PhD Project:

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

Study Protocol for Work Package 1

An evaluation of the GoodSAM first-responder system for victims of out-of-hospital cardiac arrest, and the potential for Automated External Defibrillator use within the system

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1. LIST OF ABBREVIATIONS USED IN THIS DOCUMENT

AED	Automated External Defibrillator
BSREC	Biomedical and Scientific Research Ethics Committee
CPR	Cardiopulmonary Resuscitation
CTU	Clinical Trials Unit
GCP	Good Clinical Practice
ILCOR	International Liaison Committee on Resuscitation
MRC	Medical Research Council
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
PPI	Patient and Public Involvement
RCT	Randomised Controlled Trial
ROSC	Return of Spontaneous Circulation
SOP	Standard Operating Procedure
VF	Ventricular Fibrillation
(p)VT	(pulseless) Ventricular Tachycardia

2. LAY SUMMARY

Around 28,000 people have a cardiac arrest (when the heart stops beating effectively and a person collapses) outside a hospital each year in England. Fewer than one in ten survive to go home.

The ambulance service in England reaches about two-thirds of cardiac arrest victims within eight minutes of a 999 call. Unfortunately, this means that the chance of survival may have passed when the ambulance arrives. What happens in those vital first minutes after a cardiac arrest makes the difference between life and death. The only things proven to improve survival are high-quality chest compressions during cardiopulmonary resuscitation and early defibrillation - the delivery of an electric shock to the heart.

Public Access Defibrillation is the term given to delivery of an electric shock by a member of the public before an ambulance arrives, using an Automated External Defibrillator. These are safe, automated devices found in public places, and they can be used with little or no previous training.

There is lots of evidence that shows better survival in cardiac arrest victims receiving Public Access Defibrillation compared to those who do not. However, it is only used in a small number of cardiac arrests (about 1 in 50 in England) and this greatly limits the benefit that it can have.

GoodSAM is a mobile-phone app-based alert system linked directly to London Ambulance Service. When London Ambulance Service receive a 999 call and suspect a cardiac arrest, an alert is sent via the GoodSAM mobile app to a nearby member of the public registered with the service. This person can see a map indicating the location of both the cardiac arrest and any nearby Automated External Defibrillators.

In this project the aims are to investigate the effect of the GoodSAM volunteer first-responder system on a person's chances of survival after a cardiac arrest in the community, and to determine the potential of Public Access Defibrillation. The study will be examining data from London between April 1st 2016 and March 31st 2017. In partnership with London Ambulance Service, GoodSAM and the national database of out-of-hospital cardiac arrest at the University of Warwick I will identify:

- The proportion of cardiac arrests when a GoodSAM volunteer was asked to attend and the proportion where one actually managed to reach the patient
- Actions that were taken on the patient's behalf (e.g. did they receive CPR or defibrillation from a member of the public), both overall and just when a GoodSAM volunteer was asked to attend
- Patient survival rates, both overall and just when a GoodSAM volunteer was asked to attend

- The potential for Automated External Defibrillator use. We will map the locations of cardiac arrests and Automated External Defibrillators. We will then calculate how many cardiac arrests occur close enough to an Automated External Defibrillator for one to be of potential use.

All the information used in this study is taken from existing sources and is anonymised.

This project will give us crucial insights into how many lives could be saved if the response to cardiac arrest in the community was improved and if Public Access Defibrillation was used more often. The findings will be shared with NHS England with the aim of helping to improve survival from cardiac arrest within the next 5 years.

3. BACKGROUND

3.1 Survival from Out-of-Hospital Cardiac Arrest

In 2014, survival to hospital discharge from 28,729 out-of-hospital cardiac arrests (OHCAs) in England where resuscitation was attempted was 7.9% [1]. In London, 9.0% of 4389 patients for whom resuscitation was attempted survived to hospital discharge in 2015-16 [2]. In recognition of this low survival rate, 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 [4]. The use of Automated External Defibrillators (AEDs) by bystanders conveys an additional survival benefit to that seen when bystanders perform CPR only [1]. Survival rates can be as high as 70% if a patient is defibrillated within 2 minutes of collapse [5].

Ambulance services in England aim to arrive at 75% of OHCA victims within 8 minutes [6] but, for many, the chance of survival has passed by then. In 2015-16, ambulance services in England responded to 72.5% of 'Red 1' calls (when it is suspected that the patient is not breathing or does not have a pulse) within 8 minutes, although performance deteriorated during that time period [7]. London Ambulance Service responded to 60.6% of Red 1 calls within 8 minutes in 2015-16 [2]. Effective strategies are needed to improve the community response to OHCA before the arrival of the ambulance services if survival rates are to improve.

