PROTOCOL

Drone-Delivered Defibrillators (The 3D Project)

A mixed-methods evaluation of integrating drone-delivered Automated External Defibrillators into the ambulance service response to out-of-hospital cardiac arrest

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LIST OF ABBREVIATIONS

ABBREVIATION	EXPLANATION
AED	Automated External Defibrillator
BVLOS	Beyond Visual Line of Sight
CAA	Civil Aviation Authority
CAQDAS	Computer Assisted Qualitative Data Analysis
COM-B	Capability, Opportunity, Motivation – Behaviour model
COREQ	COnsolidated criteria for REporting Qualitative research
CPR	Cardiopulmonary Resuscitation
CTU	Clinical Trials Unit
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
HRA	Health Research Authority
IRAS	Integrated Research Application System
NIHR	National Institute for Health and Care Research
NHS	National Health Service
PPI	Patient & Public Involvement
REC	Research Ethics Committee
RfPB	Research for Patient Benefit
SOP	Standard Operating Procedure
STROBE	Strengthening the Reporting of Observational Studies in Epidemiology
TDF	Theoretical Domains Framework
UAV	Unmanned Aerial Vehicle
UK	United Kingdom
UTM	Unified Traffic Management
WAST	Welsh Ambulance Service NHS Trust

1. BACKGROUND

1.1 Epidemiology and burden of out-of-hospital cardiac arrest

Globally, fewer than 10% people sustaining an out-of-hospital cardiac arrest survive to hospital discharge (1, 2). UK NHS Ambulance Services attempt resuscitation in approximately 30,000 people annually. The annual incidence in England is 57.9 per 100,000 (2021 figures), with 8.5% surviving to hospital discharge (3)

Early defibrillation and good-quality chest compressions during cardiopulmonary resuscitation (CPR) substantially increase the chance of surviving to hospital discharge (4). Defibrillation is time-critical: for every minute it is delayed survival chances fall 5-10% (5).

The immediate community response to out-of-hospital cardiac arrest is therefore vital: of all possible interventions, prompt bystander CPR and bystander used of public-access Automated External Defibrillators (AEDs) *before an ambulance arrives* make the most difference (4).

Bystander intervention may be increasingly important as demand for NHS Ambulance Services increases year-on-year. In England, for example, ambulance services reached out-of-hospital cardiac arrest patients within seven minutes on only 47.5% occasions in 2021. The response time was at least 17.5 minutes for 10% patients (3). An earlier study reported substantially longer response times and worse patient outcomes in rural areas compared to urban areas in England (6).

Public-access AED use, in particular, is associated with an approximate doubling of both survival to hospital discharge and survival with good neurological function (7). Median survival after bystander defibrillation is 53% (8). However, whilst bystanders performed CPR in 73.5% cases in England in 2021 they used an AED in only 5.5% cases (3)

1.2 Drone-delivered defibrillators: existing knowledge

It is possible to use Unmanned Aerial Vehicles (UAVs, or 'drones') to carry an AED and deliver it to the site of an out-of-hospital cardiac arrest.

Drones are already extensively used in the commercial sector and their safe operation is tightly regulated in the UK by the Civil Aviation Authority (CAA). There are few technical barriers to drone use, and the complexity concerning their use in this context relates to how *best* to use them to complement existing approaches to out-of-hospital cardiac arrest.

Researchers in Canada (9, 10), Sweden (11), Germany (12) and USA (13) have demonstrated in modelling work that optimally-located drone bases could have delivered AEDs to patients (in historical cases) before an ambulance arrived. This time saving is largest in rural areas (9-11). In 18 actual test flights in Sweden, an AED-equipped drone reached historical out-of-hospital cardiac arrests 16.4 minutes quicker (mean) than during the real event (14).

A drone-delivered AED network is reality in Stockholm, Sweden. Between June–September 2020, drone-delivered AEDs were available in three regions. Once an emergency call-handler identified an out-of-hospital cardiac arrest, there was an alert to a drone pilot. The pilot sought permission to fly from air-traffic control and remote-piloted the drone to the scene. In 12 drone flights, a drone arrived at the scene 11 times and arrived before the ambulance seven times (median time saving 1:52 minutes) (15).

There are many process issues to resolve. A drone-delivered AED was not attached to a patient on any occasion in this Stockholm pilot (15), albeit a case report from that system (December 2021) has now reported survival to hospital discharge in a patient defibrillated by a drone-delivered AED (16).

In the Stockholm study, median time from emergency call to AED delivery was 9:08 minutes, of which 3:10 minutes elapsed before drone launch (15). In simulations in

Germany it took a mean of 6:02 minutes to defibrillate the patient for the shortest (just 0.4km) of five test-flight routes (12). Most delays to defibrillation therefore would have been before and/or after the drone flight.

