PhD Project:

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

The PAD-Respond Study

Study Protocol for Work Package 2

An investigation of Automated External Defibrillator use by GoodSAM first-responders

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1. LIST OF ABBREVIATIONS USED IN THIS DOCUMENT

AED	Automated External Defibrillator
BCW	Behaviour Change Wheel
CAQDAS	Computer Assisted Qualitative Data Analysis
COM-B	Capability, Opportunity, Motivation Behavioural framework
CPR	Cardiopulmonary Resuscitation
CTU	Clinical Trials Unit
GCP	Good Clinical Practice
IRAS	Integrated Research Application System
NHS	National Health Service
OHCA	Out-of-Hospital Cardiac Arrest
OHCAO Registry	Out-of-Hospital Cardiac Arrest Outcomes Registry
PAD	Public Access Defibrillation
RCT	Randomised Controlled Trial
R&D	Research and Development
REC	Research Ethics Committee
SOP	Standard Operating Procedure
TDF	Theoretical Domains Framework

2. BACKGROUND

2.1 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.

2.2 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 randomised controlled trial (RCT) of PAD use was conducted across 24 sites in North America (the 'PAD Trial'). In the intervention group, trained responders with access to an AED responded to a nearby OHCA. Survival was nearly double in victims receiving cardiopulmonary resuscitation (CPR) and who had an AED attached 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].

Despite this capital investment, PAD was used in only 2.4% of OHCAs 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 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].

2.3 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 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 [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.

2.4 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 form bystanders. The concept was soon expanded to include all OHCA victims [42].

GoodSAM has been fully integrated with London Ambulance Service dispatch systems since 22nd October 2015, allowing 999 call-handlers to alert trained volunteers 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 volunteer 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 phones. 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 volunteer 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 use, 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.

2.5 Barriers and Facilitators to Public Access Defibrillation

A systematic review conducted in support of this application identified a number of barriers to PAD in OHCA. These include limited knowledge and awareness of AEDs and their location – including AEDs whose existence was not known to the local ambulance service – variable willingness to locate and use public-access AEDs, and difficulties in accessing public-access AEDs [44].

Certain findings are particularly relevant to a volunteer first-responder system. Training in CPR and the use of an AED, which is the minimum standard for GoodSAM first-responders, was consistently shown to improve awareness of and willingness to use an AED [45-47]. A first-responder using an app to locate an AED can only do so if the AED is registered with the ambulance service, but evidence suggests that when AEDs were actually used on OHCA victims they were often not known to the ambulance service beforehand [12] [48].

Psychological problems in volunteer first-responders are infrequent. In the Netherlands, all volunteer first-responders reported either no stress (81% of the time) or only mild stress (19%) after text-message activation to a nearby cardiac arrest. There was an association with inability to be able to successfully locate and attach an AED and reports of mild stress [49]. Responder-related adverse events in the PAD Trial were also extremely rare [50].

Overall, the evidence collected in this systematic review [44] would be considered low or very-low quality [51], as it consisted predominantly of observational data or unvalidated questionnaires and surveys administered to a limited number of people.

A better approach to investigating barriers and facilitators to AED use in a volunteer first-responder system is needed, and this is what we will investigate in this project.

2.6 The Use of A Theoretical Framework

When considering how to maximise the use of AEDs in the response to OHCA in a volunteer first-responder, it is understandable to focus on behaviours of the individual responder. It is to these people that decide whether or not to use an AED in a high-stress and unpredictable situation when the victim will often die. Making assumptions about how people will behave in such a situation, or relying

on just low-quality evidence from the existing literature, is foolhardy. Such an approach will likely fail to identify all factors that prevent or promote AED use.

Using a recognised framework will help to accurately identify and classify barriers to PAD. Linking this to models of behaviour and methods of behavioural change will allow us to consider how interventions can be developed to effect behaviour change to overcome these barriers.

The Theoretical Domains Framework (TDF) is a determinant framework [52] that is validated for implementation research [53]. It identifies and classifies groups of factors that influence certain outcomes [54-55], and can be applied to individuals, groups or populations [55]. It was originally developed to determine how healthcare professionals implemented new evidence-based recommendations but it has now been used by hundreds of researchers across many different healthcare-related disciplines [54].

The original TDF was developed by expert consensus and contained 12 domains [55]. A revised version was produced following external validation and contains 14 domains:

- Knowledge
- Skills
- Social / Professional Role and Identity
- Beliefs about Capabilities
- Optimism
- Beliefs about Consequences
- Reinforcement
- Intentions
- Goals
- Memory, Attention and Decision Processes
- Environmental Context and Resources
- Social Influences
- Emotion
- Behavioural Regulation

Each of these domains contains a number of theoretical 'constructs' related to behavioural change [53].

The TDF is most commonly used in the analysis of data from interview studies, and it is important to ensure that sampling targets individuals who perform the target behaviour (i.e. GoodSAM first-responders in this project). It is equally valid to gather insights from other people with an interest in the outcome (e.g. individuals who set-up and maintain the interface between GoodSAM and London Ambulance Service) [54].

Questionnaires [56] and study-specific questions [57] based on the TDF domains have also been developed, and so the TDF could be used to produce a question or topic guide in interview studies. The TDF can also be applied to data collected in

a number of other ways including observation of behaviours, practice and environments. [54].

