PhD Project:

Improving The Use of Public Access Defibrillation in the Volunteer Response to Out-of-Hospital Cardiac Arrest

Study Protocol for Work Package 3

"Determining the optimum activation distance for GoodSAM volunteer first-responders notified to a nearby out-of-hospital cardiac arrest"

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1. LIST OF ABBREVIATIONS USED IN THIS DOCUMENT

AED	Automated External Defibrillator
BSREC	Biomedical and Scientific Research Ethics Committee
CAG	Confidentiality Advisory Group
CPR	Cardiopulmonary Resuscitation
CTU	Clinical Trials Unit
GCP	Good Clinical Practice
EMAS	East Midlands Ambulance Service
ILCOR	International Liaison Committee on Resuscitation
LAS	London Ambulance Service
NHS	National Health Service
OHCA	Out-of-Hospital Cardiac Arrest
OHCAO Registry	Out-of-Hospital Cardiac Arrest Outcomes Registry
PAD	Public Access Defibrillation
PEA	Pulseless Electrical Activity
RCT	Randomised Controlled Trial
ROSC	Return of Spontaneous Circulation
SOP	Standard Operating Procedure
STROBE	Strengthening Reporting of Observational Studies in Epidemiology
VF/pVT	Ventricular Fibrillation / pulseless Ventricular Tachycardia

2. BACKGROUND

2.1 Survival from Out-of-Hospital Cardiac Arrest

In 2014, survival to hospital discharge from 28,729 out-of-hospital cardiac arrest (OHCA) in England where resuscitation was attempted was 7.9% (1). Ambulance Quality Indicator Data from 2017-18 shows survival to hospital discharge was 9.4% in London and 7.3% in the East Midlands (2). In recognition of this low survival, the UK Government's Cardiovascular Disease Outcomes Strategy aspires to save 1000 extra lives every year by improving OHCA survival by 50% (3).

Earlier defibrillation of the heart and good-quality chest compressions during cardiopulmonary resuscitation (CPR) greatly improves the chances of survival. CPR conducted by bystanders can at least double the chance that the patient will survive to hospital discharge (4). Public Access Defibrillation (PAD) – the use of public-access Automated External Defibrillators (AEDs) by bystanders before the arrival of the ambulance service – has been associated with an approximately doubling of survival to hospital discharge (OR 1.73) and survival with good neurological function (OR 2.12) (5). Median survival after bystander defibrillation is 53% (6). However, PAD occurred in only 2.4% OHCA in England, 2014 (1).

Ambulance services in England aim to arrive at 75% of OHCA victims within 8 minutes (7) but the chance of survival may have passed by then. We need effective strategies to improve the community response to OHCA before the arrival of the ambulance services if survival rates are to improve. The NHS Long Term Plan published in January 2019 pledges that an extra 4,000 lives will be saved each year by 2028 by developing a network of first-responders and public-access AEDs (8).

2.2 Volunteer first-responder systems for Out-of-Hospital Cardiac Arrest

Systems have been developed to alert volunteers to a nearby OHCA via their mobile phones. Once notified, volunteers can choose to offer assistance if they wish.

In Limburg, Netherlands (2012-2014), cardiac arrest victims attended by volunteers alerted by text-message were 2.8 times more likely to survive than those for whom alerted rescuers did not attend. Rescuers attended in 34.9% cases (291/833). Of these 291 cases, a lay rescuer was the first to start CPR in 24.7% of cases (72/291) and the first to connect an AED in 26.8% of cases (78/291) (9).

An earlier Dutch study (2010-2013) investigated 1536 cardiac arrest patients to whom any defibrillator (including public AED) was attached. Volunteers were activated by text-message in 58.1% of cases (893/1536), and were the first to attach an AED in 12.0% of cases (184/1536). No survival data were published (10).

In a randomized controlled trial (RCT) in Stockholm lay rescuers were activated by text-message for 45.9% cardiac arrests (306/667) between 2012 and 2014. In the intervention group, rates of bystander CPR were significantly higher, but there was no difference in 30-day survival. However, there was no mention of public-access AED provision in this study (11).

There are some potential problems with these nascent systems. Volunteers are not always activated in cases of suspected cardiac arrest and they do not always attend (9) (10) (12) or perform bystander CPR (12) (13). AEDs are rarely attached (14) (15). In a survey of users of a text-message alert system in the USA, only 10.6% rescuers (135/1274) to whom activations were sent arrived on scene, and only 11 found a victim in cardiac arrest and initiated CPR (12). There is also no evidence in the published literature about how to optimise the volunteer response, or how to improve the deployment of AEDs within such systems.

2.3 The GoodSAM volunteer first-responder system

GoodSAM is a mobile-phone, app-based alerting system allowing notification of trained volunteer first-responders to nearby medical emergencies, including cardiac arrests (16). It has been fully integrated with London Ambulance Service (LAS) dispatch systems since October 2015, and with East Midlands Ambulance Service (EMAS) dispatch systems since June 2017. It allows 999 call-handlers to alert trained volunteers via the app to a nearby cardiac arrest victim. Once a call-handler records variables likely to indicate a current or imminent OHCA, GoodSAM is automatically activated alongside the traditional ambulance response.