Once a drone delivers an AED, bystanders in simulations reported comfort in interacting with the drone (12, 17-19).

In eight single-bystander simulations in Sweden, the hands-off CPR time (the time from stopping CPR to retrieve the AED to the time that CPR commences again once the AED has been attached and delivered a shock) was a mean of 94 seconds (range 75-110 seconds) (17).

Our research team has existing experience of carrying AEDs by drone, demonstrating the use of fixed-wing aircraft to carry an AED a total of 92km over six test flights in a coastal air corridor in Wales. The AED was dropped by parachute from 120m, and landed within 50m of the target location (20).

We have subsequently developed a delivery system using a rotary-wing drone, demonstrating that we could carry an AED and safely lower it via winch at the exact location required (<5m) in simulated out-of-hospital cardiac arrests (19). Notably, the Stockholm team use a winch mechanism for their live operations (15, 16).

In our latter study (19), participants made a simulated 999-call, performed CPR and were instructed that an AED would arrive via drone. Participants felt uncomfortable leaving the patient's side and asked the 999-call-handler for permission to leave the patient - even though they had heard the AED's arrival and an audible siren indicating it was safe to approach. They appreciated that the cognitive burden of deciding whether or not to try and retrieve a distant AED had been removed from them. Hands-off CPR time was a median 109 seconds (interquartile range 87-130 seconds) in 18 simulations. However, only 19 seconds of this hands-off time was time actually away from the patient's side: only a small addition to hands-off CPR time compared to a situation where an AED is placed directly in their hands by someone else. Drone-

delivery of AEDs may therefore be appropriate for situations where there is only one bystander.

In the UK, 'Beyond Visual Line of Sight' (BVLOS) drone flights are generally limited by the CAA to research studies in pre-agreed flight corridors. However, within these corridors there are opportunities to test drone carriage of AEDs.

We are ready to demonstrate an optimised, fully-integrated drone-delivery system (from 999-call to AED attached to patient) to the CAA and to the public. This will put ambulance services across the UK in a position where they can test and implement drone-delivery AEDs as soon as possible.

1.3 The need for this study

Barriers to public-access AED use

The NHS Long Term Plan aims to improve the public-access AED network to help save 4,000 additional lives each year from cardiac arrest, and to reduce health inequalities (21). However, public-access AEDs in the UK are not optimally nor equitably placed. AED density (per square-km) varies by geographical region (lowest in North-East England), by affluence (fewer in poorer areas) and by population density (fewer where residential density is higher) (22). Areas of low AED density correlate closely with areas of high out-of-hospital cardiac arrest incidence and low bystander CPR rates, further exacerbating this inequity (6).

Our systematic review synthesised data from 68 studies to characterise facilitators and barriers to successful bystander AED use (23). Several key barriers relate to the static location of AEDs and the need for bystanders to leave a patient to retrieve one.

The path to successful public-access AED is a complicated one. First, one must determine whether an AED is close enough to retrieve and use. Where only a single bystander is present, there is a need to balance benefits of early defibrillation against harms of not delivering prompt CPR. A bystander must be able to successfully locate,

retrieve and then use a public-access AED. Studies highlight that bystanders are often reluctant to leave a patient (24, 25), and the further away a patient is from a public-access AED the less likely it is that one will be used (26).

The importance of overcoming these barriers

Direct delivery of AEDs via drone to members of the public attending an out-of-hospital cardiac arrest may be a way of overcoming the barriers to public-access AED use. Other countries have demonstrated the concept and there is real-world use in Sweden. Developing a system in the UK, and using the experience of others to optimise communications between ambulance services and drone operators, is an area ripe for immediate further study.

Survival with favourable neurological outcome is an important outcome for both patients and their relatives (27). A recent collaboration between adult out-of-hospital cardiac arrest survivors, their families and the James Lind Alliance reported that optimising community interventions and focussing on longer-term impacts were top priorities (28).

Early access to defibrillation by members of the public improves survival. More than this, those who do survive a cardiac arrest have better longer-term and functional outcomes if they received bystander defibrillation: they are less likely to have brain damage or require nursing-home care one year later (29), and are less likely to require intensive care admission (30).

As cardiac arrest researchers we believe, therefore, that increasing timely bystander AED use can improve clinical outcomes and aligns well with survivor and family priorities.

1.4 Ethical considerations

We will conduct the study in full conformance with the principles of the Declaration of Helsinki and to Good Clinical Practice (GCP) guidelines. It will also comply with all

applicable UK legislation regarding Unmanned Aerial Vehicle (UAV) flights and all appropriate University of Warwick Standard Operating Procedures (SOPs). All data will be stored securely and held in accordance with the UK General Data Protection Regulation (GDPR).

We detail specific ethical considerations for both work packages in the relevant sections.