3.2 The Effectiveness of Public Access Defibrillation

Public Access Defibrillation (PAD) is the term given to the use of public-access AEDs by bystanders before the arrival of an ambulance. AEDs are safe and automated devices that can be used effectively [8], even by those with no prior training [9].

The only large-scale randomised controlled trial (RCT) of PAD was conducted across 24 sites in North America. In the intervention group, trained responders with access to an AED responded to nearby OHCA. Survival was nearly double in victims receiving cardiopulmonary resuscitation (CPR) and AED compared to those receiving CPR alone (control group) [10]. A number of other studies have shown statistically significant and clinically relevant improvements in OHCA survival with PAD [5] [11-23].

In England and Wales, 25.9% of patients resuscitated with a public-access AED, as part of the National Defibrillator Programme between 1999 and 2005, survived to hospital discharge [11]. London Ambulance Service reported that 57.3% of patients in 2015-16 who received at least one shock from a public-access AED survived to hospital discharge [2].

PAD was used in only 2.4% of OHCA in England during 2014 [1]. In London (2015-16) PAD was deployed in 143 cases, despite the fact that 1053 cases (24.0%) occurred in public locations [2]. Thus, a clinical intervention of great efficacy has had a limited impact on OHCA survival at a population level. The UK government did announce a £1million investment to provide AEDs during 2015/16 [24], but the impact that this might have is unclear.

Only a proportion of OHCAs will occur close enough to a public-access AED for it to be of potential use. In studies from various urban centres worldwide, 6.6% - 28.8% OHCAs occurred within 100m of a public-access AED [25-28]. However, there is no observational data to indicate the maximum distance that an AED can effectively be deployed to make a difference to patient survival in OHCA.

Regardless of what this distance actually is, evidence suggests that ambulance service call-handlers are often missing opportunities to direct bystanders to a nearby AED. In Seattle (2007-2009), AEDs were applied in 4.2% OHCA victims (32/763) before an ambulance arrived. However, in the remaining 731 cases, 59 AEDs available within 0.1 mile were not used [29]. In Copenhagen (2011-13), of 66 OHCAs that occurred within 100m of an AED (that the ambulance service were aware of), dispatchers referred callers to that AED in 20 cases (30.3%) and it was applied in just 6 cases (9.1%) [30]. In Stockholm (2014) ambulance dispatchers directed callers to retrieve an AED in 2 cases (1.0%) out of 200 OHCAs that occurred within 100m of a public-access AED [25]. In southern England (2011-12), in 44 OHCA cases when the rescuer mentioned the presence of an AED during the 999 call, it was applied 18 times [6].

PAD is cost-effective if AEDs are placed strategically, based on OHCA incidence data [31]. Cost-effectiveness improves further when AED usage rates increase, even when considering associated healthcare costs in survivors [32]. Indiscriminate placement of public-access AEDs is highly unlikely to be cost-effective [33-35], and will save relatively few extra lives [32].

3.3 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) [36].

An earlier Dutch study (2010-2013) investigated 1536 cardiac arrest patients to whom any defibrillator (including public-access AEDs) 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 [37].

In an 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 [38].

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 [36-37] [39] or perform bystander CPR [39-40]. 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 [39]. 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.

3.4 The GoodSAM System

GoodSAM is a mobile-phone, app-based alerting system allowing notification of trained volunteer first-responders to nearby medical emergencies, including cardiac arrests [41].

In 2012, doctors at London's Air Ambulance service were concerned that trauma patients with potentially survivable isolated traumatic brain injuries might be dying because of 'Impact Brain Apnoea'. This may occur after head injury and is accompanied by airway obstruction, which could be easily remedied with early, basic intervention from bystanders. The concept was soon expanded to include all OHCA victims [42].

GoodSAM has been fully integrated with London Ambulance Service ambulance dispatch system since 22nd October 2015, allowing 999 call-handlers to alert trained first-responders via the app to a nearby cardiac arrest victim [43]. 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 first-responders within a 300m radius of an OHCA will receive a notification.

First-responders' positions are known in real-time because of GPS-location functions built into mobile phone. GoodSAM and London Ambulance Service also share a database of public-access AEDs. The location of the cardiac arrest and nearby AEDs are displayed on a map to the responder via the app [41].

GoodSAM first-responders are classified into different categories:

- Doctors, nurses, paramedics – governed at a national level
- Community First-Responders, Emergency Medical Technicians – governed at a regional level

- Individuals with current training in CPR/AED, but under no formal governance

GoodSAM has received funding from The Big Lottery Fund and The Cabinet Office, which is administered through the innovation charity Nesta (www.nesta.org.uk), to develop and integrate the platform with ambulance dispatch systems in NHS trusts nationwide.

3.5 The Need for This Study

In 2015, The International Liaison Committee on Resuscitation (ILCOR) identified a lack of knowledge about how best to deploy AEDs, including the effect of volunteer first-responder systems and app-based digital technology [44]. This project will provide valuable information about these key research priorities.