Up to three GoodSAM volunteer first-responders within a specified radius of an OHCA will receive a notification. First-responders' positions are known in real-time because of GPS-location functions built into mobile phones. The location of the cardiac arrest and nearby AEDs are displayed on a map that is visible to the responder via the app.

GoodSAM volunteer first-responders are classified into different categories:

Tier 1: Doctors, nurses, paramedics – governed at a national level
Tier 2: Community first-responders, Emergency Medical Technicians – governed at a regional level
Tier 3: Individuals with current training in CPR/AED, but under no formal governance

As of early 2019 GoodSAM was integrated with local ambulance service systems in London, North West, East Midlands, and Wales; in the state of Victoria in Australia; and across New Zealand. Six more local ambulance services in the UK will be integrating with GoodSAM during 2019.

2.4 Relevant information from earlier work in this PhD programme

Work Package 1

We conducted a review of all OHCAs attended by LAS (for which resuscitation efforts were made) between April 1st 2016 and March 30th 2017, and evaluated the use of GoodSAM and its potential role in patient survival. At that time, GoodSAM alerted up to three volunteers within a 300m radius of the patient.

From 4196 confirmed OHCA that we evaluated, 372 GoodSAM alerts were sent for 294 patients (7.0%). Alerts were accepted by 56 volunteers for 53 OHCAs (1.3%).

Survival to hospital discharge was seen in 9/51 (17.6%) of patients when a GoodSAM volunteer accepted an alert, 23/223 (10.3%) when an alert was not accepted, and 361/3837 (9.4%) when no GoodSAM alert was sent (because there was no volunteer within a 300m radius). In a multiple logistic regression model, the adjusted odds ratio of patient survival to hospital discharge when a GoodSAM volunteer accepted the alert was 2.38 (95% CI 0.74–7.67, p= 0.147)

In response to these findings, LAS and GoodSAM subsequently decided to increase the alerting radius from 300m for all GoodSAM volunteers to 400m for Tier 3 volunteers and 700m for Tier 1 and Tier 2 volunteers.

Evaluation of GoodSAM in EMAS (June 2017–June 2018) is ongoing, and will also form part of Work Package 1 of this PhD project. The response radius for all GoodSAM responders in East Midlands is currently 800m.

Work Package 2

We investigated barriers and facilitators to PAD use in the GoodSAM system.

We conducted interviews with GoodSAM volunteers shortly after they had received an alert in London. Several respondents reported that – often on numerous occasions – they would arrive at the scene only after the ambulance service had arrived. This was true even when alerts were answered promptly. The belief that they were unlikely to be able to help in the future made some respondents feel *less* likely to a) accept a subsequent alert and b) retrieve an AED en-route to the patient.

2.5 The need for this study

It is clear that volunteer first-responder systems may play an increasing role in the response to OHCA. GoodSAM is specifically mentioned as a case study in the 2019 NHS Long Term Plan published as a means to help patients in need of immediate assistance (p63) (8). In 2015, the International Liaison Committee on Resuscitation (ILCOR) identified a lack of knowledge about the effect of volunteer first-responder systems and app-based digital technology, and how best to optimise their use (17).

The recent work conducted in this PhD suggests that the optimum response radius for GoodSAM volunteers isn't known. The fact that a small number of cardiac arrests receive a volunteer first-response is a concern, but an increase in the activation distance by itself will not solve the problem if volunteers are travelling so far that they do not arrive before the ambulance service. There needs to be accurate data about which GoodSAM volunteers reach the patient before the ambulance service and provide meaningful interventions. This data does not yet exist.

The optimum activation distance is likely to be dependent on a number of factors and vary from area to area. A study into this issue will not only provide information not only about outcomes at different activation distances but also valuable insights about how best to investigate this issue in different regions and countries. Indeed, the lessons learned would be of benefit to other volunteer first-responder systems across the world.

This work is fully supported by and will be undertaken with the support of GoodSAM, LAS and EMAS. Warwick University Clinical Trials Unit (CTU), the host institution for both this study and the national Out-of-Hospital Cardiac Arrest Outcomes (OHCAO) registry, has an excellent professional working relationship with these organisations.

2.6 Research question

"What is the optimum activation distance for GoodSAM volunteer first-responders notified to a nearby out-of-hospital cardiac arrest?"

2.7 Ethical considerations

We will conduct this study in accordance with the Declaration of Helsinki, Medical Research Council Good Clinical Practice (GCP) Guidelines, and Warwick CTU Standard Operating Procedures (SOP).

The main ethical challenge relates to the fact that cardiac arrest causes an immediate loss of capacity, and so it is not be possible to obtain informed consent from patients to use their data. Anonymised patient outcome data will be collected from the OHCAO Registry hosted at the University of Warwick, following approval of a data-sharing agreement. Ethical approvals are already in place which will allow the analysis of anonymised data from the OHCAO Registry without further ethical review - Reference NRES 13/SC/0361; Confidentiality Advisory Group (CAG) (ECC 8- 04(C)/2013).