1.5 Study reporting

We will make results of both work packages available in open-access peer-reviewed publications.

We will report work package 1 according to COREQ (Consolidated criteria for reporting qualitative research) guidelines (31).

We will report work package 2 (simulated cardiac arrests with BVLOS drone flight to deliver an AED) according to STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines for observational studies (32) and its extension for simulation studies (33).

2. STUDY OVERVIEW

This is an 18-month project (May 1st 2023 to October 31st 2024) split into two work packages, detailed in sections 3-4 of this protocol. It is funded by the National Institute for Health and Care Research (NIHR) Research for Patient Benefit (RfPB) funding programme.

It involves collaboration between University Hospitals Coventry and Warwickshire NHS Trust (UHCW), University of Warwick, Welsh Ambulance Service NHS Trust (WAST) and SkyBound Rescuer (a commercial drone operator – https://skyboundrescuerproject.com/). There are two Patient and Public Involvement (PPI) representatives.

2.1 Overall aim and objectives

The aim of the project is to explore the optimisation and integration of a drone-delivered AED system into the pre-hospital response to out-of-hospital cardiac arrest, as a necessary pre-requisite to real-life flight operations.

Objectives:

Objective I: Explore the attitudes of real-life out-of-hospital cardiac arrest bystanders, who may or may not have used an AED, about using drones to deliver AEDs. **(Work package 1)**

Objective II: Demonstrate capability for safe BVLOS flights of an AED-capable drone in controlled flight corridors. **(Work package 2)**

Objective III: Create compatible systems between drone operator and ambulance service; optimise automated drone-activation systems and flight start-up procedures once out-of-hospital cardiac arrest is identified during a 999 call. **(Work package 2)**

Objective IV: Demonstrate an AED drone-delivery system that is fully integrated with ambulance service systems, in 'end-to-end' (from

999 call to AED use on a patient) BVLOS flights for simulated out-of-hospital cardiac arrests. **(Work package 2)**

3. WORK PACKAGE 1

3.1 Objective

Explore the attitudes of real-life out-of-hospital cardiac arrest bystanders, who may or may not have used an AED, about using drones to deliver an AED.

3.2 Approach and rationale

There is work in simulation studies suggesting that bystanders generally find it easy to interact with a drone that has delivered an AED to them (12, 17-19). In our previous simulation work participants experienced a few common issues (19), many of which involved their interaction with the 999 call-handler. They often felt uncertain about when it was safe to leave the patient to retrieve the AED, or felt uncomfortable in leaving the patient, despite audible prompts from the drone to indicate that it was indeed safe. They relied on feedback or 'permission' from the call-handler to allow them to do this. There were also difficulties in interacting with the AED itself – which has automated voice instructions helping people to use it – when 999 call-handler instructions conflicted and when the noise of the departing drone made it difficult to hear instructions.

There is a need to investigate further the behaviours of people who have used or who may use an AED at an out-of-hospital cardiac arrest, particularly with regards to how they interact with the 999 call-handler.

3.3 Study design

We will conduct semi-structured interviews with people who have actively participated in an out-of-hospital cardiac arrest. We will conduct these remotely, either using a University of Warwick-managed computer and a Microsoft Teams account or via telephone. Participants will have the opportunity to conduct the Teams interview with their video on or off.

We will interview both those who have used an AED and those who did not. We will record age, gender, whether they have used an AED or not and whether they have had previous CPR/AED training or experience or not. We will explore their personal experiences, particularly in relation to:

- Their reasons for using / not using an AED.
- Their experience with the 999 call-handler and how we might optimise this.
- Their likely reaction to an AED being delivered to them by drone.
- How best to optimise their interaction with the drone-delivered AED with, again, particular focus on the interaction with the 999 call-handler.

We anticipate that the interviews will last up to 45 minutes, and that we will interview each participant on one occasion.

A senior research fellow, skilled in qualitative research, will undertake the interviews. The researcher will start with open questions and follow-up with prompting and more directed questions as needed (34). We have developed a Brief Topic Guide that focusses on aspects relating to the participants' capability, opportunity and motivation (see explanations in **section 3.5**) to use an AED, interact successfully with a drone-delivered AED and interact successfully with the 999 call-handler.

3.4 Participants and recruitment

We will recruit adults (≥ 18 years old) who:

- have mental capacity to make decisions about study participation.
- have provided bystander interventions (CPR +/- use of an AED) during an out-of-hospital cardiac arrest.
- are able to conduct interviews in English.
- are willing to have an audio recording made of the interview.

We will exclude people if it is clear that they have not previously provided any bystander intervention during an out-of-hospital cardiac arrest or if, in the judgement

of the interviewer, are not able to understand or communicate effectively in English. We will also exclude those who do not agree to be audio recoded.

