# Evaluating the PulsePoint Mobile Device Application to Increase Bystander Resuscitation for Victims of Sudden Cardiac Arrest


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## SUMMARY OF CHANGES FROM LAST VERSION

Neurological outcome variable: Cerebral Performance Score will be collected and reported in place of modified Rankin Score, as this is the outcome measure available in the cardiac arrest registries.

# SUMMARY


**Introduction and Rationale**
Out-of-hospital cardiac arrest (OHCA) is a major public health problem. More than 45,000 Canadians suffer OHCA annually, with only 8.4% surviving to hospital discharge. Early bystander cardiopulmonary resuscitation (CPR) and defibrillator use can save lives but are rarely done.

Advances in mobile device technology have allowed the development of a system which can notify CPR-trained citizens within 400 meters of a possible cardiac arrest. The PulsePoint mobile device application (www.pulsepoint.org) empowers them to respond and provide basic life support while professional crews are being dispatched. When a mobile device receives the alert data from the PulsePoint system, the application presents a map showing the exact location of the emergency and the closest public access defibrillator.

**The question to be addressed**
In patients who suffer non-traumatic, out-of-hospital cardiac arrest in a public location, does use of the PulsePoint system increase bystander CPR or defibrillator use compared to standard dispatch procedures?

**The nature of the core expertise being brought together to address the question or issue**
The team for this project includes senior and mid-career investigators with a long track record of successful collaboration in cardiac arrest clinical research. The Nominated Principal Applicant, Dr. Steven Brooks, is a mid-career Clinician-Scientist and investigator within the Canadian Resuscitation Outcomes Consortium, with experience leading clinical studies to test knowledge translation interventions. Dr. John Tallon, the principal knowledge user applicant, served as the Vice-President of Clinical and Medical Programs at British Columbia Emergency Health Services from 2017-2020. He has extensive experience in the implementation and evaluation of new medical programs in emergency care. The principal applicants are supported by a seasoned team of senior and mid-career investigators with a long history of leading clinical studies in cardiac arrest. Knowledge user co-applicants are all senior decision-makers in their respective agencies.

**Approach**
PulsePoint will be implemented in 2 regions across Canada and the US (British Columbia and Columbus, Ohio). After a coordinated marketing campaign in each participating region to maximize the number of mobile device application downloads in the community, 9-1-1 calls for suspected cardiac arrest having at least one PulsePoint responder within 400 meters will be randomized to conventional dispatch for suspected cardiac arrest versus conventional dispatch plus PulsePoint notifications. Our primary outcome will be bystander CPR or defibrillator use prior to professional responders arriving on scene. Our primary analysis will involve comparing outcomes between the control and treatment groups among all eligible randomized patients with cardiac arrest.

**Advancing knowledge and the application of knowledge**
We hypothesize that the PulsePoint system will have an immediate impact on increasing bystander CPR and defibrillator use in participating communities. In the long term, this project will provide valuable data on how effective PulsePoint is with respect to bystander resuscitation and survival. Our data will directly inform policy decisions about PulsePoint implementation in the participating communities and guide other North American jurisdictions around these policy decisions in the future.

## RATIONALE

**Out-of-hospital cardiac arrest (OHCA) is a major public health problem**. More than 45,000 Canadians suffer OHCA annually (1), with only 8.4% surviving to hospital discharge (2). Many of these deaths are preventable with bystander resuscitation. The number-needed-to-treat for bystander CPR in public location cardiac arrests is 10, meaning that one additional life is saved for every 10 people who receive bystander CPR (3). Bystander CPR has also been associated with increased quality of life measures in survivors (4). PAD programs have been associated with a doubling in survival for victims of OHCA (5). Unfortunately, bystander CPR occurs in less 50% of cases, and public access defibrillation in less than 3% (5).

**The benefits of CPR and defibrillation are extremely time sensitive.** The probability of survival falls 7-10% per minute delay between collapse and defibrillation without CPR (6). In North America, the median time interval from the 9-1-1 call to having a professional crew on scene with a defibrillator is more than 8 minutes (7). These system limitations highlight the importance of immediate bystander resuscitation.