We will be collecting data from GoodSAM volunteers who are responding to a cardiac arrest through the GoodSAM platform. This will include their location at the time that they received an alert. We will collect no directly identifiable information about GoodSAM volunteers and so it will not be possible for the research team to identify an individual responder's location.

The visible location of responders (on a map) is already available in real-time via a web portal which specified members of ambulance services have access

to. This visible location is off-set by 50 metres. The actual responder location is recorded and held securely by GoodSAM – this is the data that will be shared with the research team. It is not available to and will not be shared with ambulance trusts.

All GoodSAM responders are adults, who require a minimal level of CPR/AED certification to register with GoodSAM. Their capacity will be presumed.

We will make an ethical application to the Biomedical and Scientific Research Ethics Committee (BSREC) at the University of Warwick. The project will comply with all LAS, EMAS and GoodSAM protocols regarding the approval of research projects. We will gain sponsorship from Warwick Medical School CTU (in accordance with their SOP) as the Host Organisation for this research.

2.8 Reporting statement

This study will be reported in line with the Strengthening Reporting of Observational Studies in Epidemiology (STROBE) guidelines (18).

2.9 Assessment and management of risk

We are not making any modifications to the response of either the statutory ambulance service or GoodSAM responders. This study poses no additional risk to patients.

This study will place no additional responsibilities or liabilities on GoodSAM volunteers than already exist. There is no specific Good Samaritan legislation in England. In 2015, the Social Action, Responsibility and Heroism Act was introduced in England and Wales (19) and covers Good Samaritans for responsible actions taken in situations of great urgency. Essentially, to be held liable for a Good Samaritan act when attending an OHCA victim, one would have to leave a victim in a worse state than one had found them in. This is unlikely given the uniformly fatal outcome from OHCA without any intervention. There are no known cases in English law where a victim has successfully sued a rescuer who came to their aid in an emergency (20).

Data will be collected from GoodSAM and the OHCAO Registry. This data will be routinely stored by these two organisations according to their own policies, and would therefore be available for scrutiny by the study team in the event of any concerns.

3. STUDY DESIGN

3.1 Study summary and flow diagram

Work package 3 will be a cross-sectional study examining the response to all GoodSAM alerts sent out to volunteers during the study period.

We will determine the proportion of GoodSAM alerts that result in a volunteer reaching the patient's side before the arrival of the ambulance service **(Figure 1)**. We will also determine whether or not outcomes for confirmed OHCA patients are affected by a GoodSAM volunteer reaching the scene **(Figure 2)**

In London, we will be able to compare the current response radius (700m for Tier 1 and Tier 2 responders, and 400m for Tier 3 responders) to the historical response radius of 300m. We will determine the effect that a 300m vs 400m/700m would have had on GoodSAM volunteers reaching the patient.

We will construct a multiple logistic regression model to determine whether a) a volunteer reaching the scene or b) GoodSAM volunteer travel distance are independent predictors of survival when adjusted for other confounders.

We will create a Receiver Operating Characteristic (ROC) curve to determine the optimum threshold for GoodSAM responder travel distance, when considering whether or not they reached the scene before the ambulance service. Additionally, we will stratify this by London Borough (in London) and by constituency (in East Midlands) and report any differences in this threshold.

We will collect patient data that is already submitted from LAS and EMAS to the OHCAO Registry. Submissions occur on a monthly basis. No additional patient data is required.

We will send a brief post-event questionnaire to GoodSAM volunteers (via the app itself) to determine whether or not they reached the patient before the ambulance service arrived. This questionnaire will be sent out **after** the end of an alert – we are not intervening in or delaying the alerting process in any way. GoodSAM will collect and hold this information, and subsequently share it with the study team.