Recruitment

We will recruit participants primarily via WAST's contacts with cardiac arrest survivor and bystander groups. Members of the research team also have extensive contacts and/or direct involvement with Resuscitation Council UK, British Heart Foundation, other local ambulance services and a national group called Sudden Cardiac Arrest UK. All have links with people who have sustained an out-of-hospital cardiac arrest and those who were involved in helping them at the time.

We will ask these organisations to send out a brief explanation of the project via email on our behalf, either as a standalone email or as part of a 'newsletter' or other regular update, according to their processes. We will also advertise the project using the institutional social media accounts of the research collaborators and the organisations mentioned above, according to each's social media policies. The organisations mentioned have diverse memberships and we will liaise closely with our PPI co-applicants to ensure that recruitment materials are accessible and relevant to all members of the communities that we serve.

All recruitment advertisements will include contact details for the study team. For those that contact us and express a willingness to proceed, we will send out a study participant information sheet and consent form using SharePoint via Teams. A secure SharePoint/Teams link with access restrictions and permissions will be sent from a University of Warwick institutional email. We will confirm that they meet the eligibility criteria at this point.

We will send one e-mail reminder to those who express an initial interest in the study but then do not follow-up one - two weeks after we have sent out the Participant Information Sheet and consent form.

We will ensure that participants have adequate time to consider their participation, ask questions (via email and/or telephone, depending on individual preference) and have them answered to their satisfaction. We will manage transfer and signing of consent forms using SharePoint via Teams by sharing links with appropriate access and permissions via email. Once we have completed the consent process we will arrange a mutually agreeable time to conduct a remote interview.

We will use an encrypted audio-recorder to record interviews and, if available, use a second encrypted device to make a backup recording. We will transfer the recording(s) from the encrypted audio-recorder and, if available, second encrypted device to a folder on a secure server on University of Warwick-managed computers immediately after the interview. Once the audio-recording(s) have been transferred, we will securely delete the recording(s) from the encrypted audio-recorder(s). In addition, we will generate researcher fieldnotes after the interview to enrich data analysis. We will document contextual information (e.g. non-verbal communication behaviours) and share reflexive insights into how the interview went, including any notable discussion points and/or tentative themes emerging from the discussion. The fieldnotes will be linked to the participant's ID number and stored on a secure server on University of Warwick-managed computers. No participant-identifying information will be recorded in the researcher fieldnotes.

The participants will have the option to have their camera on or off. At the start of each interview, we will confirm the participant’s identity and consent and check that the participant is happy to proceed.

Participants will be able to pause, stop or postpone the interview at any point. They will be able to withdraw from the study at any time, and we will not keep information about them that we already have unless they withdraw after we have completed qualitative analyses and submitted them for publication or other output. If they withdraw before we have analysed their interview data, they can choose whether information collected in the interview up to that point is used or not. If they withdraw after we have analysed their data, we may not be able to identify exactly how information that came from one participant contributed to and influenced our overall

conclusions. This is because the ongoing, iterative nature of analysis and synthesis mean that once we code and analyse individual interviews those data and findings become an intricate part of the overall narrative. We may use direct, anonymised quotes in peer-reviewed articles or other research outputs. Participants who have withdrawn can request that direct quotes are not used – at any point up until articles have been accepted for publication. For other research outputs we will remove direct quotes if requested wherever we are able to do so (e.g. before printing of a conference poster, before submission of slides for an oral conference presentation). Participants will be offered a voucher to the value of £25, even if they do not complete the entire interview or subsequently withdraw their consent after the interview has finished.

Sample size

We plan to interview until we achieve data saturation, which we anticipate will require approximately twenty-four participants. We base this estimate on reviews of other studies using qualitative interviews (35) and our previous experience of interviewing people who have responded to out-of-hospital cardiac arrests (25). We may slightly increase the number of interviews if it becomes clear that we have not reached data saturation after 24 interviews (36).

3.5 Analyses

We will perform a framework analysis using the Theoretical Domains Framework (TDF) (37) to identify barriers and facilitators to drone-delivered AED use and to effective interaction with the 999 call-handler.

We will group the 14 domains of the TDF so that we can characterise barriers and facilitators to effective use of a drone-delivered AED according to a bystander's 'Capability', 'Opportunity' and 'Motivation' – the so-called COM-B (Capability, Opportunity, Motivation – Behaviour) framework (38). We will then map the three core targets for behavioural change to identify potential interventions to enact this change using the Behaviour Change Wheel (39).

We have previous experience of using this sort of integrated model (25), and will adapt our approach here.