2.7 The Need for This Study

In 2015, The International Liaison Committee on Resuscitation identified a lack of knowledge about how best to deploy AEDs, including the effect of volunteer first-responder systems and app-based digital technology [58]. This project will provide valuable information about these key research priorities.

A co-ordinated 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 AEDs 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 improving the use of PAD. However, there has been no investigation into factors that affect AED use in a volunteer first-responder system such as GoodSAM.

This work 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.

2.8 Research Questions

This study is the second of three proposed work packages as part of Dr. Christopher Smith's PhD in Health Sciences (see section 7.6 for further details)

This study (work package 2) aims to identify barriers to Automated External Defibrillator Use by GoodSAM first-responders:

- Question 1: What epidemiological factors affect Automated External Defibrillator use by GoodSAM first-responders?
- Question 2: What other factors affect Automated External Defibrillator use by GoodSAM first-responders?
- Question 3: Which evidence-based, theoretically informed interventions to increase Automated External Defibrillator use by GoodSAM first-responders need to be tested?

3. STUDY DESIGN

3.1 What epidemiological factors affect AED use by GoodSAM first-responders in OHCA?

In work package 1, we will have mapped the location of OHCAs in London between April 1st 2016 and March 31st 2017, and the location of all AEDs known to London Ambulance Service and GoodSAM as of March 31st 2017. Currently, up to three GoodSAM first-responders receive a notification of a potential OHCA if they are within a 300m radius of the victim. Their position is known via the GPS-location functions on their smartphone.

Firstly, a determination will be made of the number of OHCA cases where:

- Both a responder(s) **and** an AED were available within 300m
- A responder(s) was available within 300m, but an AED was not available within 300m
- An AED was available within 300m, but a responder(s) was not
- Neither any responders **nor** an AED were available within 300m

This will give an indication of the proportion of OHCAs for which it would have been feasible for a GoodSAM first-responder to attend a victim with an AED.

The total number of cases when a GoodSAM first-responder was available *and subsequently* accepted a notification will have been calculated in work package 1. From these cases, multiple logistic regression modeling will investigate epidemiological factors predicting deployment of an AED to an OHCA victim in the GoodSAM system. Data on the cases where an AED was applied before the arrival of the ambulance service will also be available from work package 1.

We will report on the following Utstein variables [59] will be available from the data collected in work package 1:

- Date (by month) and time (of day) of 999 / ambulance call
- Age and gender of patient
- Bystander CPR performed
- Public or private location

We will also investigate other important variables, based on expertise within the project group and information that becomes evident during both work packages 1 and 2. These may include, but are not necessarily restricted to:

- Number of GoodSAM first-responders accepting notification (up to three responders are notified, and so up to three responders may accept the notification)
- Did a GoodSAM first-responder arrive on scene?
- Was an AED available within 300m of the OHCA

- Category of Responder. GoodSAM registers three categories of responders by their medical experience:
    - Doctors, nurses, paramedics
    - Community first-responders, ambulance technicians
    - First-aid-qualified individuals

3.2 What other factors affect AED use by GoodSAM first-responders?

Once an OHCA is diagnosed by a call-handler, the GoodSAM system is automatically activated. At this point two main factors affect whether or not assistance and/or an AED reaches an OHCA victim:

1. How the notification is made, and the information that is sent (Organisational and Technical Factors)

   This could include factors such as: wording of the notification, how the notification is displayed; volume of the notification

2. Decision-making by the GoodSAM first-responder (Behavioural Factors)

   In short, does the responder choose to accept the notification or not, and do those who accept the notification choose to retrieve an AED en-route to the patient or not.

Thus, this part of work package 2 will investigate which of these factors might affect the retrieval of an AED by a GoodSAM first-responder notified about an OHCA. Information will be collected from different sources and by different methods, as detailed below, to increase the validity of our findings [54].

<u>Organisational and Technical Factors</u>

A number of familiarisation visits will be made (by the primary investigator, CMS) to the Emergency Operations Centre at London Ambulance Service. This is where emergency (999) calls are received by call-handlers, calls are prioritised and professional resources (e.g. ambulance cars, ambulances) are deployed.

The aims of this will be to observe and better understand the systems being used by London Ambulance Service, and how GoodSAM interacts with these systems. This will provide insight into potential barriers that are inherent to the systems being used. Observation is an appropriate method in emergency research to assess how clinical care (or a process relating to it) is delivered in a specific environment or context [60].

Brief field notes and observations will be recorded on paper contemporaneously. Transcription of these into electronic format will happen soon after the visit, allowing additional reflection on the visit findings without allowing the key messages to be misinterpreted.

It is anticipated that these visits will be supervised and involve informal short discussions with members of staff working at the time, when safe and appropriate to do so. No comments will be attributable to any individual. The Primary Investigator has substantial clinical experience as a senior decision-maker in a busy Emergency Departments and so will be aware of the important of not interrupting time-sensitive clinical tasks being performed.

In addition, face-to-face key-informant interviews will be conducted with individuals instrumental in setting up the technical interface between GoodSAM and London Ambulance Service's dispatch systems, to identify potential difficulties identified during installation and ongoing maintenance of the GoodSAM system.

Key Informant – Interviews

Face-to-face interviews will be conducted by the primary investigator (CMS), at time and place convenient to the interviewee. We will develop a brief topic guide, informed by the behavioural frameworks being used in this study, a systematic review conducted in support of this project [44] and substantial topic expertise in the project group.

