroke and balloon for STEMI, with secondary outcomes for ambulance metrics as arrival at hospital to triage, arrival at hospital to off-stretcher and arrival at hospital to hospital departure times with
hospital metrics as door to first medical review, door to CT (stroke only), door to procedure
(STEMI only). Author KB had full access to all the data in the study and takes responsibility
for its integrity and the data analysis. Data quality checks were undertaken.

Results

There were 604 patients with suspected acute stroke and 247 with suspected STEMI
identified by paramedics and hospital personnel (Table 1). Pulsara was activated for 64% of
stroke cases and 69% of STEMI cases. When Pulsara was activated, the majority (57%) of
stroke cases were initiated by paramedics. Hospital ED staff activated a Pulsara case on
behalf of the paramedics in 16% of cases for STEMI, while 42% of cases were self-
presenting. Patients were similar in age and gender for stroke and STEMI cohorts regardless
of whether Pulsara was, or was not, activated (Table 2).

Stroke

For suspected stroke cases, the median times (IQRs) for paramedic metrics with (n=206) and
without (n=272) Pulsara are reported in Table 3. Compared to cases where Pulsara was not
initiated, use of Pulsara by paramedics resulted in triage 4 minutes faster (p=0.0001), off
stretcher 8 minutes faster (p=0.0001), and paramedics departed hospital 5 minutes faster
(p=0.0001). Overall, the time between patient ambulance loaded and hospital arrival for
stroke was 5mins faster if Pulsara was used (18mins vs 13mins P<0.0009). On arrival at
hospital, 92% of stroke patients with Pulsara were triaged as Emergency (category 1&2),
compared to 47% without Pulsara (p=0.000).

Hospital-based time metrics for patients with suspected stroke are reported in Table 4.
Compared to cases where Pulsara was not used, patient first medical review was 17 minutes
faster (p=0.0001), and CT scan undertaken 44 minutes faster (p=0.0001) when Pulsara was
used. As Pulsara was used in 96% (52/54) of patients receiving thrombolysis, door to needle times were compared with the equivalent pre-Pulsara period (same time period, 12 months earlier). Door-to-needle time improved by 6 minutes (p=0.36) with a higher but non-significant proportion receiving treatment within 60 minutes (12% pre-Pulsara vs 25% Pulsara; p=0.15).

**STEMI**

For STEMI cases, median time (IQRs) for paramedic metrics with (n=73) and without (n=84) Pulsara are reported in Table 5. Compared to cases where Pulsara was not initiated, use of Pulsara resulted in triage 3 minutes faster (p=0.004), and off stretcher 5 minutes faster (p=0.014). Paramedics departed the hospital 14 minutes slower (p=0.031). Overall, the time between patient ambulance loaded and hospital arrival for STEMI was 23 minutes faster if Pulsara was used (45 minutes vs 22 minutes p<0.006). On arrival at hospital, 100% of STEMI patients with Pulsara were triaged as Emergency (categories 1 & 2), compared to 86% without Pulsara (p=0.19).

Hospital based metrics for STEMI cases are reported in Table 6. Time from patient arriving in ED and first medical review was similar (1 minute faster, p=0.25), PCI procedure start time improved by 6 minutes (p=0.42), and door-to-balloon by 17 minutes although not significant (p=0.41). With Pulsara, there was increased proportion of PCI procedures (door-to-balloon time) started within 90 minutes (50% no Pulsara to 78% Pulsara, p=0.20).

**Discussion**

Our prospective, real-world feasibility study is the first to systematically examine the use of Pulsara for the treatment of stroke and STEMI across the entire patient care journey; that is, from patient assessment in the community to patient treatment in hospital. Health services’
agreement and subsequent participation in the trial indicates the feasibility of implementing a single communication system across multiple health services (i.e., AV and two regional hospitals). This agreement extended across clinicians within multiple disciplines (e.g., ED, Radiology, Neurology, Cardiology). There was excellent uptake in the use of Pulsara by clinicians with over 90% use in stroke cases receiving thrombolysis, and STEMI cases undergoing PCI. For all eligible cases however, Pulsara was not activated for approximately one third of both stroke and STEMI cases. During this research study, clinicians had to use usual communication systems and Pulsara was an additional step, that was not undertaken in 100% of eligible cases. Our process evaluation data suggests that paramedics report that cases where Pulsara was not used were largely due to issues of technology (e.g., forgot password/PIN), time constraints (e.g., added time) or human error (e.g., remembering to use the app) reasons. Implementation of the Pulsara digital communication application resulted in faster metrics of the patient arriving at hospital and being at triage when Pulsara was used, as well as patient off ambulance stretcher times for both stroke and STEMI cases. Hospital metrics for stroke cases also improved significantly with door-to-first medical review and door-to-CT completed more rapidly. Improvements in door-to- treatment times for suspected stroke (door-to-needle) and STEMI (door-to- procedure/balloon) did not reach significance, possibly due to small sample sizes, however they were in the expected direction.