We will use a University of Warwick approved commercial transcription service to transcribe interviews. We will upload audio that has been saved in a password-protected folder on a secure server on University of Warwick-managed computers via the transcription company's secure portal, and we will receive a transcription back from them via the same secure portal. Once transcription has been completed and we have checked its accuracy, we will securely delete the audio files from the secure university server. No participant-identifying information will form part of the transcription.
The senior research fellow will be principally responsible for coding and keeping analytic memos during the analysis process to document their developing ideas and thoughts about the analysis, including ensuring that the information arising from the interviews can be sufficiently matched to the domains of the TDF for us to proceed with this framework. Coding will be done iteratively, with periodic checking with other members of the research team who have experience in this work (Dr Christopher Smith, Dr Keith Couper, Dr Nigel Rees). At the discretion of the senior research fellow, we may use a Computer Assisted Qualitative Data Analysis (CAQDAS) package to assist with data organisation and coding.

3.6 Ethical and safety considerations

This work package involves adult participants, presumed to have mental capacity to make decisions relevant to participation in this study, who have assisted (CPR +/- AED use) at real-world cardiac arrests. This is a potentially sensitive topic, and the participant information includes numbers for support agencies. This includes GP, NHS 111 and telephone numbers and webpage contacts for MIND, Samaritans and Sudden Cardiac Arrest UK – the latter provides help and support to survivors and 'co-survivors' (people involved in a cardiac arrest) in the aftermath of the event. The senior research fellow conducting the interviews will also follow a 'Sensitive Call Action' procedure developed by Warwick Clinical Trials Unit (CTU) **(appendix 1).** This outlines clear actions that the interviewer can take should there be an immediate concern for the wellbeing of the interview participant, and may include the researcher asking a senior

member of staff from the University for help and/or calling 999. Should this occur, the researcher will notify the participant first. These options are made clear to the participant in the Participant Information Sheet. Our PPI representatives have reviewed this information.

In this work package, the risk to the interviewer is minimised by the remote nature of the interviews. However, this is still a sensitive topic. In the same way that the participant can, the senior research fellow can contact their GP, NHS 111 and access telephone numbers and webpage contacts listed in the Participant Information Sheet for MIND and Samaritans. They can also seek support from the University of Warwick's wellbeing services.

We will keep a record of any adverse events of which we become aware. If there are any Serious Adverse Events related to the interview, then we will inform the sponsor within 24 hours of us becoming aware, in line with University of Warwick SOPs.

We are interviewing people who responded in a ‘Good Samaritan’ role to an out-of-hospital cardiac arrest. We will not provide any medical advice, including advice about the management of cardiac arrest. We will also emphasise at the start of the interview that we are not in any way making judgements about what happened during their own experience, rather we are seeking to understand how we might optimise the use of drone-delivered AEDs in the future.

Remote interviewing, as well as being a pragmatic option, may result in a greater degree of actual or perceived anonymity (particularly with the option to turn cameras off). Additionally, when dealing with sensitive issues this may result in more honest or complete answers (41).

4. WORK PACKAGE 2

4.1 Objectives

Demonstrate capability for safe BVLOS flights of an AED-capable drone in controlled flight corridors.

Create compatible systems between drone operator and ambulance service; optimise automated drone-activation systems and flight start-up procedures once out-of-hospital cardiac arrest is identified during a 999 call.

Demonstrate an AED drone-delivery system that is fully integrated with ambulance service systems, in 'end-to-end' (from 999 call to AED use on a patient) BVLOS flights for simulated out-of-hospital cardiac arrests.

4.2 Development work

Demonstrate capability for safe BVLOS flights of an AED-capable drone in controlled flight corridors.

We have partnered with a UK drone company, SkyBound Rescuer (https://SkyBoundrescuerproject.com/), who specialise in using automated drones for public safety.

SkyBound have developed a comprehensive Operational Safety Case that details the testing of an AED-capable drone in BVLOS flight using dedicated air corridors. We will liaise with and receive all necessary approvals from the UK Civil Aviation Authority (CAA) to perform the drone flight required in this work package.

Create compatible systems between drone operator and ambulance service; optimise automated drone-activation systems and flight start-up procedures once out-of-hospital cardiac arrest is identified.

SkyBound and WAST have agreed a plan of work to integrate automated remote drone activation procedures with their Emergency Operations Centre, and to provide appropriate training in these procedures. Once an out-of-hospital cardiac arrest is identified during a 999 call and a request has been made to SkyBound's software, the drone can launch instantaneously and automatically. SkyBound and WAST will also develop communication procedures between drone operator and the Emergency Operations Centre during drone flight, thus providing the 999 call-handler with real-time information about the drone and its location that they can relay to the bystander at the scene of a cardiac arrest.

4.3 Approach and rationale

Demonstrate an AED drone-delivery system that is fully integrated with ambulance service systems, in 'end-to-end' BVLOS flights for simulated out-of-hospital cardiac arrests.