In these particular interviews it is accepted that the respondents' technical understanding of GoodSAM and London Ambulance Service systems will be substantially better than the interviewer, and so relevant deviations from the topic guide will be facilitated. Interviews may take place at the participant's place of work. Interviews will take no longer than 30 minutes. If appropriate, practical demonstrations of the GoodSAM system and its interface with London Ambulance Service systems can be demonstrated by the participant after the end of the formal interview process. If this is the case, field notes will be made and incorporated with the interview findings afterwards.

Interviews will be recorded using an encrypted audio device provided by the University of Warwick. Brief notes will be taken contemporaneously if necessary. The primary investigator (CMS) will subsequently transcribe the recording.

Key Informant – Consent

Potential key-informant interviewees will be identified through existing contacts with GoodSAM and London Ambulance Service. We will contact them by e-mail, with a follow-up telephone call if there is no initial response.

The University of Warwick provides a standardised Participant Information Sheet and Consent Form, which we will refer to when preparing our information. Study information and consent statements will form the body of the e-mail. An e-mail and work telephone contact will be provided if potential participants have additional questions about taking part in the study. If they wish to participate, we will ask them to reply to indicate that they have read and understood the study information and consent statements, and that they agree to take part in the study.

At this point, the primary investigator (CMS) will arrange a date and time for the interview either by e-mail or, if the participant prefers, by phone or text. There will be at least 24 hours between receipt of the participant information and consent statements and the interview.

A written version of the consent form (with identical statements) will be brought to the face-to-face interview. Consent will be re-confirmed prior to starting the interview and the form signed by participant and interviewer. Consent can be withdrawn at any time prior to publication of research findings. The interviewee can terminate the interview at any point.

Key Informant – Sampling

Key informant interviews will be limited by the small number of participants with the relevant expertise and involvement in the development of the GoodSAM / London Ambulance Service interface. Up to three interviews are anticipated.

<u>Behavioural Factors in GoodSAM First-Responders</u>

GoodSAM First-Responders – Interviews

Remote synchronous interviews will be held via telephone with GoodSAM first-responders within seven days of them receiving a notification to attend an OHCA.

Interviews will share many features with retrospective verbal protocol analysis [61]. Questions will encourage interviewees to 'think aloud' about the choices that they made and the perceived reasons for these decisions [62]. Such a strategy is well recognised in usability testing [62-63], when a new system or process is being evaluated for ease of use, and so can be adapted for use here, with participants recalling the decision-making processes around one event.

It can be difficult to accurately predict what people will think and do in a certain situation, particularly in times of stress and when decisions have to be made quickly and with a limited amount of information [64-65]. For this reason, asking people what they actually did shortly after the event, and why, is an appropriate means to understanding how a closed system (such as GoodSAM activation in cases of OHCA) works, and how it might be optimised. Conducting the interviews shortly after the event will allow for reasonably accurate recall [66-67]. Participants can describe their actions and observations, but also reflect on their performance [68].

Rationalisation of their actions is a potential concern [62] [69], but this can be mitigated to some degree by performing interviews a short time after the event occurred [62]. We will also emphasise at the start of the interview that we are not in any way making judgements on the decisions they made, only trying to understand what might make these decisions easier in the future.

Telephone interviews, whilst pragmatic in this study, may also help participants volunteer more information. The greater degree of anonymity afforded by remote interviewing may result in more honest or complete answers when dealing with sensitive issues – quite possibly in 'life-or-death' situations – particularly if it involves questions on actions taken or not taken by interview participants [70].

Interviews will be short (less than 15 mins) and focussed on the decisions to respond to the notification and whether or not to retrieve an AED. We will develop a topic guide, which will appropriately be informed by the behavioural frameworks being used in the study, a systematic review conducted in support of this project [44] and substantial topic expertise in the project group. The focus will be on barriers and facilitators to PAD. In line with previous work using the think-aloud technique in the assessment of decision-making, we will ensure that the participant is asked to provide information about:

- The final choice made (re: retrieval of an AED)
- The difficulties in making this choice
- Other options to their choice, with appropriate comparisons

We will review early interview data and refine interview prompts if needed.

We will make audio calls to the participant's phone using Skype, and record the audio using QuickTime player.

All first-responders who received a GoodSAM notification in the study time-period will be eligible for inclusion. If the volunteer indicates that they did not respond the reasons for this and the factors that might influence their decision to respond and use an AED in the future will be explored.

GoodSAM First-Responders – Consent

Information about this phase of the study, including study dates during which contact might be made, will be made available to all registered GoodSAM first-responders ahead of the study via e-mail. All GoodSAM first-responders are required to register with a valid e-mail address. There will be an opportunity to opt-out at this stage.

Consecutive GoodSAM first-responders notified about a nearby OHCA will be contacted after the event and asked to consent to interview. Initial contact will be made via e-mail and one follow-up will be sent in the event of non-response. Study information and consent statements, based on the templates produced by the University of Warwick, will form the body of the e-mail. An e-mail contact will be provided if potential participants have additional questions about taking part in the study.

If they wish to participate, we will ask them to indicate this by replying to the e-mail with a valid telephone number for us to contact them on. At this point, the primary investigator (CMS) will arrange a date and time for the interview by e-

mail or text. There will be at least 24 hours between receipt of the participant information and consent statements and the interview.

At the start of the telephone interview, and once recording has begun, the interviewer will review participant understanding of the study and go through the individual consent statements (asking for a "yes" or "no" response in each case.) Once consent has been re-confirmed in this manner, the interview questions will begin.