Previous studies evaluating the use of Pulsara have not compared metrics across both pre-hospital and within hospital for treatment of stroke and STEMI. A single hospital comparison of tPA stroke cases (n=34 pre/n=34 post use of Pulsara) demonstrated a 28% significant improvement (77 to 56 minutes, p=.001) in door to needle time (DTNT), as well as greater proportion of cases achieving DTNT <60 minutes (32% to 82%, p=0.001) after Pulsara implementation. In a larger retrospective cohort study of stroke codes at 12 medical centres (n = 2589) using Pulsara, those cases activated by EMS were more likely to receive tPA than
those with ED activation (20% vs 12%, p<.0001). Cases with EMS activation had shorter
door to CT (6 minutes, 95% CI [-10.3, -2]) and shorter DTNT (12.8 minutes, 95% CI [-21, -
4.6]). For treatment of STEMI, a pre (4 month) / post (6 month) retrospective hospital study
that implemented Pulsara reported reduced door to balloon times (DTBT) by 22% (91
minutes to 71 minutes, p=.05), and greater numbers of DTBT cases <60 minutes (56% to
80%).

The importance of time to treatment is well-established. The mantra for urgency in the
treatment of STEMI and stroke has been that “time is muscle” and “time is brain”
respectively, with a focus on reperfusion achieved within 60 minutes (stroke), 30 minutes (for
STEMI thrombolysis) and 90 minutes (for STEMI-PCI). Treatment however can be
inconsistent. One in three STEMI patients in Australia did not receive any form of
reperfusion and of those who did, only one in three received it in an optimal time frame. Comparing STEMI populations from regional (predominantly receiving thrombolysis) and
metro hospitals (predominantly receiving PCI) indicated no difference in reperfusion rates,
and no difference in long term outcomes. This emphasises that time to reperfusion is more
important than modality of reperfusion. It is clear that reducing total system delay (from
first medical contact to reperfusion therapy) is more strongly associated with mortality than
patient delay in seeking care. In recent 2018 data from an Australian registry (Victorian
Cardiac Outcomes Registry; VCOR), it was found that 81% of PCI cases are treated within
90 minutes (median time to PCI 58 minutes [IQR: 39, 83]). This increased to 89% with pre-
hospital notification. However, in the 1/3 of cases where there was no pre-hospital
notification, only 61% were treated with PCI <90 minutes (median time to PCI 80 minutes;
IQR: 56, 112 ).

Improvements in one aspect of healthcare may have implications in another areas. For
example, with the use of Pulsara for STEMI cases (with pre-hospital notification, sharing
ECGs etc.), the entire cardiac team was often fully mobilised before the patient arrived in the ED triage area. Patients were transferred directly from triage to the cath lab on the ambulance stretcher, rather than moving the patient to an ED stretcher. This streamlined care was reflected in a longer time for paramedics to depart hospital (by 14 minutes; p=0.031). Recent advances in stroke care now support the pre-hospital delivery of thrombolysis via the Mobile Stroke Unit (i.e., a specialised ambulance with a CT scanner and stroke team). Immediate and accurate sharing of patient clinical and treatment information with the receiving hospital is essential. A single communication system such as Pulsara that covers both the pre- and within-hospital settings further supports the integration of treatment advances that span both community and medical settings.