A coordinated response between ambulance services and members of the public is vital to improve survival from OHCA [4]. Bystander CPR and the use of public-access AED result in substantial improvements in OHCA survival, even if ambulance response times are short [1].

Low rates of PAD mean that there is huge potential to improve the use of public-access AEDs as part of this community response. Mobilising trained and willing volunteers using the GoodSAM app is one potential way of overcoming such barriers and improving the use of PAD. However, there has been no investigation into the impact of GoodSAM on cardiac arrest outcomes so far.

This work represents the first time that the impact of GoodSAM has been independently evaluated. It is fully supported by and will be undertaken with the support of both GoodSAM and London Ambulance Service. Warwick University Clinical Trials Unit (CTU), the host institution for both this project and the national Out-of-hospital Cardiac Arrest Outcomes (OHCAO) registry, has an existing professional working relationship with both organisations.

3.6 Research Questions

Work package 1 is part of a larger body of work that will constitute a PhD in Health Sciences. The following research questions will be addressed in this work package:

- Question 1: What is the effect of the GoodSAM volunteer first-responder system on survival from OHCA in London?

- Question 2: What is the potential for AED use in London for OHCA victims?

4. STUDY DESIGN

4.1 Question 1: What is the effect of the GoodSAM volunteer first-responder system on survival from OHCA in London?

We will analyse all cases of confirmed OHCA in London between 1st April 2016 and 31st March 2017. There will be four data streams (see also Figure 1):

- OHCA cases for which a GoodSAM notification was accepted, and the GoodSAM first-responder arrived on scene
- OHCA cases for which a GoodSAM notification was accepted, but the GoodSAM first-responder did not arrive on scene
- OHCA cases for which a GoodSAM notification was declined or not responded to
- OHCA cases for which a GoodSAM notification was not sent

GoodSAM became fully integrated with London Ambulance Service on 22nd October 2015. The time period chosen for analysis represents the most recent data available.

Data sources:

a) OHCAO registry at the University of Warwick:

The registry holds information about all English OHCA cases where resuscitation was attempted, including bystander CPR, AED use and survival to hospital discharge. For reference, London Ambulance Service submitted 4632 cases to the OHCAO registry in 2014. Data for April 2016 – March 2017 is now available for analysis in the OHCAO registry.

b) GoodSAM

GoodSAM can provide information on the number of notifications and acceptance of notifications sent to first-responders.

Analysis and reporting:

Data will be presented according to 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) [45]. We will determine and report the following information, (with the sources of the information in brackets):

System (OHCAO)

- Number of confirmed OHCA cases submitted by London Ambulance Service

Dispatch (GoodSAM)

- Number of GoodSAM notifications for OHCA patients
- Date and time of GoodSAM notification

Patient (OHCAO)

- Age and gender
- Bystander CPR performed
- AED available and/or applied before arrival of ambulance service
- Initial heart rhythm (VF/VT, PEA or asystole)

First-responder (GoodSAM)