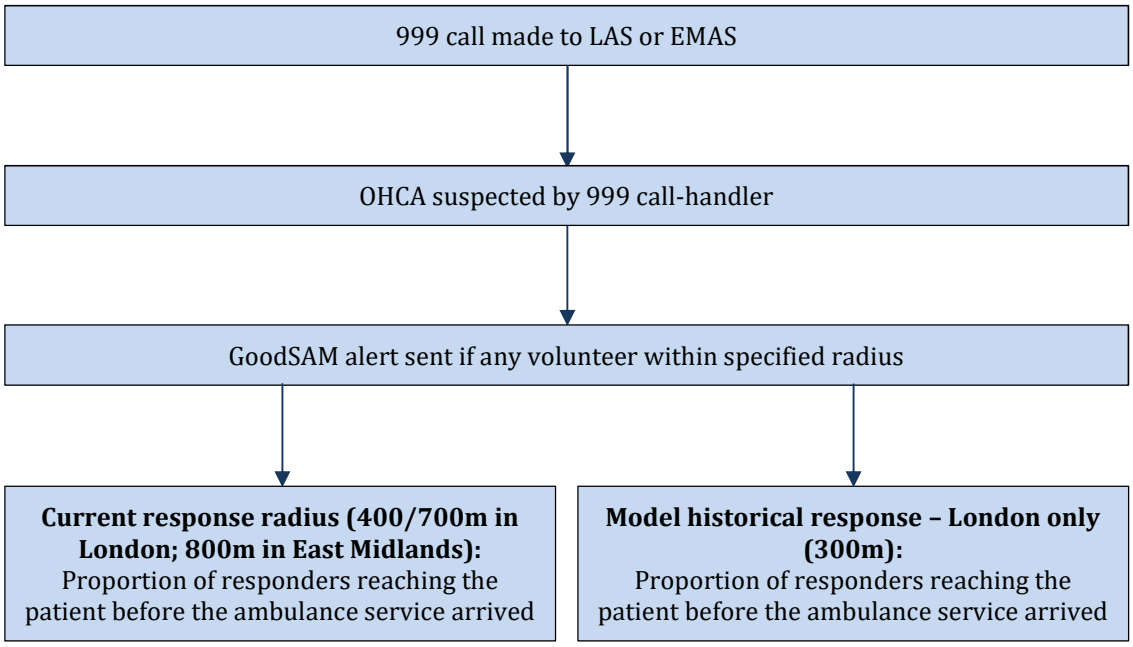

Figure 1: GoodSAM volunteers reaching the patient before the ambulance service

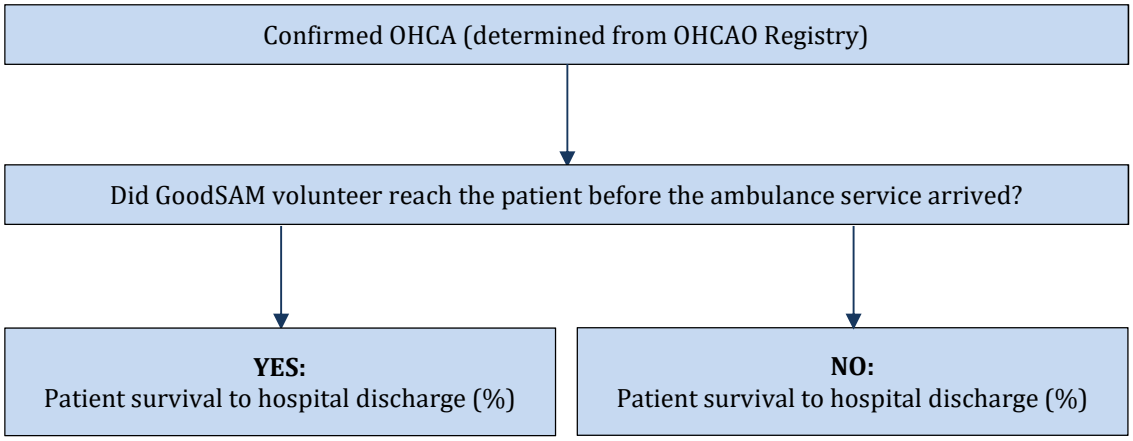

Figure 2: Patient survival by GoodSAM volunteer arrival on scene

3.2 Aim of the study

The aim of this study is to determine the number of GoodSAM volunteers responding to a suspected OHCA that currently reach the patient's side before the arrival of the ambulance service, and to calculate the optimum activation distance for GoodSAM volunteers.

3.3 Outcome measures

3.3.1 Primary outcomes

We will report the number and proportion of GoodSAM alerts (which are accepted) that result in a GoodSAM volunteer reaching the patient's side before the arrival of the ambulance service.

This will be by means of a post-event questionnaire that is delivered to GoodSAM responders who accept an alert (on the same day).

3.3.2 Secondary outcomes

We will report:

- Optimum activation distance (based on both response radius and by actual travel distance using roads and paths) for GoodSAM responders. This will be based on a ROC curve, based on whether or not a GoodSAM volunteer reached the patient's side before the arrival of the ambulance service.

We will also report the two patient-related secondary outcomes only in confirmed OHCA where resuscitation was attempted by the ambulance service:

- Survival to Hospital Discharge
- ROSC

We will also report the process variables detailed in **section 5.3 (page 20)**

3.4 Eligibility criteria

3.4.1 Inclusion criteria

For the primary outcome we will include cases for which the GoodSAM volunteer has received and accepted a notification – note that this will include cases where the patient is subsequently found not to be in cardiac arrest.

For the secondary patient-related outcomes we will only include the following cases:

- Those that are confirmed as OHCA where resuscitation was attempted by the ambulance service. These are the cases that are submitted to the OHCAO Registry.

- Those where we can match OHCA cases to GoodSAM activations. Date, time and location of OHCA are recorded by both GoodSAM and the OHCAO Registry so this should not pose any difficulties

3.4.2 Exclusion criteria

We will exclude cases:

- Where the GoodSAM volunteer accepting an alert is a member of LAS or EMAS staff who is already attending the OHCA in a professional capacity

3.5 Participant identification

GoodSAM volunteers will be identified by the very fact of their registration with the app, which allows them to receive a GoodSAM alert. GoodSAM already record information about whether or not an alert is accepted or declined – we will not alter this process in the course of this study.