Our study has a number of strengths, including evaluation with two acute medical conditions involving different clinician groups, across multiple health services. A number of limitations, however, need to be considered when reviewing results. First, the design of this feasibility study was pragmatic with a non-randomised controlled design that was not powered for clinical effectiveness or patient outcomes (e.g., morbidity/mortality). This limitation includes no control for case mix. As Pulsara was an additional communication system, it was up to individual paramedic and hospital clinicians to decide to activate the app for eligible cases, which did not consistently occur. It is possible that, in some cases, paramedics may have not activated Pulsara if it was felt that the patient symptoms were perhaps too mild. For example, 92% of stroke cases with Pulsara vs 47% (p<0.000) without Pulsara were categorised as Emergency care (ED triage categories 1 & 2). This difference was less evident for STEMI cases. However, this reflects practice in the real world where paramedic clinical judgment is focused on the optimal rapid treatment of patients, particularly if they feel the symptoms are severe. Another consideration is that for STEMI PCI cases, the sites were not equivalent prior to the Pulsara implementation period (i.e., no cath lab at one site during the pre-Pulsara
period but opened the same week that the Pulsara intervention period commenced); comparisons were therefore between cases that used and did not use Pulsara. This approach accounted for changes across time, such as other improvements within the hospital/s. Pulsara was also used in a very high proportion of cases receiving stroke thrombolysis (96%), illustrating clinicians’ willingness to use Pulsara for their acute cases. However, this uptake necessitated a pre-post comparison for DTNT times (comparison times were sourced from the same period in the previous year at each hospital). Second, although the overall small number of tPA/PCI cases in these regional hospitals were low and precluded achieving statistical significance, the consistent clinically significant time improvements suggest improved patient outcomes are likely. Our inclusion of both ambulance and walk-in (no time for medical team to mobilise prior to patient arrival) cases suggests our reported time saving are conservative. Finally, it is also important to note that for medicolegal surety, the usual communication systems were retained throughout the study period; that is, the use of Pulsara was in addition to usual communications. We would therefore anticipate even faster timelines when Pulsara is not an additional step, but the only communication system utilised. Despite this, the ease of use and benefits of time saved for paramedics and ED clinicians in removal of repetition of information was readily apparent with clinicians electing to use Pulsara in addition to usual systems.

In conclusion, the use of Pulsara led to shorter timelines in the care of patients with suspected stroke and STEMI. While stroke thrombolysis/PCI numbers were perhaps small, the gains were similarly apparent, with increased numbers within defined treatment time windows (<60/<90 minutes). Strong uptake suggests the clinical utility of such a communication system. Patient-centred care needs a patient-centred communication system incorporating patients identified in the community by first responders, then assessed and treated by multiple clinicians within the community and hospital setting. Our research provides evidence that
Pulsara can be used as a single digital communication system to enhance the emergency management of patients across multiple conditions. Identifying significant improvements in the time lines for other acute conditions such as trauma, sepsis and mental health warrants further research.
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Table 1: Activation of Pulsara

| Activation status, and location                      | Stroke | STEMI |
|-----------------------------------------------------|--------|-------|
|                                                     | N=604  | N=247 |
| Not activated                                       | 215 (36%) | 76 (31%) |
| Activated cases                                      | 389 (64%) | 171 (69%) |
| Ambulance Victoria (AV)                             | 223 (57%) | 71 (42%) |
| Emergency Department on behalf of AV                 | 41 (11%) | 28 (16%) |
| Emergency Department (walk-in, inpatient)            | 125 (32%) | 72 (42%) |
### Table 2: Demographics of participants for stroke and STEMI

| Demographic | Stroke N=604 | STEMI N=247 |
|-------------|-------------|-------------|
|             | Without Pulsara N=215 | With Pulsara N=389 | Without Pulsara N=76 | With Pulsara N=171 |
| Sex, male n (%) | 107 (50%) | 195 (50%) | p=0.69 | 52 (68%) | 123 (72%) | p=0.51 |
| Age, years median (IQR) | 76 (63, 84) | 75 (62, 82) | p=0.25 | 66 (57, 79) | 63 (55, 74) | p=0.35 |
Table 3: Ambulance metrics for suspected stroke

| AV Metric                      | Without Pulsara | With Pulsara | Time difference (p value) |
|-------------------------------|-----------------|--------------|--------------------------|
|                               | N=206           | N=272        |                          |
| Arrive Hospital and Triage time | N=204           | N=272        | -4 mins p=0.0001         |
|                               | 7 (3, 11)       | 3 (2, 7)     |                          |
| Arrive Hospital and Off-stretcher time | N=203 | N=272 | -8 mins ^ p=0.0001 |
|                               | 19 (11, 29)     | 11 (7, 17)   |                          |
| Arrive Hospital and Depart Hospital time | N=206 | N=272 | -5 mins ^ p=0.14         |
|                               | 50 (36, 58)     | 45 (35, 57)  |                          |