- Category of GoodSAM first-responder

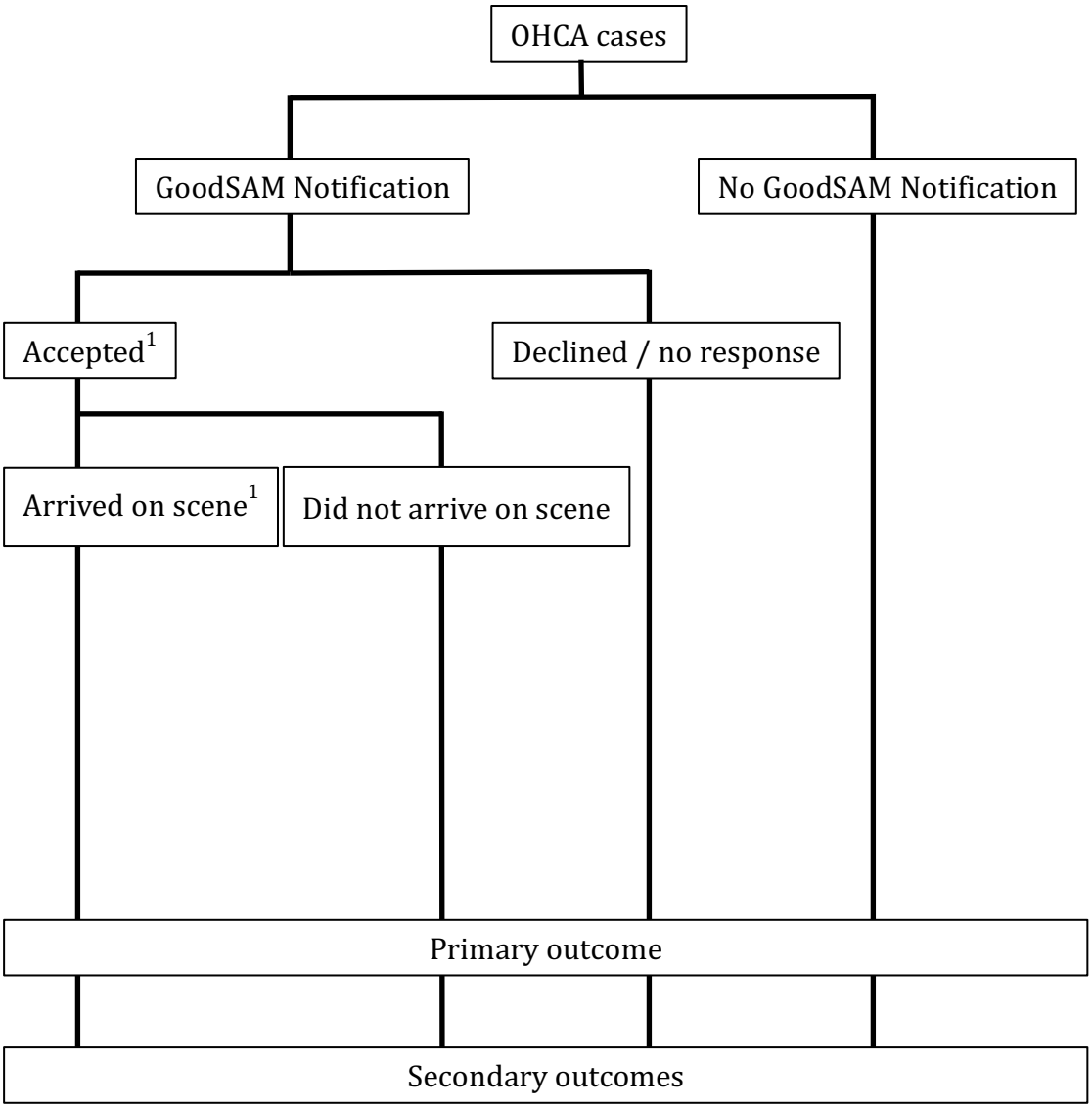
Process

- Proportion of GoodSAM notifications accepted, declined and not responded to (GoodSAM)
- Proportion of GoodSAM first-responders that made it to scene (GoodSAM)
- Time from GoodSAM notification to arrival on scene (GoodSAM)
- Ambulance response time (OHCAO)

Outcome (OHCAO)

- Return of Spontaneous Circulation (ROSC)
- Survival to hospital discharge

The data fields have been chosen to enable us to use data that already exists and, in the case of the OHCAO database, where permissions already exist to use the data. There is no OHCA location or date/time data directly recorded and, as such, we are not collecting data that can be used to identify individual patients.



[1] At least one first-responder accepted or arrived on scene

Figure 1: Flow Diagram for Research Question 1

4.2 Question 2: What is the potential for AED use in London for OHCA victims?

We will determine the proportion of OHCA cases that occurred within a specified distance of a public-access AED. This will represent the potential number of cases where an AED could have been deployed.

The maximum distance that an AED can successfully be deployed is not known. In the literature, 100m has often been considered the 'effective coverage area' for an AED [25-26] [28] [46]. In the Netherlands, volunteers alerted to a possible OHCA by a text-alert system are instructed to retrieve an AED if they are within 500m of it before proceeding to the victim, providing total travel distance does not exceed 1000m [36-37]. In London, up to three GoodSAM first-responders are activated if they are within a 300m radius of the victim.

Data Sources:

Exact OHCA location will be available from the OHCAO Registry. The locations of public-access AEDs will be supplied by London Ambulance Service. These locations can be converted to GPS co-ordinates using freely available internet-based software.

OHCA location data will be requested separate to the data for research question 1 (section 3.1), so there will be no means of using this data to directly identify individual cardiac arrest events.

Analysis and Reporting:

OHCA and AED locations will be mapped using a commercially-available Geographical Information System software package (ArcGIS: https://www.arcgis.com/features/index.html). We will map confirmed OHCA between 1st April 2016 and 31st March 2017, identified from cases submitted to the OHCAO Registry, and AED locations from London Ambulance Service.

Spatial analysis will allow the calculation of the number and proportion of OHCA that occur within a specified distance of a public-access AED. We will present the number of OHCA occurring within 100m-500m (at 100m intervals) of a public-access AED.

These figures will serve as a proxy for the number of potential cases where an AED could be deployed to an OHCA. We will report for all confirmed OHCA, for those when a GoodSAM first-responder received a notification, and for those when a GoodSAM first-responder accepted a notification.