**The evolution of mobile devices to include Internet connectivity, global positioning service and mapping capabilities provides an opportunity to incorporate a new layer of planned emergency response: The CPR-trained citizen**. Traditionally, people have become bystanders to cardiac arrest by chance, not design. Mobile device technology allows us to develop a new layer of response to cardiac arrest by linking CPR-trained citizens with the local 9-1-1 service. By notifying CPR-trained citizens within 400 meters of a possible cardiac arrest emergency, the PulsePoint application empowers them to respond and provide immediate basic life support while professional crews are being dispatched.

## SIGNIFICANCE

PulsePoint represents a revolutionary change in the way we respond to OHCA. Preliminary data on the use of the crowd sourcing technology to increase bystander resuscitation are promising. We conducted a survey of users from US communities where PulsePoint has been implemented. We found that those who received a PulsePoint notification and arrived prior to professional rescuers provided CPR in 80% of suspected cardiac arrest cases (8). Recent data from a randomized controlled trial in Stockholm, Sweden demonstrated a 14% absolute increase in bystander CPR associated with a text message-based crowd sourcing solution similar to PulsePoint (9). In contrast to our proposal, the Stockholm solution only recruited during the daytime and did not incorporate PAD locations. Our trial is needed to measure the impact of PulsePoint implemented on a 24-hour basis in urban, suburban and rural North American settings.

Assuming PulsePoint is as effective as the Stockholm texting solution (9), implementation of PulsePoint across Canada could increase the proportion of public location OHCA episodes receiving bystander CPR from 50% to 64%. This would represent an absolute increase of approximately 1200 cases of bystander CPR resulting in an additional 120 lives saved per year. Survival benefit from increased public access

defibrillator use associated with the PulsePoint intervention would be in addition to these impact estimates. Our study will determine if these estimates of benefit are reasonable in the North American setting and provide rationale for broader implementation.

## OBJECTIVES

**Primary:** To determine if the PulsePoint system can increase the proportion of patients with OHCA who receive bystander CPR or PAD use prior to the arrival of professional responders.

**Secondary:** To measure the relationship between cardiac arrest event characteristics (e.g. initial rhythm, type of location, time of day), system characteristics (e.g. PulsePoint user density) and the probability of bystander resuscitation after PulsePoint activation.

**Project Outputs:** This project will provide the data required for decision-makers in emergency health services to evaluate PulsePoint. Specifically, this project will provide the following outputs:

1) Quantification of the improvement in bystander CPR and PAD use for victims of OHCA associated with PulsePoint implementation.

2) Quantification of the increase in cardiac arrest survival attributable to PulsePoint implementation.

3) An understanding of how cardiac arrest and system factors influence the effectiveness of the application.

## APPROACH

### Study Design

This study will be a pragmatic, blinded, multi-centre, randomized controlled trial (RCT).

### Setting

The PulsePoint system will be implemented in the British Columbia Emergency Health Service and Columbus Fire (Ohio). Participating regions include urban, suburban and rural communities with a combined population of approximately 6 million people.

### Inclusion Criteria:

1) Patients with 9-1-1 calls assigned as “suspected” or “confirmed” cardiac arrest and,
2) Are confirmed to be EMS-treated, public location out-of-hospital cardiac arrest.

### Exclusion Criteria:

1) Traumatic cardiac arrest, or
2) Cardiac arrests occurring in the context of a dangerous scene as determined by the 9-1-1 call-taker, or

3) EMS-witnessed cardiac arrest, or
4) Cardiac arrests not treated by EMS ("Do Not Resuscitate", signs of obvious death), or
5) Cardiac arrests occurring in nursing homes and health care facilities.