A post-event questionnaire is already automatically sent to GoodSAM volunteers via the app at the completion of the alert, and this data is held by GoodSAM in accordance with their existing practices. For the purposes of this study, we will need to ask some additional questions, as detailed in **section 5.3 (page 20).** The required changes to this questionnaire will be made prior to the start of the study.

Relevant data will be shared with the project team if the GoodSAM volunteer indicates their consent (see **section 3.7**). We will not collect any personal identifiable data about GoodSAM volunteers.

Confirmed cardiac arrest patients will be identified by the inclusion of their data in the OHCAO Registry. The data fields that we will request from the OHCAO Registry **(see section 5.3, page 20)** are considered non-identifiable by the Confidentiality Advisory Group (CAG).

3.6 Site training

There are already well-established processes for the collection of data required for this study. GoodSAM already have the technical expertise to deliver an in-app post-event questionnaire.

All data will be transferred to the primary investigator (Dr Christopher Smith) and he will collate and analyse this data with the support of his PhD supervisory team at the University of Warwick. We do not anticipate any additional training needs.

3.7 Informed consent

We are not altering the standard clinical care for patients, the statutory ambulance response or the GoodSAM volunteer response in any way.

We will collect anonymised patient outcome data from the OHCA Outcomes (OHCAO) Registry. Ethical approvals are already in place which will allow the analysis of anonymised data from the OHCAO Registry without further ethical review - Reference NRES 13/SC/0361; CAG (ECC 8- 04(C)/2013).

Following an alert, we will send a short message via the app informing them of the information that we will be collecting and why. They will be asked if they wish to provide consent to sharing this information with the study team. If they consent, they will be asked to fill in the post-event questionnaire. The message, consent statement and post-event questionnaire are detailed in the **Appendix (section 11)** of this protocol.

All GoodSAM volunteers are adults, and all are presumed to have capacity to consent.

4. DATA MANAGEMENT

4.1 Data collection and management

We will handle and store any personal data collected during the study in accordance with the University of Warwick's Data Protection Policy and Information Classification and Handling Procedures, and Warwick CTU SOP 15 on Information Handling and Electronic Data Security.

GoodSAM and the OHCAO Registry are the two sources for the information that we will using in this study. Data from the OHCAO Registry is held at the Clinical Trials Unit at the University of Warwick and can be placed into an encrypted folder to which the Principal Investigator will have access.

GoodSAM does not share information with third parties and is registered with the Information Commissioner's Office (no: ZA094052). Its full data protection policy is available at: https://www.goodsamapp.org/assets/pdf/DataProtectionPolicy.pdf

Data from GoodSAM will be sent as a password protected file via e-mail to the Principal Investigator (with a @warwick.ac.uk address). This will subsequently be added to the encrypted folder

We will create an electronic record for each included case, into which we will input the relevant data from the source information. The data that we will collect is detailed in **section 5.3 (page 20).**

4.2 Data storage

Source information and electronic records will be stored in an encrypted folder (Symantec PGP Encryption) on a Windows 10 Desktop computer. The computer is located in a private, locked office in the Clinical Trials Unit. The Principal Investigator has access to this folder and machine. We will not collect or store and personally identifiable data, either in source information files or in the electronic record that we will create.

The list of documents that will be stored in this folder are:

- Study protocol (latest version and previous versions)
- Participant Information / Consent information (latest and previous versions)
- Post-event questionnaire template
- Data Sharing Agreement with GoodSAM
- Data Sharing Agreement with OHCAO
- Ethics Submission
- Ethics Approval
- Source information – GoodSAM
- Source information – OHCAO Registry
- Electronic data collection form

4.3 Data access and quality assurance

Dr Christopher Smith and the PhD supervisors will have access to the data in the encrypted folder. The Principal Investigator will be responsible for entering data and ensuring the accuracy of this process.

The accuracy of data input will be checked when required by the PhD supervisors. Dr Christopher Smith will be assisted in statistical analysis by Professor Ranjit Lall.

4.4 Data shared with third parties

The approved study protocol will be published on Dr Christopher Smith's University of Warwick webpages.

We will not share individual case data or any personal identifiable data.

4.5 Archiving

All of the data collected in this study, source data and all other documents will be created and held electronically. These will all be held in the encrypted folder. This data will be held for at least ten years from the date of any publication which is based upon this study, in line with the University's Research Data Management Policy:

https://warwick.ac.uk/services/ris/research_integrity/code_of_practice_and_policies/research_code_of_practice/datacollection_retention/research_data_mgt_policy

The principal investigator will be responsible for its storage and eventual deletion. Encryption programmes provided by the University can securely remove this data and, in any case, we will seek advice from IT Services about the best way to do this at that time.

5. STATISTICAL ANALYSIS

5.1 Study population

The group of interest is GoodSAM volunteers who are close enough to a suspected OHCA to receive a GoodSAM alert. In the 2016-17 data from London (Work Package 1) there were approximately four to five GoodSAM alerts sent out per day; we can anticipate that this number will rise with the increased response radius that has been implemented in London since then.

We will also report on outcomes specific to confirmed OHCA cases. We will identify patients with confirmed OHCA by the fact of inclusion of their data in the LAS or EMAS submissions to the OHCAO Registry at the University of Warwick.