We have previously demonstrated that study participants can interact with a drone-delivered AED (19). What has not been tested before in the UK is a fully-integrated system that allows the BVLOS delivery of an AED via drone following diagnosis of cardiac arrest during a 999 call.

In this work package, we will ask study participants to come to the aid of simulated out-of-hospital cardiac arrest patients and to call '999'. The call will be directed to a WAST training call centre, which operates in the same way as a real 999 call, and used by us in our previous simulation study (19). In all other regards, the processes demonstrated in this work package (cardiac arrest diagnosis, automated drone activation, drone flight, real-time communications between drone and Emergency Operations Centre, AED delivery) will occur as they would in a real-world scenario.

When delivering an AED via drone, one important consideration is how long it takes a bystander to retrieve and attach the AED. Unnecessary delays in performing CPR can be detrimental to patient outcome, but potential delays caused by retrieving and using an AED must be balanced against the potential benefits of early defibrillation. Not all

patients in cardiac arrest will be suitable for defibrillation. It is not possible to know this in advance – an AED performs heart rhythm analysis and then shocks / does not shock according to its findings. Knowing how quickly a shock can be delivered and how long a bystander has to spend away from a patient to retrieve an AED will be an important consideration when implementing effective drone-delivered AED systems in the future.

Our previous simulation study demonstrated the importance of the bystander / 999 call-handler interaction in the process of retrieving and using a drone-delivered AED. This study will use information from audio/video analyses and from conversations to help ambulance services determine how best to communicate information about the arriving drone, and how best to offer advice during the 999 call about using an AED effectively.

Successful completion of this work package is one of the necessary pre-requisites for testing drone-delivery of AEDs for real-world out-of-hospital cardiac arrest. Other work is necessary too, such as modelling optimal locations for AED-capable drone sites so that a drone-delivered AED can reach a high proportion of patients in a suitable time-frame. Such modelling work is beyond the scope of this project but is planned for future work. It is feasible and has been conducted in other countries (9, 13, 42).

4.4 Study design

This will be an end-to-end test of drone-delivery of AEDs for simulated out-of-hospital cardiac arrest.

A study participant will find an adult ‘patient’ (a resuscitation manikin) in an outdoor location. They will be instructed only that: the person has collapsed in front of them and is not breathing and that they should call ‘999’. We will provide participants with a mobile phone with a pre-programmed number to make this call. The 999 call will connect to a WAST call-handler at a training centre.

The call-handler will handle it as a real-world call, asking questions, diagnosing cardiac arrest and providing telephone CPR instructions according to existing protocols. Once

cardiac arrest has been diagnosed during the 999 call, an automated instruction will be sent to a remote-located drone. This will start up, determine an appropriate flight-path and fly an AED to the cardiac arrest location. The drone pilot and 999 call-handler will have a 'live' line of communication during the flight.

The call-handler will inform participants that they have dispatched an AED via drone and update them when the drone's arrival is imminent. The drone will hover at the target location and lower the AED to the ground via winch. Video-recording equipment is integral to the drone and the drone operator can review in real-time that it is safe and appropriate to lower the AED to the ground. The winch will retract and the drone will hover above the AED to help indicate its location. The drone operator will indicate to the call-handler that it is safe to approach the drone, and the call-handler will relay this information to the participant. Once the participant has retrieved the AED the drone will start its flight back to its start location. The participant will then attach the AED to the patient. The AED will prompt them to deliver a single shock to the patient and the scenario will end.

The drone system will integrate with a commercial Unified Traffic Management (UTM) system (Guardian UTM) to simulate delays caused by receiving necessary BVLOS permission from the Civil Aviation Authority that would occur in unrestricted real-world flights outside of the designated corridor used for this study.

We can feasibly run six end-to-end scenarios per day. Each flight session (one day) will have received Civil Aviation Authority approval and will have a specific operational risk assessment prepared by SkyBound and the study team. We will rectify critical issues identified from participant feedback and by audio/video review after each flight session. Experience from our commercial partners suggests that for development of a system like this we will need up to four flying sessions, with critical issues identified in one session rectified before the next.

4.5 Participants and recruitment

We will recruit adults ($\geq$ 18 years old) who:

- have mental capacity to make decisions about study participation.
- believe themselves to have the physical and mental capability to perform CPR and use an AED in an outdoor environment.
- believe themselves able to use a mobile phone to communicate with a 999 call-handler.

We will ***exclude*** participants who are or who believe themselves to be pregnant, or those that are unable to complete the simulation because of physical or psychological distress.