Note: ^These results are if Pulsara was initiated by AV or hospital. N varies due to missing data.
Table 4: Hospital metrics for suspected stroke

| Hospital Metric                        | Without Pulsara | With Pulsara | Time difference (p value) |
|----------------------------------------|-----------------|--------------|--------------------------|
| Median minutes (IQR)                   |                 |              |                          |
| Door to first medical review           | N=155           | N=319        | -17 mins                 |
|                                        | 23 (8, 67)      | 6 (2, 14)    | p=0.0001                 |
| Door to CT completed                   | N=130           | N=300        | -44 mins                 |
|                                        | 71 (43, 147)    | 27 (18, 44)  | p=0.0001                 |
| Door to Needle                         | N=26            | N=51         | -6 mins                  |
|                                        | 84 (74, 106)    | 78 (58, 101) | p=0.36                   |
| Door to Needle < 60 mins              | 3/26            | 13/51        | p=0.15                   |
| n, %                                   | 12%             | 25%          |                          |

Note: *Pulsara used on 96% (52/54) tPA cases, so with and without Pulsara comparisons cannot be made. Comparisons made between with and pre-Pulsara period (equivalent months in prior year). N varies between first medical review and CT as not all cases received a CT scan.
Table 5: Ambulance metrics for suspected STEMI

| AV Metric                                      | Without Pulsara | With Pulsara | Time difference (p value) |
|-----------------------------------------------|-----------------|--------------|----------------------------|
| Median minutes (IQR)                          | N=73            | N=84         |                            |
| Arrive Hospital and Triage time               | 6 (3, 10)       | 3 (2, 6)     | -3 mins p=0.004            |
| Arrive Hospital and Off-stretcher time        | 19 (10, 32)     | 14 (7, 23)   | -5 mins p=0.014            |
| Arrive Hospital and Depart Hospital time for all suspected STEMI cases | 56 (40, 84) | 70 (50, 90) | +14 mins** p=0.031        |
| Arrive Hospital and Depart Hospital time for Primary PCI cases only | N=8 | N=31 | +16 mins** p=0.008 |
| Arrive Hospital and Depart Hospital time for non-Primary PCI cases only | N=39 | N=29 | +2 mins** p=0.59 |

Note: #includes if AV or ED activate App. ## Extended time with patients being transferred on ambulance stretchers to Cath Lab and paramedics staying to watch PCI procedure (new Cath Lab). N varies due to missing data.
# Table 6: Hospital metrics for suspected STEMI

| Hospital Metric                     | Without | With | Time difference | (p value) |
|-------------------------------------|---------|------|-----------------|-----------|
|                                     | Median minutes (IQR) | Without Pulsara | With Pulsara | (p value) |
| Door to first medical review       | N=52    | 4 (0, 14) | 3 (0, 7) | -1 min | p=0.25 |
| Door to Procedure start time       | N=6     | 41 (27, 87) | 35 (19, 59) | -6 mins | p=0.42 |
| Door to Balloon time               | N=4     | 73 (49, 110) | 56 (34, 88) | -17 mins | p=0.41 |
| Door to Balloon < 90 minutes       | 2/4     | 50%  | 36/46 | 78% | p=0.20 |

Note: Includes if AV or ED activate App. Procedure time reported as balloon time may have delays within operation and balloon time not captured for all cases. Direct admits precluded door times for 8 patients. N varies as not all cases had a procedure/balloon and there were missing data for some balloon times.
Legend

Figure 1: Screen shots Pulsara™ STOP Stroke/STEMI (version 4.6 originally implemented June 2016, version 11 in use November 2020): a) select patient condition, b) enter patient symptoms, c) adding images (e.g., driver’s licence) or messages, d) alert Emergency Department. See [www.Pulsara.com](http://www.Pulsara.com) for video.
Figure 1: Screen shots Pulsara™ STOP Stroke/STEMI (version 4.6 originally implemented June 2016, version 11 in use November 2020): a) select patient condition, b) enter patient symptoms, c) adding images (e.g., driver’s licence) or messages, d) alert Emergency Department. See www.Pulsara.com for video.
Completed for the submitted manuscript titled

Streamlining acute stroke and cardiac treatments using the Pulsara™ multi-disciplinary digital communication app: a pragmatic feasibility study.