5.2 Post-event questionnaire

The following questions are asked on the post-event questionnaire:

- Did you get to the scene?: **Yes/No**
- How did you get to scene?: **foot/bicycle/motored vehicle/other**
- Did you get to the patient?: **Yes – before the ambulance/Yes – after the ambulance/No/I was on-duty with the ambulance service**
- Was the patient in cardiac arrest?: **Yes/No/Not applicable (did not get to patient)**
- What assistance did you provide?: **CPR/defibrillation/other/not applicable (did not get to patient)**

GoodSAM also record a volunteer as 'on scene' when their mobile phone location is in the same vicinity as the patient. If there is conflict we will give precedence to the respondents' answers via the post-event questionnaire – when provided soon after the alert we feel that this will be more accurate than the app which uses proximity via the mobile phone's GPS capability. We will feedback the rate of discrepancy (NOT using individual examples) to GoodSAM for purposes of quality improvement.

5.3 Data being collected

We will present data taking note of the Utstein guidelines – an internationally recognised and standardised methodology for reporting OHCA that records 23 core elements across five domains (system, dispatch, patient, process, outcome) (21). We will determine and report the following information (with the source of the information in brackets):

Primary outcome (GoodSAM):

- Number and proportion of accepted GoodSAM alerts that result in a GoodSAM volunteer reaching the patient's side before the ambulance service (GoodSAM)

Secondary outcome (OHCAO Registry):

- Survival to Hospital Discharge
- ROSC

Process and other variables:

- *System (OHCAO Registry)*
    - Number of confirmed OHCA cases submitted by LAS or EMAS
    - Date and Time of OHCA

- *Dispatch (GoodSAM)*
    - Number of 999 calls meeting criteria for GoodSAM activation
    - Date and time of 999 calls meeting criteria for GoodSAM activation
    - Number of GoodSAM alerts sent out in time period*
    - Date and time of GoodSAM alerts sent out in time period *

*Alerts will only occur if there is a volunteer within the pre-determined radius

- *Patient (OHCAO Registry, reported for cardiac arrest patients only)*
    - Age and gender
    - OHCA witnessed by ambulance service
    - Bystander* CPR performed
    - Bystander* AED used
    - Initial heart rhythm (VF/pVT, PEA or asystole)
    - OHCA location type (residential or non-residential)
    - OHCA location (by London borough or East Midlands constituency)
    - Distance to nearest public-access AED?

* any bystander, not just GoodSAM volunteers

- *Process*
    - Ambulance response time *(OHCAO)*
    - Number and proportion of GoodSAM volunteers who accepted or declined alert *(GoodSAM)*
    - Number and proportion of GoodSAM volunteers who reached the scene *(GoodSAM)*
    - Location of GoodSAM volunteer at time of alert *(GoodSAM)*
    - Accuracy of location at time of alert *(GoodSAM)*
    - Travel modality used – motor vehicle, bicycle, foot *(GoodSAM)*
    - Travel distance – using most likely route via roads and paths *GoodSAM)*
    - Travel time – estimated from distance and using average walking or driving speed *(GoodSAM)*

We will determine travel distance by recording the position of the GoodSAM responder at the time of the alert (provided as GPS coordinates only from GoodSAM) and the position of the suspected cardiac arrest incident (available from both GoodSAM and OHCAO).

We will report number and proportion of eligible cases for which we receive a completed post-event questionnaire and are subsequently included in our analyses.

For all analyses we will report separate results for the LAS and EMAS datasets.

5.4 Primary outcome analysis

We will provide point estimates (with 95% confidence intervals) for the proportion of GoodSAM volunteers that reach the patient before the arrival of the ambulance service. We will compare this to the proportion that would have reached the patient before the ambulance service had the response radius still been 300m (London only). The outcome is binary (yes / no) and so we will analyse differences between groups using logistic regression, and adjust for important covariates.

	Current response radius	Historical response radius (modelled, London only)
Reached Scene: **YES**	n	n
Reached Scene: **NO**	n	n

5.5 Secondary outcome analysis

1. We will determine whether or not outcomes for confirmed OHCA patients are affected by a GoodSAM volunteer reaching the scene:

	Survival to Hospital Discharge: **YES**	Survival to Hospital Discharge: **NO**
Reached Scene: **YES**	n	n
Reached Scene: **NO**	n	n

	ROSC: **YES**	ROSC: **NO**
Reached Scene: **YES**	n	n
Reached Scene: **NO**	n	n

2. We will construct an adjusted multiple logistic regression model to determine whether or not a) GoodSAM volunteer reaching the patient

before the ambulance service or b) GoodSAM volunteer travel distance is an independent predictor of survival when adjusted for other confounders. We will run this for each of the LAS and EMAS datasets. These confounders may include:

- Day of week
- Time of day
- Ambulance response time
- OHCA location type (residential or non-residential)
- OHCA location (by London borough or East Midlands constituency)
- Patient age and gender
- EMS witnessed OHCA
- Presenting rhythm (VF/pVT, PEA or asystole)
- Bystander CPR performed
- Bystander AED performed
- EMS response time
- Pre-hospital ROSC

3. We will create a Receiver Operating Characteristic (ROC) curve to determine the optimum threshold for GoodSAM responder travel distance, when considering whether or not they reached the scene before the ambulance service. Additionally, we will stratify this by London Borough or East Midlands constituency and report any differences in this threshold.