Recruitment

We will recruit participants primarily by advertising via our contacts with WAST. We will seek the assistance of other groups such as Resuscitation Council UK and British Heart Foundation if necessary. We will also liaise with and advertise to local (to the simulation location) CPR training groups (e.g. St John, HeartStart) and other interested community groups. We will ask these organisations to send out a brief explanation of the project via email on our behalf, either as a standalone email or as part of a 'newsletter' or other regular update, according to their processes. We will also advertise the project using the institutional social media accounts of the research collaborators and the organisations mentioned above, according to each's social media policies. The organisations mentioned have diverse memberships and we will liaise closely with our PPI co-applicants to ensure that recruitment materials are accessible and relevant to all members of the communities that we serve.

We will look to recruit some participants who have had CPR/AED training (+/- have real-world experience of performing CPR and/or using an AED) and some who have not. A 2017 survey of UK adults showed that 40% of the adult population had not been trained in CPR, and 80% had not been trained in AED use (43). If, during the recruitment process, we note that we are disproportionately recruiting either trained or untrained participants, we will adjust our advertisement process so that we subsequently recruit only from the under-represented group.

All recruitment advertisements will include contact details for the study team. For those who contact us and express a willingness to proceed, we will send out a study participant information sheet and consent form using SharePoint via Teams. A secure SharePoint/Teams link with access restrictions and permissions will be sent from a University of Warwick institutional email in order that potential participants can familiarise themselves with the study details and the statements on the consent form. Correspondence via SharePoint/Teams will include information on the date/time and exact location of the study. We will confirm that they meet the eligibility criteria at this point.

We will send one e-mail reminder to those who express an initial interest in the study but then do not follow-up one - two weeks after we have sent out the Participant Information Sheet and consent form.

We will ensure that participants have adequate time to consider participation, ask questions and have them answered to their satisfaction, and to complete the consent form. On the study day itself we will re-confirm eligibility, answer any further questions and obtain written consent. We will then proceed with the simulation.

We anticipate that simulations will take up to 30 minutes to complete. We will ask people to arrive 30 minutes before the start of the simulation, and the post-simulation questionnaire and conversation will take no more than 15 minutes. Even allowing for delays, participants will spend a maximum of 90 minutes at the simulation site – it may well be far less. We refer to our previous drone simulation study experience when making these estimates (19). Participants will be able to stop the simulation at any point if they feel unable to continue. We will have a live communication channel to the drone pilot to inform them if this happens before the drone arrives so that the drone pilot can recall the drone to its base.

Participants will be able to withdraw from the study at any time. If they withdraw after we have analysed their post-event conversations and audio/video files associated with a particular simulation, we may not be able to identify exactly how all information that came from one participant contributed to and influenced our overall conclusions. We

will not keep information about them that we already have unless they withdraw after we have completed quantitative analyses and submitted them for publication or other output. We will securely delete audio and video recordings once we have completed and documented our analysis of them. Participants will be offered a voucher to the value of £25, even if they do not complete the simulation or subsequently withdraw their consent after the simulation has finished.

Sample size

In our previous simulation study we recruited 18 participants without difficulty and gathered a wealth of information about how processes surrounding AED delivery by drone might be optimised (19). Given this and the daily maximum limit on flights, we have set an *a priori* sample size of 20 participants here.

4.6 Outcomes

Clinical timings

Members of the study team will be present during simulations and will manually record this at the simulated out-of-hospital cardiac arrest site, and confirm the timings following analysis of video recordings:

- Total time from 999-call to AED application (and to first shock).
- Time away from the patient's side.
- Hands off CPR time.

Hands-off CPR time is the time between stopping chest compressions and recommencing chest compressions when attaching and using an AED. 'Time away from patient's side' allows us to quantify the *additional* hands-off CPR time caused by leaving the patient to retrieve the AED that the drone has delivered nearby.

Drone timings

The study team will record these following analysis of 999 call audio and drone-mounted video, supplemented by manual recordings by the study team at the simulated out-of-hospital cardiac arrest site:

- Time from 999-call to 'ready for flight' and 'start of flight' (following Guardian UTM approvals).
- Total flight time.
- Time from arrival on scene to AED safe to retrieve and to AED attached to patient.

Additional information

We will collect participant feedback immediately following the end of the simulation, using the approach from our previous simulation study (19):

- Questionnaire, based on the 'System Usability Scale', developed to evaluate usability of new devices or systems (44) **(appendix 2)**.
- Brief (≤5 minute) conversation. We will ask about age, gender and previous CPR/defibrillator training and real-world experience. We will ask them their thoughts about the simulation, using a style from resuscitation courses evaluating behaviours during mock cardiac arrests (45) **(appendix 3)**.

4.7 Analyses

We will report timings and score from the questionnaire based on the System Usability Scale using median and interquartile range.

The study team will review other data collected during the study itself:

- Audio recordings of 999-calls and voice/text interactions between drone pilot and 999 call-handler.
- Video from the drone itself during flight.
- Video from the scene of participant interaction with drone and AED.