Consent can be withdrawn at any time prior to publication of research findings. The interviewee can terminate the interview at any point.

These consent processes will take account of guidelines issued by Warwick Clinical Trials Unit (see: https://www2.warwick.ac.uk/fac/med/research/ctu/conducting/during/consent), and at all times adhere to the principles of Good Clinical Practice.

GoodSAM First-Responders – Sampling

At the start of the study period, consecutive GoodSAM responders will be approached after they have received a notification. We will stratify them according to a) Category of responder and b) availability of an AED within 300m of the OHCA (see Table 1).

Table 1: Interviews by AED availability and GoodSAM First-Responder Category

	AED available within 300m (n=15)	AED not available within 300m (n=15)
Doctors, nurses, paramedics	n=5	n=5
Community first-responders, ambulance technicians	n=5	n=5
First-aid-qualified individuals	n=5	n=5

This stratified consecutive sampling will start on a pre-determined day of the week. It will continue until five participants have consented for interview so that we can ensure all interviews are conducted within seven days of a GoodSAM notification. Once these interviews have been completed we will re-start sampling in the same manner, but on a different day of the week. The pattern will continue until all interviews have been conducted. We anticipate that in this manner we will recruit participants who received a GoodSAM notification on weekdays *or* weekends.

The non-response rate to GoodSAM notifications will be determined in the first work package of Dr. Smith's PhD project. We will know this before interviews commence. It may be that the consent-to-interview rate will be lower among GoodSAM notification non-responders. If this is the case we will develop

appropriate strategies to oversample and obtain a representative sample of responders and non-responders.

We have set an initial sample size of 30. This will allow a number of interviews across the different categories described in the table above, as well as being a pragmatic and achievable number of interviews to analyse. The project aims to interview a group with some degree of homogeneity and a certain level of expertise, concentrates on a specific area (the use of an AED) in a specific situation (first-response to an OHCA) and uses an existing theoretical framework to help guide the discussion (see below): these factors should diminish the sample size required [71]. Thirty is also consistent with a sample of PhD studies using qualitative methodologies that reported a mean sample size of 31 and a mode of 30 [72].

After this initial interview schedule, analysis of interviews will stop when no more new information emerges from three consecutive interviews, indicating data saturation. This will first be tested for interviews 28, 29 and 30, and then after each subsequent interview until this criterion is satisfied [73].

Data Analysis

Use of a Theoretical Framework

Thematic content analysis of all interviews will be undertaken using the Framework Method [74], which itself is considered to be a type of Thematic Analysis [75]. Source data is assigned a code from a pre-determined list, and similar codes are grouped into categories. The Framework Methods is appropriate for use on data with a degree of homogeneity [75] – this is anticipated here as the interviewees have a common trait (being GoodSAM responders) and are being interviewed about a specific task (AED retrieval in the response to OHCA in the GoodSAM system).

The framework will be primarily informed by use of the Theoretical Domains Framework (TDF) [53] and supplemented by the systematic review conducted in support of this project [44]. In the TDF, codes are referred to as 'constructs' and the categories within which they are grouped are called 'domains'.

The primary investigator (CMS) will transcribe the data, review the transcriptions and any contemporaneous notes that were taken at the time of the interview, and subsequently code the data. A second researcher (FG) will undertake transcript analysis of a proportion of interviews. The two researchers will compare coding and categorisation and resolve any differences through discussion. Only items that are relevant to the target behaviour will be coded and categorised [54].

We will analyse data using a Computer Assisted Qualitative Data Analysis (CAQDAS) programme (NVivo: http://www.qsrinternational.com/nvivo/nvivo-products). Transcripts will be added to NVivo, relevant codes added to portions of text, and a matrix created to identify portions of the interview that correspond

to domains of the TDF. Notes and memos will be added where appropriate to highlight important nuances obvious in verbal recordings but not in written transcripts (e.g. tone, voice inflections indicating uncertainty, sarcasm) [70]. We will also explore whether or not there are commonalities between cases e.g. are similar issues reported by a certain category of GoodSAM first-responder, or do issues across the same TDF domains recur [76-77].

We will clarify the distinction between GoodSAM first-responder interviewees and key-informant interviews, and also add pertinent notes from field observations and our systematic review [44].

3.3 Which evidence-based, theoretically informed interventions to increase AED use by GoodSAM first-responders need to be tested?

The TDF will have been used to classify barriers and facilitators to AED use, as described in section 3.2. This final phase of this project involves the structured development of potential interventions to improve AED use in GoodSAM first-responders, centred around the use of the Behaviour Change Wheel (BCW) and described in detail below [78]. Whilst there are a number of behavioural frameworks available the BCW was developed by behavioural scientists with experience in the field of healthcare, and takes account of 19 systematically identified behavioural change frameworks [79].

Throughout the process, decisions about which behaviours to target and which implementations to develop will be made by consensus of members of the project's supervisory and steering group. Within this group there is substantial expertise on PAD and representatives of both GoodSAM and London Ambulance Service will help ensure that feasible and relevant interventions are chosen for further development.

The steps below are attributable to the work by Mitchie et al [78] unless referenced otherwise.