6. STUDY ORGANISATION AND OVERSIGHT

6.1 Governance arrangements

This PhD project is being undertaken at The University of Warwick. The PhD and all associated study will be subject to all policies and procedures laid out by Warwick Medical School. We will follow all relevant procedures as laid out in the Warwick CTU SOPs.

6.2 Ethical and other approvals

We will request ethical approval from BSREC at the University of Warwick.

We will have formal data sharing arrangements with GoodSAM and the OHCAO Registry. LAS, EMAS and GoodSAM are all represented on the project's steering committee and support the study. This protocol, and all associated documents prepared for the BSREC submission, have been reviewed by members of the steering group.

We will not begin any data collection or analysis until we have received all necessary approvals.

6.3 Indemnity

NHS indemnity covers NHS staff, medical academic staff with honorary contracts, and those conducting the study. NHS bodies carry this risk themselves or spread it through the Clinical Negligence Scheme for Trusts, which provides unlimited cover for this risk. The University of Warwick provides indemnity for any harm caused to participants by the design of the research protocol.

We do not anticipate any risk of harm to participants due to the design of this study.

6.4 Study timetable and milestones

The following timeline is proposed:

Protocol and Ethical Submission	Apr – Jun 2019
Data Sharing Agreements	Apr – Jun 2019
Testing and integration of post-event questionnaire	May – Jun 2019
Main Study Period (six months)	Jul 1st – Dec 31st 2019
Data Collection (GoodSAM), post-event questionnaire	Jul 2019 – Jan 2020
Data Collection (OHCAO Registry)*	Oct 2019 – Apr 2020
Data Analysis	Apr – May 2020
Data synthesis and write-up (for PhD)	May – Jun 2020
Publication, presentations, dissemination	Jun – Nov 2020

** registry data is submitted monthly, with a three month delay*

6.5 Administration

All study co-ordination will be based at Warwick CTU at the University of Warwick.

6.6 Study management

6.6.1 PhD supervision

This project is **the third** of three interconnected pieces of work being conducted as part of PhD in Health Sciences being undertaken by Dr Christopher Smith. The project will be supported by Professor Gavin Perkins (Director of CTU) as primary supervisor and by Professor Frances Griffiths (Head of the Department of Health Sciences) and Professor Ranjit Lall (Professor of Clinical Trials) as secondary supervisors.

All three PhD supervisors have extensive experience in providing supervision and/or support for PhD projects and clinical trials.

6.6.2 Steering group

We will provide three-monthly updates to the Steering Group throughout the project. Further meetings and discussions will be held with some or all of the steering group if required during the period of study. Some of this group may have expertise relevant to work packages 1 and 3 rather than work package 2.

Steering group membership:

- Mr. Mark Wilson (GoodSAM founder, consultant neurosurgeon)
- Dr. Rachael Fothergill and Mr. Christopher Hartley-Sharpe (London Ambulance Service)
- Mr. Rob Spaight and Mr. Neil White (East Midlands Ambulance Service)
- Dr. Claire Hawkes (Senior Research Fellow)
- Professor Ivo Vlaev (Warwick University Business School, Behavioural Science department)
- Professor Theo Arvanitis (Warwick University Institute of Digital Healthcare)
- Mr. Julian Hague (PPI Representative)
- Mr. John Long (PPI Representative)

LAS, EMAS and GoodSAM are integral to the success of this project. The steering group has official representation from all three organisations to ensure effective and regulated access to cardiac arrest datasets, responders and ambulance service personnel. Their experience in developing and refining protocols for the work packages will be advantageous.

Mr. Long and Mr. Hague are PPI representatives. They were approached and agreed to participate because of their previous interest in cardiac arrest research. They both recognise the potential of PAD to improve survival for

cardiac arrest victims in the community

6.7 Essential documentation

All data and files relating to the project will be held in a dedicated encrypted folder on a secure file server at the University of Warwick. It will be clear from the naming and location of documents which are current versions and which are earlier drafts or versions.

GoodSAM and the OHCAO Registry will hold their own source information documents according to their own procedures. No new electronic data or forms generated as a result of this study will be shared or stored outside of the University of Warwick.

6.8 Financial support

Dr. Christopher Smith is a NIHR-funded Doctoral Research Fellow (November 1st 2017 – October 31st 2020, NIHR DRF 2017-10-095) and PhD Health Sciences student at the University of Warwick.

There will be costs associated with modifying the post-event questionnaire and delivering this via the app. These costs have already been accounted for: estimated costs had already formed part of the funding application to the NIHR for the Doctoral Research Fellowship.

We will not seek any additional sources of funding.