5. OVERALL STUDY CONDUCT

5.1 Good Clinical Practice

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

5.2 Ethical Considerations

We will make an ethics application to the University of Warwick's Biomedical and Scientific Research Ethics Committee (BSREC) to conduct the project detailed in this protocol. The design of this work package means that there is no patient- or responder- identifiable data generated or processed at any time.

The main ethical challenge in this programme of research 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 victims to use their data. 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). A data-sharing agreement has been completed with the OHCAO Registry to access their data.

There is no specific Good Samaritan legislation in England. In 2015, the Social Action, Responsibility and Heroism Act was introduced in England and Wales [47] 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 [48]. This study will place no additional responsibilities or liabilities on GoodSAM first-responders than already exist.

We will collect anonymised data from GoodSAM about the number of notifications made and accepted, the category of responder, and time taken for a first-responder to reach the scene. There is a data sharing agreement is in place between the University of Warwick and GoodSAM to allow this once ethical approvals have been gained. GoodSAM responders are members of the public acting in a Good Samaritan capacity and we are *not* collecting their data because of their professional role. GoodSAM are a social enterprise who are independent of the NHS.

There is a data sharing agreement in place between the University of Warwick and London Ambulance Service for access to a list of registered AED in London once ethical approvals are gained. These are devices that are in public places.

6. DATA MANAGEMENT

We will handle and store any personal data collected during the study in accordance with the Data Protection Act 1998 and Warwick CTU SOP 15 on Information Handling

(http://www2.warwick.ac.uk/fac/med/research/hscience/ctu/conducting/planning/sop2016)

6.1 Data Collection and Storage

The Primary Investigator will collect and store all data on a private data folder available on a secure file server at the University of Warwick. Access to this file server is only possible with username and password access. Minimum standards for password strength are detailed in Warwick CTU SOP 15, part 2.

We will develop a standardised electronic data collection form to collect data. No direct personal identifiable data will be collected.

We will anonymise all data collection - it will not be possible to directly identify individual OHCA victims or GoodSAM first-responders. Transfer of anonymised source data from the OHCAO Registry and AED locations from London Ambulance Service will be to the University e-mail address of the Primary Investigator.

For the duration of this project, the Primary Investigator will be set up as a 'user' on an electronic dashboard run by GoodSAM. He will have access only to the data fields outlined in this application. Data required for the project can be inputted directly onto electronic collection forms (which will be stored only on the University's secure file server)

When maps are produced (in the ArcGIS) with OHCA locations, these will also be stored on the secure file server at the University of Warwick. If maps are produced for publication, presentation or other dissemination of the study findings, this will be for illustrative purposes only and the scale will be such that individual locations cannot be identified.

At all times, we will handle electronic data in accordance with the following policies and protocol in place at the University of Warwick:

- Warwick CTU Standard Operating Procedure 15 (Information Handling), Part 2 (Electronic Data Security): https://www2.warwick.ac.uk/fac/med/research/hscience/ctu/conducting/planning/sop/sop2/sop_15_p2_v2.1.pdf

- Warwick CTU Standard Operating Procedure 15 (Information Handling), Part 3 (Data Transfer): https://www2.warwick.ac.uk/fac/med/research/hscience/ctu/conducting/planning/sop/sop2/sop_15_p3_v1.0.pdf

- The University of Warwick Information Classification and Handling Procedure: http://www2.warwick.ac.uk/services/gov/informationsecurity/handling/information_classification_and_handling_procedure_v1.2.1_approved.pdf

These guidelines take account of the principles of Good Clinical Practice and the requirement of the Data Protection Act (1998).

6.2 Data Access

The Primary Investigator will be principally responsible for data analysis, with assistance from the PhD / project supervisors. A copy of the source epidemiological data from the OHCAO Registry and GoodSAM will be sent to the Project / PhD supervisors via e-mail to serve as a backup.

We will use Microsoft Excel to record epidemiological data and data analysis will be performed using the statistical programme SPSS. These programmes is available on Desktop computers at Warwick CTU.

Results of analyses will be made available to co-investigators and other members of the project Steering Group for comment prior to preparation of materials for peer-reviewed publication or other public dissemination.

6.3 Data Shared with Third Parties

There will be no sharing of data with third parties.

6.4 Archiving

We will archive study documentation at Warwick CTU for at least ten years after completion of the study, in accordance with Warwick CTU SOP 23 on Archiving of Trial Data:

- http://www2.warwick.ac.uk/fac/med/research/hscience/ctu/conducting/after/archiving/23_archiving_v1.4.pdf.

The Primary Investigator will store anonymised data locally (with a copy for the PhD supervisors) on a private data folder on the University of Warwick's secure file server.