**Trial Interventions:**

*The PulsePoint System*

PulsePoint is a crowd sourcing solution designed to facilitate bystander CPR and AED use for victims of out-of-hospital cardiac arrest while professional rescuers are being dispatched. The PulsePoint system links CPR-trained individuals in the community including off-duty medical professionals and trained lay people with the 9-1-1 response to suspected cardiac arrests. The system allows "CPR Needed" notifications to be sent to mobile devices running the "PulsePoint Respond" application in close proximity to suspected cardiac arrest events in the community. The PulsePoint system was developed by the PulsePoint Foundation, a not-for-profit organization based in California. The PulsePoint Foundation works with EMS agencies around the world to implement and maintain the system. As of May 2017, the system is active in more than 1200 communities.

The PulsePoint system software is implemented into the 9-1-1 dispatch systems of participating emergency medical services systems. The PulsePoint interface software monitors each 9-1-1 call on dispatch computers and is automatically triggered by particular conditions including call type (e.g. suspected cardiac arrest) and location type (public location). When triggered, the system pushes location data to all PulsePoint mobile application users within 400 meters of the emergency location.

When a mobile device running the PulsePoint Respond application receives the alert data from the PulsePoint system, the device alarms with auditory, tactile (vibration) and visual stimuli (Figure 1). The application presents a map showing the exact location of the suspected cardiac arrest and the closest public access defibrillator (Figure 2). The PulsePoint notification process happens automatically and in parallel with the traditional dispatch of emergency responders (paramedics and fire fighters).

**FIGURE 1.** *A PulsePoint alert.*

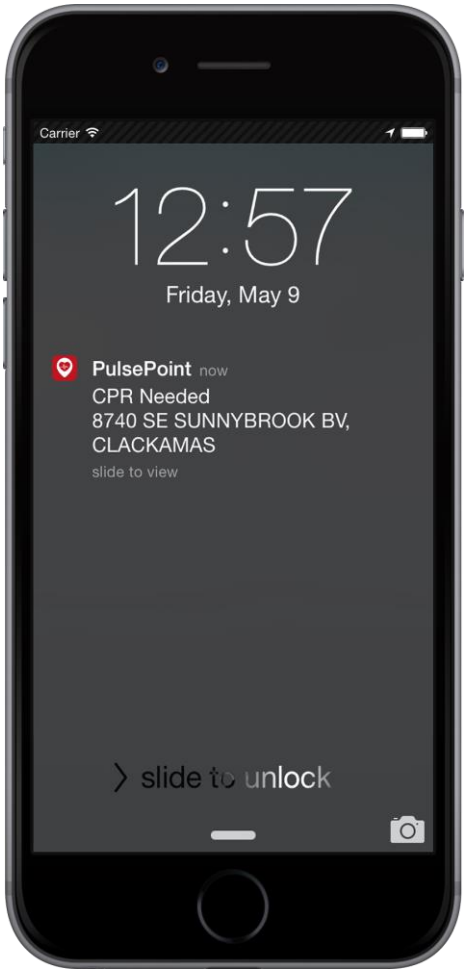
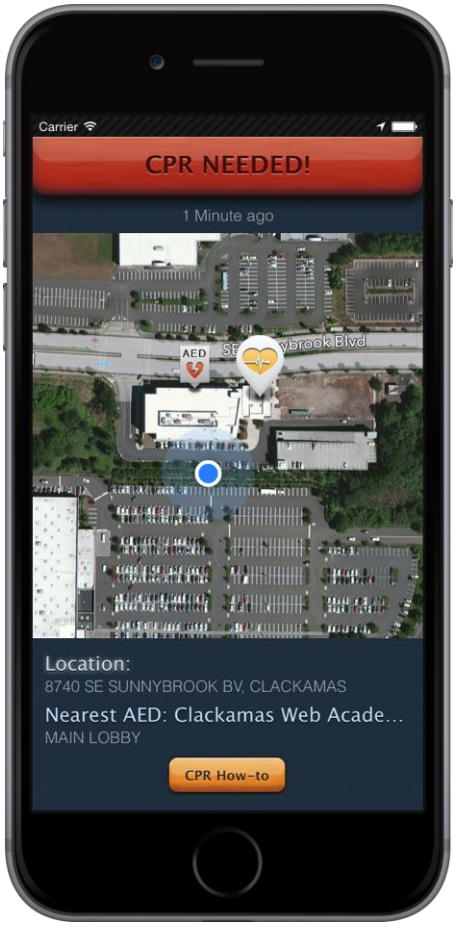