1. Defining Behaviours

The setting and individuals able to perform the desired behaviours have already been defined – GoodSAM first-responders receiving notifications of nearby OHCA. Information will have been gathered and classified using the TDF in section 3.2

2. Select and Target Behaviours
3. Specify Target Behaviour

From the behaviours identified and classified using the TDF, the potential attractiveness and impact of changing the behaviour will be determined, through discussion with experts within the study's supervisory and steering groups. Potential target behaviour will be further described according to factors such as how and when the target behaviour needs to occur, and what tools or resources are required to facilitate this

A list of target behaviours that have the potential to improve AED use in the GoodSAM system will be achieved by consensus.

4. Identify what needs to change

The domains of the TDF have been successfully linked to the COM-B (Capability, Opportunity, Motivation) behavioural framework. COM-B characterises three core targets for behavioural change [57] in order to inform the design of healthcare interventions.

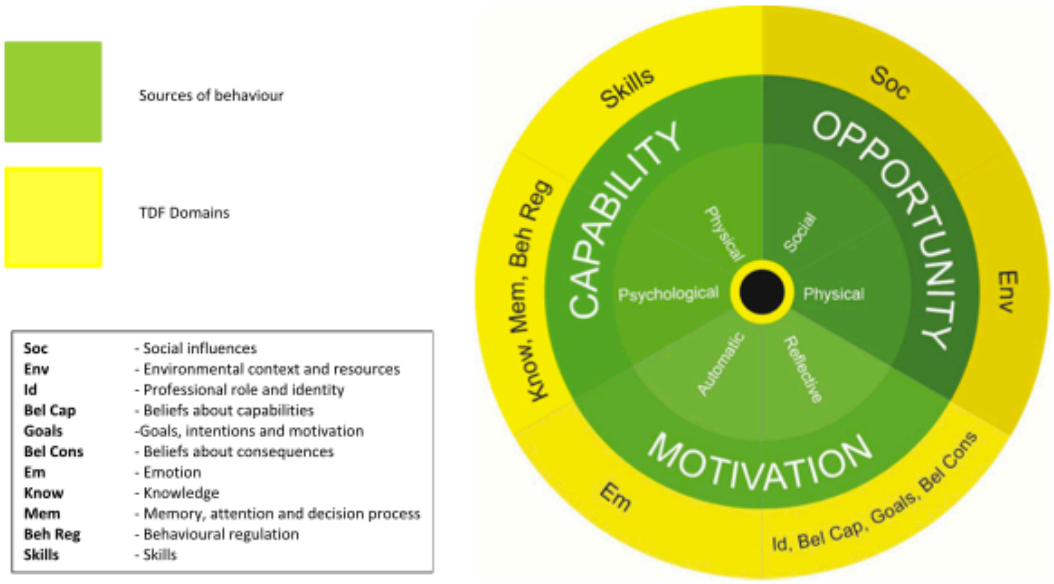

Figure 1: Link between TDF Domains and the COM-B Model [57]

These can be further subdivided [78]:

- Capability
  - Physical: e.g. skills or strength
  - Psychological: e.g knowledge or beliefs
- Opportunity
  - Physical: e.g. resources, environment or barriers
  - Social: e.g. interpersonal interactions, social and cultural norms, taking cues from others)
- Motivation
  - Reflective: actions that require planning
  - Automatic: e.g. emotions, impulses, reflex actions

The potential target behaviours identified and described in steps 2 and 3 will be mapped from their TDF domain to the COM-B model.

In turn, COM-B is embedded in the 'Behaviour Change Wheel' (BCW). This framework describes nine intervention categories addressing the core

behaviours of the COM-B model, and seven policy categories that enable implementation of these interventions [78].

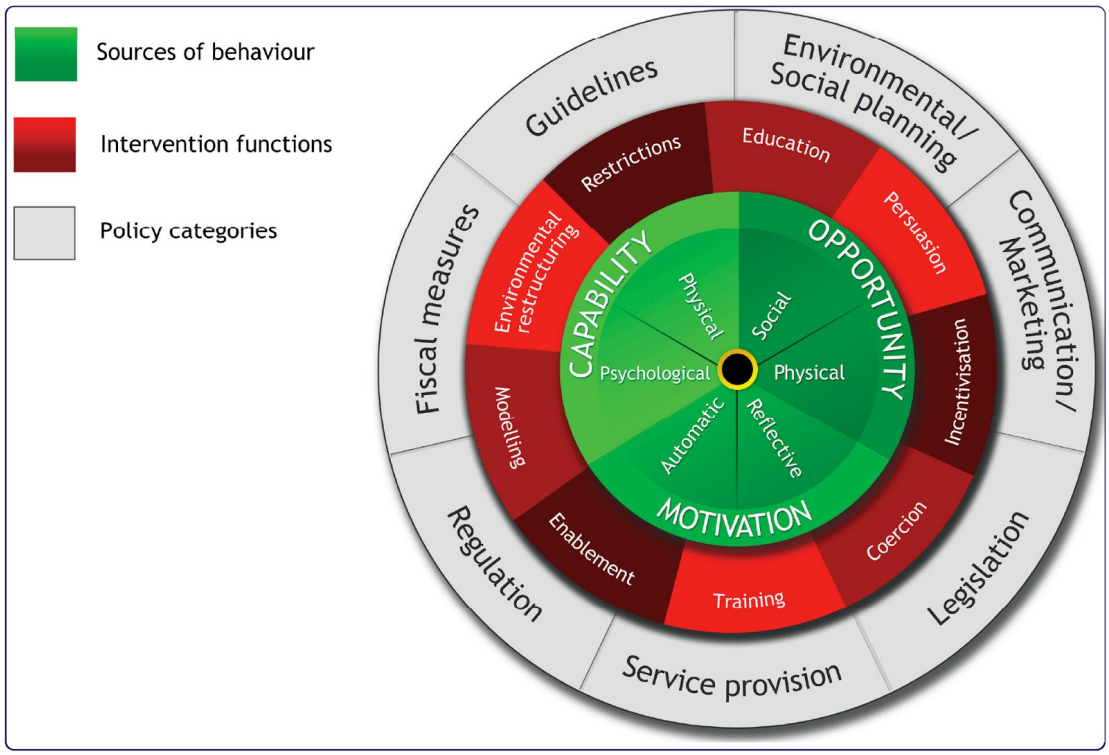

Figure 2: The Behavioural Change Wheel, from Michie et al [79]