7. DATA ANALYSIS

7.1 Primary Outcome

- Survival to hospital discharge rate in out-of-hospital cardiac arrest victims

7.2 Secondary Outcomes and Process Variables

The following, as discussed in section 3.1, will be reported in keeping with the Utstein style:

System
- Number of confirmed OHCA cases submitted by London Ambulance Service

Dispatch
- Number of GoodSAM notifications for OHCA patients
- Date and time of GoodSAM notification

Patient
- Age and gender
- Bystander CPR performed
- AED available and/or applied before arrival of ambulance service
- Initial heart rhythm (VF/VT, PEA or asystole)

First-responder
- Category of GoodSAM first-responder

Process
- Proportion of GoodSAM notifications accepted, declined and not responded to
- Proportion of GoodSAM first-responders that made it to scene
- Time from GoodSAM notification to arrival on scene
- Ambulance response time

Outcome
- ROSC

When mapping the locations of out-of-hospital cardiac arrests and Automated External Defibrillators, the outcomes will be the proportion of out-of-hospital cardiac arrests that occur within 100m, 200m, 300m, 400m and 500m of an Automated External Defibrillator.

The feasibility of imputing missing data will be assessed once the completeness of data is known.

7.3 Data Analysis Plan

The following outlines the data that will be collected, its source, and its format.

Table 1: Process, Patient and GoodSAM Variables

Variable	Format	Response options	Description	Data Source
Number of OHCA Cases	Number	Number	Number of OHCA cases in 2016-17 submitted by London Ambulance Service to the OHCAO Registry	OHCAO Registry
Number of GoodSAM notifications	Number	Number	Number of GoodSAM notifications from the OHCA cases in 2016-17 submitted by London Ambulance Service to the OHCAO Registry	GoodSAM
Number of OHCA cases for which there was a GoodSAM notification	Number, percentage	Number; percentage	The proportion of OHCA cases for which a GoodSAM notification was made – allows for the fact that multiple notifications may be made for the same OHCA event	GoodSAM
Date of ambulance call	dd/mm/yy	dd/mm/yy	Date that the 999 call about the OHCA event was made to London Ambulance Service	OHCAO Registry
Time of ambulance call	hh:mm:ss	hh:mm:ss	Time that the 999 call about the OHCA event was made to London Ambulance Service	OHCAO Registry
Time of patient collapse	hh:mm:ss	hh:mm:ss; unknown	Recorded time that the patient collapsed	OHCAO Registry
Time ambulance at patient's side	hh:mm:ss	hh:mm:ss; unknown	Recorded time that first ambulance personnel were in direct contact with the patient	OHCAO Registry
Ambulance Response time	mm:ss	mm:ss; unknown	Calculated from the difference between 'Time ambulance at patient's side' and 'Time of patient collapse'	Calculated value
Date of GoodSAM notification	dd/mm/yy	Date format; [left blank] (if notification not sent)	Date that the automatic notification to GoodSAM was sent out by London Ambulance Service. May be one, multiple or no notifications per OHCA event (see explanatory text below)	GoodSAM
Time of GoodSAM notification	hh:mm:ss	Time format; [left blank] (if notification not sent)	Time that the automatic notification to GoodSAM was sent out by London Ambulance Service. May be one, multiple or no notifications per OHCA event (see explanatory text below)	GoodSAM
Outcome of GoodSAM notification	Number, percentage	Accepted; no response; declined; unknown	The proportion of GoodSAM notifications that were accepted, declined or not responded to by first-responders, once a notification has been made	GoodSAM
GoodSAM first-responder arrives at scene	Text	Yes; No	Did a GoodSAM first-responder record that they had arrived on scene? As a proportion of all first-responders and only in those who accepted the notification	GoodSAM
Time from GoodSAM notification to arrival on scene	mm:ss	mm:ss	For those GoodSAM first-responders who arrived on scene, the time interval between GoodSAM notification being sent and arrival on scene	GoodSAM

Patient age	Number	Number; unknown	Patient age, in years. Left blank if value unknown	OHCAO Registry
Patient gender	Text	Male; Female; unknown	Patient gender. Left blank if value unknown	OHCAO Registry
Bystander CPR performed	Text	Yes; No; unknown	Was bystander CPR performed before the arrival of ambulance? Left blank if value unknown	OHCAO Registry
AED available before arrival of ambulance	Text	Yes; No; unknown	Was a 'Public Access Defibrillator'* available to a member of the public before the arrival of ambulance? (* term used in OHCAO Registry)	OHCAO Registry
AED applied before arrival of ambulance	Text	Yes; No; unknown	Was a 'Public Access Defibrillator'* used by a member of the public before the arrival of ambulance? (* term used in OHCAO Registry)	OHCAO Registry
Initial cardiac arrest rhythm	Text	VF; pVT; asystole; PEA; unknown	First recorded heart rhythm on arrival of ambulance	OHCAO Registry
Category of GoodSAM Responder	Number	1; 2; 3; unknown	Categories as previously described in this protocol: 1. Doctors, nurses, paramedics – governed at a national level 2. Community first-responders, Emergency Medical Technicians – governed at a regional level 3. Individuals with current CPR/AED training, but no formal governance	GoodSAM