Carrier
12:57
Friday, May 9
PulsePoint now
CPR Needed
8740 SE SUNNYBROOK BV,
CLACKAMAS
slide to view
slide to unlock

**FIGURE 2.** *The interactive PulsePoint alert map showing the location of the user (blue dot) in relation to the location of the emergency (yellow heart icon) and nearby public access defibrillators (red heart icon).*




*Technical implementation of PulsePoint*

EMS agencies participating in this study will work with the PulsePoint Foundation to implement the PulsePoint interface software into their dispatch computer systems. The PulsePoint interface communicates with the PulsePoint server to facilitate PulsePoint notifications in the event of a suspected cardiac arrest emergency in the community.

*PulsePoint Community Implementation Strategy*

Prior to beginning patient recruitment, participating communities will execute a coordinated marketing campaign aiming to maximize the number of CPR-trained individuals who download the PulsePoint app onto their mobile device within the community. CPR-trained members of the community will be encouraged to download the free-of-charge "PulsePoint Respond" mobile device application from iTunes or Google Play. Communications personnel will be supported by the PulsePoint Foundation with this community rollout with the use of marketing materials and strategies. The strategies include a media launch event, social media strategy, and distribution of marketing materials. Various community stakeholders will be engaged to increase the penetration of the message and optimize app downloads. High priority user groups within each community will be specifically targeted through the use of

leadership contacts and mail distribution lists. These high priority target groups include paramedics, firefighters, hospital-based health care providers, lifeguards, police officers, and basic life support course trainers and graduates.

*Criteria for study launch in participating communities*

The following implementation criteria must be met before a site begins enrolling patients:

1) All PulsePoint system software has been installed in computer-assisted dispatch (CAD) systems of participating agencies.
2) A successful "sandbox" period during which communication between the agency CAD system and the PulsePoint server has been completed.
3) A successful "soft launch" of the PulsePoint system has occurred where real data (actual 9-1-1 calls) is being exchanged between the CAD and the PulsePoint server appropriately triggering the system for calls which meet trigger criteria.
4) A successful "public launch" of the PulsePoint system has occurred in conjunction with the execution of the media and communications plan to the community at large.
5) Successful pilot testing of randomization procedures and data transfer procedures within the participating agency have been completed.

*Randomization procedures*

Randomization will occur at the time the 9-1-1 call is processed for dispatch of emergency responders and activation of the PulsePoint system. Due the nature of the intervention and the time-critical nature of the emergency, randomization will need to occur before information is available to evaluate all inclusion and exclusion criteria. As a result, this trial will require post randomization exclusions to occur on the basis of information captured by paramedics **after** randomization has already occurred.

Computer randomization, within the PulsePoint system, will be done for all 9-1-1 calls associated with a public location (e.g., non-residential) and tagged with any of the following medical priority dispatch codes:

The eligible MPDS codes are:

09D01 – Ineffective Breathing

09E01 – Respiratory Arrest

09E02 – Breathing Uncertain

11D01 – Choking not alert

11D02 – Choking abnormal breathing

11E01 – Choking verified

12D01 – Convulsions not breathing

14D01 – Drowning unconscious

This randomization will occur automatically and simultaneously with dispatch of professional responders to the scene. Randomization will use permuted blocks stratified by site using random variable undisclosed block sizes to avoid imbalance by group between sites. Dispatchers, emergency medical providers, and patients will be blinded to group allocation until the analysis is complete.