7. MONITORING AND QUALITY ASSURANCE

7.1 Training

The Primary Investigator and Co-Investigators will all have up-to-date GCP training and qualifications. Evidence of GCP training will be held at Warwick CTU and available for scrutiny if required.

In addition, the Primary Investigator has detail a training plan as part of his NIHR Doctoral Research Fellowship. This includes courses that are relevant to this work package:

- Mixed Methods in Health Research (MSc module, University of Warwick, February 27th – March 3rd 2017)
- Qualitative Research Methods in Health (MSc module, University of Warwick, December 4-8th 2017)
- Introduction to Regression Analyses (short course, University College London, 15-16th January 2018)
- Introduction to Qualitative Interviews (short course, University of Oxford, 31st January 2018)
- Introduction to Logistic Regression (short course, University College London, 30th April 2018)
- Analysing Qualitative Interviews (short course, University of Oxford, 17-18th May 2018)
- Research Methods in Clinical Trials (short course, University of Birmingham, 25-27 March 2019)

7.2 Data quality

The Primary Investigator will be principally responsible for data entry. The PhD supervisors will review and approve all data entry forms and data collection processes before data collection begins. They will carry out periodic checks of data quality at their discretion to assure the accuracy of the data entered.

7.3 Quality assurance

We will record any deviations from the study protocol and GCP. We will comment on deviations that have the potential to affect the scientific accuracy of the results of any part of the study.

Serious breaches – that have a significant effect on the data or scientific accuracy of any part of this study – will be reported to Warwick CTU and BSREC within seven days. The study investigators will take whatever immediate action is required to safeguard data.

8. PATIENT AND PUBLIC INVOLVEMENT

Patient and public involvement is central to this proposal and the conduct of this PhD study. Public Access Defibrillation is performed by members of the public for members of the public in times of great need and potential distress. A public perspective about how to conduct research in a way appropriate and sensitive to both bystanders and victims is therefore absolutely crucial.

There are two PPI representatives on the Steering Committee who will ensure that the project remains sensitive to the needs of cardiac arrest victims, lay responders and the public.

Periodic updates of this PhD project are presented to the Community Research Action Group (CRAG) to obtain a broader perspective of public. CRAG is a regional public-involvement group hosted by Heart of England NHS Foundation Trust (http://www.heartofengland.nhs.uk/research/patient-public-involvement-ppi-crag-2/).

9. DISSEMINATION AND PUBLICATION

The results will be shared with the Co-Investigators and the Steering Group. Public relations teams at the University of Warwick, GoodSAM, LAS and EMAS will assist in public dissemination by use of press releases, web-based and social media and newsletters, according to their current operating procedures.

The Primary Investigator will share pertinent findings where appropriate via Twitter, taking account of the University of Warwick's social media policies (https://www2.warwick.ac.uk/services/externalaffairs/marketing/digital/social).

Presentation of this work is anticipated at the annual European Resuscitation Council conference in October 2020.

A peer-reviewed publication will be prepared to share the results. We anticipate that this will be submitted in the second half of 2020. This study will be reported in line with the STROBE guidelines (18).

The results of the project will be shared with members of the public via Healthwatch England, an independent consumer group that represents the views of the public in health matters. The group can have a substantial impact on health policy by interaction with those that commission and deliver healthcare in England.

There may well be further chances to disseminate the important work of this project, either via conference, publication or other media. We will avail ourselves of any such opportunities as they arise.

A summary of the final study report will be made available to the NIHR (who are funding Dr Smith).

The final PhD thesis, including work included in this work package, will be made available online via the University of Warwick's Research Archive Portal.

10. REFERENCES

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11. APPENDIX

SCREEN – PARTICIPANT INFORMATION AND CONSENT

Dear GoodSAM responder, **Date: xx.xx.2019**

GoodSAM is collaborating on a National Institute for Health Research (NIHR) evaluation led by researchers at the University of Warwick to investigate the optimum distance range within which we should send an alert to GoodSAM responders about a suspected cardiac arrest.

If you agree to take part in this evaluation, **anonymised** data from the post-event questionnaire that follows and your location (as latitude/longitude only) at the time of your most recent alert will be shared with researchers at the University of Warwick. We will keep your decision about participating confidential and will not be known to your employer or to any other third party.

Please be aware that as we will not be able to identify individual GoodSAM responders from that data provided, it will not be possible to identify and remove your data should you wish to withdraw your consent at a later date.

Participation is entirely voluntary and it will not affect your status as a GoodSAM responder in any way.

I wish to participate in this evaluation

I **do not** wish to participate in this evaluation

EXAMPLE QUESTIONNAIRE

Did you get to the scene?	Yes	☒
	No	☐
How did you get to scene?	Foot	☒
	Bicycle	☐
	Motored vehicle	☐
	Other	☐
Did you get to the patient?	Yes – before the ambulance	☒
	Yes – after the ambulance	☐
	No	☐
	I was on-duty with ambulance service	☐

Was the patient in cardiac arrest?

Yes	☒
No	☐
N/A (did not get to patient)	☐

What assistance did you provide?

CPR	☒
Defibrillation	☒
Other	☐
N/A (did not get to patient)	☐