Table 2: Outcome Measures

Variable	Format	Response options	Description	Data Source
Primary outcome: Survival to hospital discharge	Text	Yes; No; unknown	Was the patient discharged alive from hospital?	OHCAO Registry
Return of Spontaneous Circulation at hospital handover	Text	Yes; No; Unknown	Return of Spontaneous Circulation (ROSC) recorded at hospital handover	OHCAO Registry
Return of Spontaneous Circulation at any time	Text	Yes; No; Unknown	Return of Spontaneous Circulation (ROSC) recorded at any time during the resuscitation effort	OHCAO Registry

Matching data from OHCAO and GoodSAM

There is no unique identifier that allows automatic matching of OHCA cases and GoodSAM notifications.

The data table will first be constructed with all the variables collected from the OHCAO Registry. Data will be re-ordered (automatically, by computer) according to date and time of ambulance call (earliest time-point first). The columns 'Date of

ambulance call' and 'Time of ambulance call' will then be copied / pasted into a separate table. For example:

Event number	Date of ambulance call (dd/mm/yy)	Time of ambulance call (hh:mm:ss)
1	01/01/16	00:03:21
2	01/01/16	05:54:03
3	01/01/16	08:01:45
4	01/01/16	09:54:47

A separate table will be constructed with information gathered from GoodSAM. Information. This data will similarly be ordered according to date and time of GoodSAM notification. OHCAO and GoodSAM information will then be matched manually, i.e.:

Event number	Date of ambulance call (dd/mm/yy)	Time of ambulance call (hh:mm:ss)	Date of GoodSAM notification	Time of GoodSAM notification	Notification sent out	Notification response
1	01/01/16	00:03:21	01/01/16	00:04:02	Yes	Accept
			01/01/16	00:04:02		No response
2	01/01/16	05:54:03			No	
3	01/01/16	08:01:45	01/01/16	08:02:59	Yes	Accept
4	01/01/16	09:54:47			No	

This data will then be re-integrated with other variables collected from OHCAO and GoodSAM into one table.

Mapping OHCA and AED Locations

OHCA location will be provided from the 'Location of ambulance Occurrence' data field in the OHCAO registry. AED locations will be provided directly by London Ambulance Service.

These locations will be converted into GPS co-ordinates

7.4 Statistical Analyses

Formal statistical analysis will be performed using SPSS statistical software (SPSS v22.0, IBM, New York, USA), under the supervision of the study statistician, Dr. Ranjit Lall. A formal statistical plan will be developed in accordance with WCTU SOP 21 – Statistics Analysis Plan.

For the outcome measures described above:

- Survival to hospital discharge will be assessed using Cox proportional hazards model. A hazard ratio between groups will be calculated, using the 'No GoodSAM Response' group as the comparator / standard.

- Categorical data will be reported using point estimates and 95% confidence intervals

- Continuous data will be assessed for normality and then described as mean +/- standard deviation (normally distributed) or median +/- interquartile range (non-normally distributed) as appropriate.

- Comparisons between groups will be performed using a one-way repeated measures ANOVA

8. STUDY ORGANISATION AND OVERSIGHT

8.1 Governance Arrangements

This PhD project is being undertaken at The University of Warwick. Professor Gavin Perkins is the primary supervisor. The PhD and all associated study will be subject to all policies and procedures laid out by Warwick Medical School.

8.2 Regulatory Authorities / Ethical approval

We will request ethical approvals for this study, as detailed in section 4.2. The required ethical approval for the study will be sought using BSREC at the University of Warwick

Data sharing arrangements are in place for data being provided by London Ambulance Service, GoodSAM, and the OHCAO Registry.

8.3 Study Registration

We will publish this study protocol online and it will be freely available via the University of Warwick's Research Archive Portal.

8.4 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.

However, harm is not anticipated as this study involves collection of existing, anonymised data only.

8.5 Study Timetable and Milestones

The aim is to have started data collection by the beginning March 2018, and have completed data collection and analysis by the end of May 2018. The anticipated progress is outlined in a GANTT chart (Table 3).

This represents the longest anticipated time required to complete the project, and includes contingencies for events such as illness and difficulties or delays in obtaining source data.

We plan to report the results and prepare of a scientific article for peer-reviewed publication by September 2018.