*Experimental - Conventional Emergency Dispatch PLUS PulsePoint notification*
Eligible 9-1-1 calls randomized to the experimental arm of the study will undergo usual dispatch of emergency services personnel as per pre-existing local protocols **and** activation of the PulsePoint system. When triggered, the system will push location data to all PulsePoint mobile application users within 400 meters of the emergency. Devices receiving the alerts from the PulsePoint system will alarm with auditory, tactile (vibration) and visual stimuli (Figure 1). The application will present a map showing the exact location of the emergency and the closest public access defibrillator (Figure 2).

*Control - Conventional Emergency Dispatch without PulsePoint notification*
Patients randomized to the control arm will receive conventional emergency medical dispatching procedures as per pre-existing local protocols (e.g. dispatch of emergency vehicles, attempted dispatch-assisted CPR) **without activation of the PulsePoint system.** 9-1-1 calls randomized to the control arm will not be associated with any PulsePoint alerts.

**Outcome Measures**
*Primary outcome*
*1)* "Bystander resuscitation" defined as the occurrence of either bystander CPR (chest compressions and or ventilations) or bystander application of a defibrillator

*Secondary effectiveness outcomes*
1) Bystander CPR
2) Bystander defibrillator use (attachment of pads on the chest)
3) Bystander defibrillator shock delivered
4) Return of spontaneous circulation
5) Survival to hospital discharge
6) Survival to hospital discharge with good functional outcome (Cerebral Performance Score 1 or 2)

*Secondary safety outcomes*
1) EMS response time interval (9-1-1 call to arrival on scene)
2) EMS on scene time interval (arrival on scene to departure from scene)
3) Crew reports of bystander interference with the resuscitation effort

*Secondary system performance outcomes*
1) The number of PulsePoint application downloads in each participating community
2) The number of application users notified for each PulsePoint notification
3) The sensitivity of the PulsePoint activation as it relates to activation for true cardiac arrests
4) The false positive rate for PulsePoint activation resulting from activation of the system for conditions other than cardiac arrest

**Data Collection and Management**
Data for this study will be gathered from pre-existing cardiac arrest registries and source documents where necessary. A study database will be built and managed by the coordinating centre (Queen's) research coordinator.

*British Columbia Registry of Out-of-Hospital Cardiac Arrest*

Jim Christenson (a co-investigator and steering committee member for this study) is the Principal Investigator for the BC registry of OHCA. This registry continues to capture consecutive cardiac arrests in most of the Province. Data relating to cardiac arrest patients for the PulsePoint RCT will be extracted from the BC OHCA registry.

For the purposes of this study, BC ROC study team will also establish a local dataset for study participants who are enrolled and randomized but who are ultimately found to be suffering from a condition other than cardiac arrest. Limited data such as age, sex and paramedic problem code will be collected.

Collection of both streams of data occurs through a pre-existing partnership and data transfer agreement between the BC Resuscitation Research Team and BC Emergency Health Services.

*CARES Database*

CARES is an American out-of-hospital cardiac arrest database hosted at Emory University in Atlanta, Georgia. This database will be used to capture study data from Columbus, Ohio. CARES is a secure, web-based data management system in which participating communities enter and retain ownership of local cardiac arrest data and generate their own reports for quality improvement and research. Communities can compare their EMS system performance to de-identified aggregate statistics at the local, state, or national level and discover promising practices that could improve emergency cardiac care. This data has also been used in a number of scholarly publications related to the epidemiology of cardiac arrest. Study coordinators from the Columbus, Ohio study site will transfer de-identified CARES data for each enrolled patient to the coordinating centre for data entry into the study database.

*Columbus' EMS patient care source documents*

For the purposes of this study, the Ohio State study team will also query their Columbus paramedic records to establish a local dataset for study participants who are enrolled and randomized but who are ultimately found to be suffering from a condition other than cardiac arrest. Limited data such as age, sex, and paramedic problem code will be collected.

*PulsePoint Enterprise Server Data*

The density of active application users within the study area (active application users/km2) will be captured at regular intervals during the study. For every PulsePoint notification, the number and location of all alerted smartphones will be captured.