5. Identify Intervention Functions
6. Identify Policy Categories

The next step is to identify 'intervention functions' – i.e. a broad methodology by which change is effected. These are mapped from COM-B and a detailed matriz of how COM-B intercepts with the intervention functions of the BCW is available [78]. It is accepted that that intervention may have more than one function –e.g. an intervention can 'educate' and 'persuade'.

Policies, whether they already exist or need to be created de novo, are required to ensure an intervention function is delivered appropriately. The BCW has links between intervention functions and policy functions.

The utility of potential intervention and policy functions will be determined using the APEASE criteria:

- **A**ffordability
- **P**racticability – can it be delivered all of the time, and not just within the confines of a well-conducted clinical study
- **E**ffectiveness (and cost-effectiveness)
- **A**cceptability – to all groups involved in the effects of behavioural change (e.g. bystanders, victims, emergency services)

- **S**afety (or side-effects) – there may be unanticipated consequences that affect some aspect of safety for either bystander or victim
- **E**quity

The goal by this stage is for the project team to have identified a list of feasible interventions that could be tested to determine their effectiveness in increasing AED use in the GoodSAM first-responder system. These will be framed as research questions using the P-I-C-O (Population, Intervention, Comparator, Outcome) format and ranked according to importance – i.e. which should be investigated first – by the project team.

This prioritised list of research questions is the intended output of this section.

This integrated and robust method to synthesise new evidence and develop potential interventions aligns with Medical Research Council guidance on complex intervention development. Once intervention(s) are developed, they still need to undergo evaluation and potential modification if required [80-81].

One or more of the research questions will be investigated in future work. This work will again be informed by the BCW and associated behavioural change theory. The Behavioural Change Technique Taxonomy [78] [82] details 16 groups of behavioural change techniques that will be vital in designing an intervention that is implemented effectively. A recognised taxonomy to inform the appropriate mode of delivery will also be used [78].

4. OVERALL STUDY CONDUCT

4.1 Good Clinical Practice

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

4.2 Ethical Considerations

This project involves discussions with members of the public. Some of these people may have training in medicine or another allied health profession but they will have been acting in a 'Good Samaritan' role in case of immediate emergency. All interview participants will be adults, and capacity will be presumed.

There is no specific Good Samaritan legislation in England. In 2015, the Social Action, Responsibility and Heroism Act was introduced in England and Wales [83] 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 [84]. This study will place no additional responsibilities or liabilities on GoodSAM first-responders than already exist.

It will be necessary to talk to participants shortly after they have received a notification. In many cases we will be discussing a sensitive issue – bearing witness to and providing assistance to an OHCA victim. The steering group will work carefully, with clear input from the team's Patient and Public Involvement representatives, to review interview conduct, topic guides and all participant information sources. There is a clear University of Warwick procedure to offer help and support to any participant who experiences distress as a result of their experience as a GoodSAM. There is an Action Card, and we can suggest the following sources:

- Their own GP
- NHS 111
- Bystander Support Network (http://bystandernetwork.org/): an online community-engagement network set up to help people who have been involved in a community-based cardiac arrest case
- Samaritans: 116 123 (from any UK phone)
- MIND: 0300 123 3393 (phone) or 86463 (text)
- In addition, for those who are **employees of London Ambulance Service**, they can contact the Senior LINC on-call (24/7) on 0207 9227539

In addition, if there is immediate concern about the participant's wellbeing, we will try to ascertain their physical location and call 999 – again, according to existing University procedures.

Telephone interviews have been used in recent research of resuscitation actions by lay bystanders. Researchers concluded that remote interview by telephone was feasible and allowed a degree of privacy and security to the interviewee whilst allowing the research team to gather information in reasonable proximity to a sensitising event [85].

We will develop standard operating procedures for identifying and contacting GoodSAM First-Responders via e-mail after they have received a GoodSAM notification.

We will make an ethics application to the University of Warwick's Biomedical and Scientific Research Ethics Committee (BSREC). Participants are being recruited as members of the public acting in a Good Samaritan capacity and *not* by virtue of their professional role. Identification, contact and follow-up of participants will be facilitated solely by GoodSAM – a social enterprise who are independent of the NHS.

We will gain appropriate approvals from both GoodSAM and the University of Warwick regarding the conduct of this research project and the approvals required for access to data and participants.

No participant-identifying information will be associated with transcripts of interviews, nor reported in any project outputs.