Table 3: Study Timetable and Key Milestones

	1	2	3	4	5	6	7	8	9	10
	Nov-17	Dec-17	Jan-18	Feb-18	Mar-18	Apr-18	May-18	Jun-18	Jul-18	Aug-18
Work Package 1										
Protocol Development										
Data Sharing Arrangments finalised										
Ethics Submission										
Data Collection (Research Q1)										
Data Synthesis (Research Q2)										
Mapping and Analysis (Research Q2)										
Reporting, dissemination, publication										

8.6 Administration and Funding

Dr. Christopher Smith is a NIHR-funded Doctoral Research Fellow (from November 1st 2017 to October 31st 2020) and full-time PhD Health Sciences student at the University of Warwick.

No costs have been incurred in the data sharing arrangements with London Ambulance Service, GoodSAM or the OHCAO Registry.

This project ('Work Package 1') is one of three interconnected pieces of work being conducted as part of this PhD. Dr. Smith will manage the project supported by Professor Gavin Perkins is the primary supervisor. Professor Frances Griffiths will provide supervision and support for the qualitative aspects of the project. Dr. Ranjit Lall will provide statistical expertise. All three PhD supervisors / co-investigators have extensive experience in providing supervision and/or support for PhD projects and clinical trials.

Further support and expertise will be provided by the Steering Group.

8.7 Steering Group

We will provide three-monthly updates to the Steering Group every three months 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 2 and 3 rather than work package 1.

Steering group membership:

- Professor Gavin Perkins (Primary Project Supervisor, Professor of Critical Care Medicine)
- Professor Frances Griffiths (Project Supervisor; Professor of Medicine in Society / Head of Social Science and Systems in Health)
- Dr. Ranjit Lall (Project Supervisor, Statistician / Principal Research Fellow)
- Mr. Mark Wilson (GoodSAM founder, consultant neurosurgeon)
- Dr. Fionna Moore, Dr. Rachael Fothergill and Mr. Christopher Hartley-Sharpe (London 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)
- Professor Freddy Lippert (University of Copenhagen / Copenhagen Emergency Medical Services)
- Mr. Julian Hague (PPI Representative)
- Mr. John Long (PPI Representative)

London Ambulance Service and GoodSAM are integral to the success of this project. The steering group has official representation from both 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.

Both Dr. Hawkes and Professor Vlaev have experience in the use of behavioural frameworks and the use of policy to change behaviours, and so are extremely useful members of the steering group.

Professor Theo Arvanitis recently led on a British Heart Foundation funded study investigating the feasibility of introducing a national Public Access Defibrillation database. He is Head of Research at the Institute of Digital Healthcare at the University of Warwick and can offer important advice about the technical aspects of any intervention developed.

Professor Lippert has an established track record of impactful research about Public Access Defibrillation. His research team will share information about Public Access Defibrillation and first-responder systems in Copenhagen to allow for a 'benchmark' or international comparator. His team have further agreed in principle to test relevant interventions that my project develops in their own Emergency Medical Services system.

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 Public Access Defibrillation to improve survival for cardiac arrest victims in the community.

8.8 Essential Documentation

All data and files relating to the project will be held in private folders of Dr. Christopher Smith on the secure file server at Warwick University.

9. MONITORING AND QUALITY ASSURANCE

9.1 Training

The Primary Investigator and Co-Investigators 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)
- ArcGIS Introduction (short course, IT Training Solutions, Salford, 26-27th September 2017)
- Introduction to Regression Analyses (short course, University College London, 15-16th January 2018)
- Introduction to Logistic Regression (short course, University College London, 30th April 2018)

9.2 Data Quality

The Primary Investigator will be principally responsible for data entry. The PhD supervisors / co-investigators 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.

9.3 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 parts of the study will be commented on in peer-reviewed publications.

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 as soon as possible. The study investigators will take whatever immediate action is required to safeguard data.

10. 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.

To obtain a broader perspective of public views an outline of the study research plan was presented to the Community Research Action Group in November 2015 and December 2016. This 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/). Yearly updates of the study will be presented to the group for comment and feedback.

PPI involvement is far more relevant to work packages 2 and 3, but this protocol has been shared with our PPI members (and all members of the steering group) for input and feedback.

11. DISSEMINATION AND PUBLICATION

The results will be shared with the Co-Investigators, the Steering Group, GoodSAM and London Ambulance Service. Public relations teams at the University of Warwick and at GoodSAM and London Ambulance Service 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 2018 and the biennial Resuscitation Council (UK) conference in November 2019.

A peer-reviewed publication will be prepared to share the results. We anticipate that this will be submitted by September 2018. We will refer to Warwick CTU SOP 22 – Dissemination and Publication – for information on reporting guidelines for various types of studies. A requirement of Dr. Smith's NIHR funding is that the article will be available open-access, and details will also be shared with the University of Warwick's Research Archive Portal.

The results of the project will be shared with members of the public in London via Patients' Forum Ambulance Services (London) Ltd. This is an independent body that reviews the performance of London Ambulance Service for the benefit of patients and the public. Information will also be made available both locally and nationally 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.

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