# ANALYSIS PLAN

*Specification of the population for analyses*

Study inclusion and exclusion criteria will be applied to the population of patients undergoing randomization. Participating sites will evaluate all randomized patients for inclusion and exclusion criteria. Data from cases meeting inclusion and exclusion criteria will be transferred to the coordinating centre at Queen's for entry into the study database.

**The primary analysis population will include all patients meeting inclusion and exclusion criteria where there was at least one PulsePoint device identified within 400 meters of the emergency location.**

*Analysis related to the primary objective*

We will undertake a descriptive analysis of our patient population with respect to demographics in cardiac arrest characteristics. Demographics and cardiac arrest characteristics of patients excluded from the primary analysis on the basis of having no PulsePoint device identified within 400 m will be compared with the included population to evaluate for selection bias. The primary comparison will be done using the Mantel-Haenszel Chi-Square test stratified by site with the treatment effect estimated by the absolute risk difference and odds ratio each presented with 95% confidence intervals. Our secondary analysis will use a multilevel, hierarchical logistic regression model to explore the association between PulsePoint notification and bystander resuscitation notification while controlling for potential confounders and accounting for the clustered nature of the data within four distinct agencies. Variables such as patient age, sex, witness status, time of day and EMS response interval will be entered into the model as independent variables in multivariate regression to obtain adjusted effects. Odds ratios along with 95% Wald confidence intervals will be reported for significant variables. A similar analysis will be conducted for binary secondary outcomes. Potentially confounding variables available in the Epistry database such as age, sex, initial cardiac arrest rhythm, public versus private location, EMS response interval and the use of therapeutic hypothermia will be included in the model to obtain adjusted effect estimates.

*Analysis related to the secondary objective – Impact of user density*

PulsePoint application user density will be defined as the number of smartphones with an active version of the PulsePoint application running per $km^2$. The data obtained by the enterprise server will result in a spatial point process. Using spatial models we will create maps of participating regions that will indicate various levels of density using a color shading scale. Stratifying by time of day (day versus night) and time of week (weekday versus weekend) 4 maps, (one for each combination of variables), will be created using kernel smoothing techniques (12). To examine trends over time these maps will be created using data up to 3 months, 3 – 6 months, and every 6 months thereafter. A bivariate symmetrical kernel with a border function will be used along with a variable bandwidth. Training and testing data sets will be established. The training data set will be used to estimate parameters for the kernel smoother while the testing data set will be used to validate them. Cross-validation will be used for bandwidth selection. A two-stage model will enable us to examine the relationship of PulsePoint application density at time of cardiac arrest and bystander CPR. In the first stage, a Poisson model will be used to examine the number of PulsePoint notifications, amongst those who have the PulsePoint application, while adjusting for other important variables. This model will provide a mean surface intensity (a measure of density), which, in stage two, will be introduced into a logistic regression model as a covariate that examines bystander CPR as an outcome. Using the density measure, odds ratios can be used to examine how a one unit increase (or decrease) in the density increases (or decreases) the odds of bystander resuscitation.

*Planned subgroup analyses*

***Rural versus urban***

Each included episode will be classified as urban versus rural based on whether it occurred in a “Census metropolitan area” defined by Statistics Canada. The interaction between rural-urban status and PulsePoint notification will be explored in the logistic regression model.

***Initial cardiac arrest rhythm – Shockable versus non-shockable***

We will examine for effect modification of the association between PulsePoint notification and outcomes by initial cardiac arrest rhythm (shockable versus non-shockable).

**Sample size and recruitment rate**

We estimate bystander CPR will occur in 50% of the control group (11). We have set the minimum clinically significant difference in the primary outcome between groups at 15%. This magnitude of effect is consistent with differences observed during a recent RCT by Ringh et al (9) exploring the effectiveness of a similar crowd sourcing strategy. Setting power to 80% and alpha to 0.05, we will require 340 patients in the primary analysis group (170 control patients, 170 treatment patients). We have recruited 155 eligible patients to date. Although we achieved our best monthly recruitment rate of 15 patients recently after efforts to increase the device count in our study sites, the average recruitment rate has been 7 patients per month. Based on the nature of our study and follow up data, we have not had any loss to follow-up. Based on a conservative estimate of 10 patients per month going forward, we will require approximately 19 more months of recruitment to achieve a sample size of 340.