5. DATA MANAGEMENT

We will handle and store any personal data collected during the trial 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)

5.1 Data Collection and Storage

Epidemiology data

We will obtain epidemiological data from the OHCAO Registry and GoodSAM. Data sharing arrangements are in place with both organisations. Source data locations are outlined in section 6.1

The Primary Investigator will access and store this data in a private data folder located on the University of Warwick's secure file server. Access to this file server is only possible with username and password access. 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 collected – it will not be possible to identify individual OHCA victims or GoodSAM first-responders. Transfer of anonymised source data from the OHCAO Registry 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 are stored only on the University's secure file server)

The Primary Investigator will be responsible for data entry throughout.

Interview data

The Primary Investigator will conduct telephone interviews in a private room at the Clinical Trials Unit. He will transcribe interviews the same day. Recordings and transcriptions will be stored in separate folders on the University's secure file server.

Personally identifying data on GoodSAM first-responders will be limited to name, e-mail address and contact telephone number, which we will record only for the purposes of consenting and subsequently arranging a telephone interview time for participants. We will not store any personal identifying data with interview transcripts.

The Primary Investigator will store transcripts, consent forms and participant contact information in a private data folder located on the University of Warwick's secure file server, as described above. He will store personal identifying data on GoodSAM first-responders in a stand-alone file and this file will be individually password-protected.

Minimum standards for password strength are detailed in Warwick CTU SOP 15, part 2 (see below).

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 Unit 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 This includes a requirement for encryption to use a 256-bit AES on devices that are storing study data.

- 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).

5.2 Data Access and Quality Assurance

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 collect epidemiological data, and NVivo to aid coding and analysis of interview and observational data. These programmes are available on Desktop computers at Warwick CTU.

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

5.3 Data Shared with Third Parties

There will be no sharing of any data or information collected with third parties.

5.4 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.

6. DATA ANALYSIS

6.1 Epidemiological Data

A logistic regression model will be constructed to determine which factors affect the whether or not an AED is used by GoodSAM first-responders who accept a notification to provide assistance to an OHCA victim. The binary outcome of interest is 'AED use by bystander (yes or no)'. The following outlines the data that will be collected, its source, and its format:

Table 2: Epidemiological Data Collection and Source

Variable	Format	Response options	Description	Data Source
Number of OHCA Cases	Number	Number	Number of OHCA cases in 2016 submitted by London Ambulance Service to the OHCAO Registry	OHCAO Registry
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
Number of OHCA cases with a GoodSAM responder available within 300m	Number	Number (%)	Number of OHCA cases where at least one GoodSAM first-responder was available within a 300m radius	GoodSAM
Number of OHCA cases with an AED available within 300m	Number	Number (%)	Number of OHCA cases where at least one AED was available within a 300m radius	Mapping project from Work Package 1
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
Number of responders accepting a GoodSAM notification	Number	Number (n = 1,2 or 3)	Number of responders accepting a GoodSAM notification. This will be n = 1, n = 2 or n = 3.	GoodSAM
Category of responder(s) accepting a GoodSAM notification	Number	Number (n = 1,2 or 3)	Category (1,2 or 3 – as previously described) of GoodSAM responder accepting a notification	GoodSAM
GoodSAM first-responder arrives at scene	Text	Yes; No	Did a GoodSAM first-responder record that they had arrived on scene? Time taken for the first responder to arrive on scene	GoodSAM
Time from GoodSAM	mm:ss	mm:ss	For those GoodSAM first-responders who arrived on scene, the time interval	GoodSAM

notification to arrival on scene			between GoodSAM notification being sent and arrival on scene	
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
Location Type	Text	Public; Private	Type of location, either public or private. Determined from 'location of EMS occurrence data' collected in Work Package 1	Determined from data collected in Work Package 1

The following data table will be constructed to collect and subsequently analyse information on all the OHCA cases:

Table 3: Epidemiological Data for Analysis (1)

Case No.	Date of ambulance call (dd/mm/yy)	Time of ambulance call (hh:mm:ss)	GoodSAM responder available within 300m	AED available within 300m
#1	01/01/16	00:03:21	Yes	Yes
#2	01/01/16	05:54:03	No	Yes
#3	01/01/16	08:01:45	No	No
#4	01/01/16	09:54:47	Yes	No

From the cases where the answer to the question "GoodSAM responder available within 300m" was YES, data will be collected and added into the following table:

Table 4: Epidemiological Data for Analysis (2)

Case No.	Date of ambulance call (dd/mm/yy)	Time of ambulance call (hh:mm:ss)	AED available within 300m	AED applied before arrival of ambulance	Number of responders accepting	Category of responder	Responder arrives at scene
#1	01/01/16	00:03:21	Yes	No	2	1	Yes
						2	No
#4	01/01/16	05:54:03	Yes	No	1	3	Yes
#5	01/01/16	08:01:45	No	No	1	2	Yes
#8	01/01/16	09:54:47	No	Yes	1	3	Yes

Table 4: Epidemiological Data for Analysis (2) (continued)

Case No.	Time to responder arrival on scene	Patient age	Patient gender	Bystander CPR?	Location type
#1	03:12	64	M	No	Public
#4	06:18	73	M	No	Private
#5	07:12	69	F	Yes	Private
#8	01:19	43	M	Yes	Private

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.

Using the potential candidate predictor variables from Table 4, backward and stepwise selection procedures will be used to construct the logistic model, whilst keeping the clinically relevant variables in the model. We have used the rule of thumb of a minimum of ten outcome events per predictor [86] for a logistic regression model to constrain the number of variables that are entered into the model.