**Revised Standards for Quality Improvement Reporting Excellence (SQUIRE 2.0)**
September 15, 2015

| Text Section and Item Name | Notes to authors |
|----------------------------|------------------|
| □ The SQUIRE guidelines provide a framework for reporting new knowledge about how to improve healthcare |
| □ The SQUIRE guidelines are intended for reports that describe system level work to improve the quality, safety, and value of healthcare, and used methods to establish that observed outcomes were due to the intervention(s). |
| □ A range of approaches exists for improving healthcare. SQUIRE may be adapted for reporting any of these. |
| □ Authors should consider every SQUIRE item, but it may be inappropriate or unnecessary to include every SQUIRE element in a particular manuscript. |
| □ The SQUIRE Glossary contains definitions of many of the key words in SQUIRE. |
| □ The Explanation and Elaboration document provides specific examples of well-written SQUIRE items, and an in-depth explanation of each item. |
| □ Please cite SQUIRE when it is used to write a manuscript. |

**Title and Abstract**

**1. Title**

Indicate that the manuscript concerns an initiative to improve healthcare (broadly defined to include the quality, safety, effectiveness, patient-centeredness, timeliness, cost, efficiency, and equity of healthcare)

Yes, p1
2. Abstract

a. Provide adequate information to aid in searching and indexing
b. Summarize all key information from various sections of the text using the abstract format of the intended publication or a structured summary such as: background, local problem, methods, interventions, results, conclusions

Introduction

Why did you start?

3. Problem Description

Nature and significance of the local problem

4. Available knowledge

Summary of what is currently known about the problem, including relevant previous studies

5. Rationale

Informal or formal frameworks, models, concepts, and/or theories used to explain the problem, any reasons or assumptions that were used to develop the intervention(s), and reasons why the intervention(s) was expected to work

6. Specific aims

Purpose of the project and of this report

Methods

What did you do?

7. Context

Contextual elements considered important at the outset of introducing the intervention(s)

8. Intervention(s)

a. Description of the intervention(s) in sufficient detail that others could reproduce it
b. Specifics of the team involved in the work

9. Study of the Intervention(s)

a. Approach chosen for assessing the impact of the intervention(s)
b. Approach used to establish whether the observed outcomes were due to the intervention(s)

10. Measures

a. Measures chosen for studying processes and outcomes of the intervention(s), including rationale for choosing them, their operational definitions, and their validity and reliability

Yes, p5
Yes pp 7-8
Yes p 8
Yes, p 8
Yes p 8
Yes, p 9 Setting
And p 10 Procedure
Yes, p 9
Intervention and Figure 1, p 6
contribution of authors and p2
acknowledgements
Yes pp 8-9 Design,

Statistical analyses,
primary and secondary
outcomes; data
b. Description of the approach to the ongoing assessment of contextual elements that contributed to the success, failure, efficiency, and cost
c. Methods employed for assessing completeness and accuracy of data

11. Analysis
a. Qualitative and quantitative methods used to draw inferences from the data
b. Methods for understanding variation within the data, including the effects of time as a variable

12. Ethical Considerations
Ethical aspects of implementing and studying the intervention(s) and how they were addressed, including, but not limited to, formal ethics review and potential conflict(s) of interest

Results
What did you find?

13. Results
a. Initial steps of the intervention(s) and their evolution over time (e.g., time-line diagram, flow chart, or table), including modifications made to the intervention during the project
b. Details of the process measures and outcome
c. Contextual elements that interacted with the intervention(s)
d. Observed associations between outcomes, interventions, and relevant contextual elements
e. Unintended consequences such as unexpected benefits, problems, failures, or costs associated with the intervention(s).
f. Details about missing data

Discussion
What does it mean?

14. Summary
a. Key findings, including relevance to the rationale and specific aims
b. Particular strengths of the project

15. Interpretation
a. Nature of the association between the intervention(s) and the outcomes
b. Comparison of results with findings from other publications
c. Impact of the project on people and systems
d. Reasons for any differences between observed and anticipated outcomes, including the influence of context
e. Costs and strategic trade-offs, including opportunity costs

16. Limitations
a. Limits to the generalizability of the work p.16
b. Factors that might have limited internal validity such as confounding, bias, or imprecision in the design, methods, measurement, or analysis
c. Efforts made to minimize and adjust for limitations

17. Conclusions
a. Usefulness of the work
b. Sustainability
c. Potential for spread to other contexts
d. Implications for practice and for further study in the field
e. Suggested next steps

Yes p 16 and p17

18. Funding
Sources of funding that supported this work. Role, if any, of the funding organization in the design, implementation, interpretation, and reporting
Yes p 3 Sources of funding; funders had no role in any aspect of the conducting or reporting on the study