*Data Safety and Monitoring Committee*

The Data and Safety Monitoring Committee (DSMC) will act in an advisory capacity for The PulsePoint RCT to review all data and will communicate directly with the principal investigator. The DSMC will consist of a Chairperson and 2 members. The membership will include individuals with expertise in prehospital care, biostatistics and the conduct of clinical trials. The principal investigator and research coordinator will attend all meetings of the DSMC.

The DSMC responsibilities are to: 1) evaluate the progress of the trial, including periodic assessments of data quality and timeliness; 2) consider factors external to the study when relevant information becomes available, such as scientific or therapeutic developments that may have an impact on the safety of the participants or the ethics of the trial; 3) review study performance, make recommendations and assist in the resolution of problems reported by the Principal Investigator; 4) protect the safety of the study participants; and 5) will review at 3 month intervals any adverse events that are potentially related to PulsePoint system activation hat are identified by participating EMS agencies (for example, crowd control issues or harmful acts by PulsePoint responders; etc.).

*Knowledge translation plan*

We are using an integrated knowledge translation approach to accomplish our project objectives. All of the knowledge users involved in this project have decision-making authority related to new medical programs. This study has been designed by the team with policy decisions in mind from the outset. As such, we have ensured that the questions being asked are relevant for decision-makers and outputs from this project will support real world policy decisions.

End-of grant knowledge translation will be facilitated through a number of mechanisms. We will use the CanROC network of emergency service providers across Canada to communicate results. Investigators on this grant are members of influential agencies such as the Heart and Stroke Foundation of Canada, the American Heart Association, the International Liaison Committee on Resuscitation, the Paramedic Chiefs of Canada, and the Canadian Association of Fire Chiefs. All members of the team will be encouraged to present our results to each of these agencies and distribute them broadly to

membership. The results of this trial will be submitted to high impact factor journals for publication and presented at both national and international conferences within the resuscitation science field.

*Potential challenges and mitigation strategies*

**Implementation delays**

Feasibility of PulsePoint in a Canadian setting has been demonstrated in Kingston, Ontario. The PulsePoint Foundation has developed expertise in system implementation with more than 1200 communities now served by the application in the United States. However, implementation of PulsePoint can occasionally be delayed unexpectedly. We will consider no-cost extension of our grant time frame to extend the study timeline if necessary to accrue the necessary number of patients.

**PulsePoint User Recruitment**

Marketing strategies and public outreach aiming to optimize the number of users in the community are a key component of pre-launch activities. Dr. Brooks led the successful implementation of PulsePoint in Kingston, Ontario in collaboration with the communications departments of the City of Kingston, HSFC, Queen's University, and many others. With support from the PulsePoint Foundation which has developed a comprehensive communications plan for implementation in any community, the Kingston implementation achieved more than 1200 users (1% of the population) within two weeks of launch. Since then there have been 68 suspected cardiac arrests in public locations for which 547 PulsePoint notifications were sent. This is the highest average for any PulsePoint community globally (>1200 communities). This very successful communications plan will be replicated and improved for launch in other study communities.

## TIMELINE

**June 2016 – December 2016** - Hiring study related staff, engagement of study sites to prepare for PulsePoint implementation.

**December 2016-November 2020** - REB applications, development of data management plan, data sharing agreements, PulsePoint technical implementation.

**November 2020** - All participating regions launch PulsePoint by this time, 1-2 month roll out period, communications plan activated to recruit PulsePoint users in participating communities, randomization piloted and refined prior to recruiting phase.

**June 2021-June 2026 (anticipated) -** Patient recruitment and randomization.

**July 2026 –December 2026** - Analysis, manuscript drafting, end-of-grant knowledge translation.

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