6.2 Interview and Observational Data

Information from interviews and observations about barriers to AED use by GoodSAM first-responder will be classified into domains of the TDF. The steps anticipated in recording analysing this data are:

- Audio record interviews. Take contemporaneous 'field notes' if required
- Transcribe data
- Add transcription file to NVivo
- Annotate transcription with 'field notes' if appropriate
- Annotate transcription with codes corresponding to constructs of the TDF domains
- Create a matrix to help us classify and understand the data, as illustrated in Table 5.

Table 5: Matrix Output from NVivo (for illustrative purposes only, where * indicates statements corresponding to a named TDF Domain)

	TDF Domains													
	1	2	3	4	5	6	7	8	9	10	11	12	13	14
GoodSAM first-responder interviews	*		*							*				
		*		*			*							
											*		*	
				*		*	*							
									*					
								*						
Key Informant Interviews			*			*		*					*	*
			*				*	*						
Data from Observations		*		*	*						*	*		

We will create further data tables when mapping TDF domains to COM-B, and subsequently to the Intervention and Policy Categories of the BCW

7. STUDY ORGANISATION AND OVERSIGHT

7.1 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.

7.2 Regulatory Authorities / Ethical approval

We will request ethical approvals for this study, as detailed in section 4.2. The required ethical approval for the trial will be sought through the University's Biomedical and Scientific Research Ethics Committee (BSREC).

7.3 Study Registration

This study protocol will be published online and freely available via the University of Warwick's Research Archive Portal.

7.4 Indemnity

The University of Warwick provides indemnity for any harm caused to participants by the design of the research protocol.

7.5 Study Timetable and Milestones

It is feasible to complete a TDF-based interview study in 12 months [54]. We have allocated 15 months for this work package to allow for delays that may be caused by the ethics approval process, and contingencies for events such as illness and difficulties or delays in obtaining source data.

The GANTT chart overleaf demonstrates the anticipated project timetable (Table 6).

Reporting of the results and preparation of a scientific article for peer-reviewed publication is planned for February 2019.

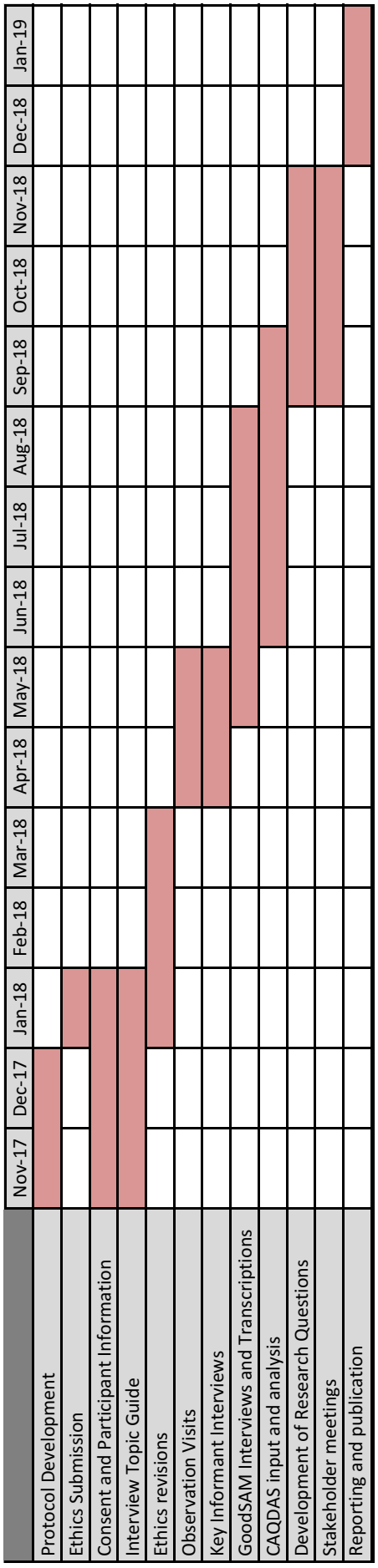

Table 6: Study Timetable and Key Milestones

Warwick Medical School
CLINICAL TRIALS UNIT

7.6 Administration

Dr. Christopher Smith is a NIHR-funded Doctoral Research Fellow (from November 2017) and PhD Health Sciences student at the University of Warwick

This project ('Work Package 2') 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.

7.7 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 1 and 3 rather than work package 2.

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 (Clinical Audit and Research Department, 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 entire PhD 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

7.8 Essential Documentation

All data and files relating to the project will be held on computers in Warwick CTU.

8. MONITORING AND QUALITY ASSURANCE

8.1 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)
- NVivo Training Workshop (short course, University of Surrey, 28th February – 1st March 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)

8.2 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.

8.3 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 affect on the data or scientific accuracy of any part of this study – will be reported to Warwick CTU and the relevant Research Ethics Committee (REC) within 7 days. The study investigators will take whatever immediate action is required to safeguard data.

9. 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.

Specifically they will provide expertise on:

- The optimal way to ask GoodSAM first-responders to participate in interviews for work package 2. Many of these volunteers will not have formal medical training, and all may have had a difficult experience when responding to a cardiac arrest in a 'Good Samaritan' capacity
- The content and language used in Participant Information sheets
- Development of the Topic Guide for interviews with GoodSAM first-responders

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. It 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.

10. 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 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 in February 2019. Work from this work package will be published in line with Standard Reporting of Qualitative Research guidelines [87].

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.

11. REFERENCES

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