- Feedback from 999-call-handler and drone operator.
- Real-time observations and field-notes about the out-of-hospital cardiac arrest simulations.

We will review participant feedback and on-site observations after each flight session to identify any critical issues before subsequent sessions. We will collate the summated information following the simulation to identify key themes related to: drone activation process, real-time in-flight communications between drone and ambulance service, and interaction between bystander and drone. Our aim is to iteratively improve the integrated drone-dispatch process throughout the study period, and in preparation for future flight operations for real-life out-of-hospital cardiac arrests.

4.8 Ethical and safety considerations

We are conducting simulated cardiac arrest scenarios, but this may be a sensitive topic for some bystanders (for example, if they have real-life experience of finding a collapsed casualty). The Participant Information Sheet includes information about sources of help for any participant who experiences distress. Our PPI representatives have reviewed this information.

During the simulation itself a participant can stop at any time if they experience distress, and a member of the research team will be immediately on hand to stop the simulation or provide support if required.

We will keep a record of any adverse events of which we become aware. If there are any Serious Adverse Events related to the simulation, then we will inform the sponsor within 24 hours of us becoming aware. Should this happen, we will approach the Warwick CTU Quality Assurance team for the appropriate template to submit the report.

Drone flight will take place in a pre-determined flight corridor and be subject to approval from the CAA, following the submission and approval of a detailed Operating Safety Case. The development work allows for 45 days of flying and development work

before the start of this work package – this has been fully costed and resources and time have been appropriately allocated for this.

The Guardian UTM system deconflicts our drone flight with manned and unmanned traffic, by redirecting or grounding other aircrafts or by rejecting or altering the flight plan. SkyBound's automated drone station also has technology to monitor manned and unmanned aircrafts within the airspace. These technologies will automate the BVLOS permission activities required to get airborne and allow the drone to respond as quickly as possible.

Flights will be conducted by an experienced and fully-trained drone pilot employed by SkyBound. We will control access to the simulation study site so that there are no ‘uninvolved’ personnel present at the site where the drone will lower the AED (i.e. only study personnel and the study participant for that particular simulation will be present).

5. DATA MANAGEMENT

5.1 Data collection and management

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

All data in work package 1 will be collected in electronic format: e-mailed signed consent forms, interview recordings, transcripts, researcher fieldnotes, CAQDAS files.

For work package 2 there will be some data collected at the study site initially on paper – signed consent forms, post-event conversation notes, post-event questionnaire. As soon as is reasonably practicable, we will return paper-based documents completed at the study site to the University of Warwick, where they will be saved in electronic format. We will arrange secure transfer of audio and video files recorded during the simulation to an encrypted, password-protected folder on a University of Warwick managed device as soon as is practicable following the simulation, and certainly within 48 hours.

WAST will provide Dr Christopher Smith with a link to a secure server to access audio recordings of the 999 calls. Dr Christopher Smith will access this server at the University of Warwick and transfer the recordings directly to an encrypted password-protected folder (Symantec PGP encryption) on a secure University of Warwick file server.

There will be video recordings from the drone itself during flight (recorded by SkyBound) and at the simulation site (using a commercial service). These, similarly, will be made available to Dr Christopher Smith to access via secure server and to transfer directly to an encrypted password-protected folder (Symantec PGP encryption) on a secure University of Warwick file server. Any original video files showing participants will be deleted as soon as this transfer has been made.

5.2 Data storage

We will keep all data in an encrypted, password-protected folder (Symantec PGP encryption) on a secure University of Warwick file server.

We will store electronic consent forms separately to all other participant documents, in a password-protected subfolder. These will have a numbering system that allows them to be matched to other participant documents in other subfolders, should this be needed. All other participant-related documents will have a number only.

5.3 Data access and quality assurance

Only Dr Christopher Smith, Dr Keith Couper, the senior research fellow and the statistician directly employed to this project will directly access study documents in the encrypted folder. They will only be able to access the study folder after logging in to their University of Warwick accounts via University-managed computers. We will encrypt the study folder using (Symantec PGP Encryption)

If study team members are accessing the folder off-campus, they will first have to have connected to the University's Virtual Private Network.

5.4 Data shared with third parties

We will send an audio recording to an outside commercial transcription service via their secure portal, and we will receive a transcription back from them via the same secure portal. No participant-identifying information will form part of the transcription. We may share fully anonymised data with other members of the study team not primarily based at the University of Warwick for the purposes of quality assurance and review. We may make fully-anonymised datasets available as part of any peer-reviewed publication, according to the requirements of that journal. We will not share any data with any other third party. We will not share individual case data or any personal identifiable data at any time.

5.5 Archiving

We will hold personal identifiable information, including the names, email addresses and/or phone numbers of participants until the end of the study. We will hold personal data on consent forms only until the peer-reviewed scientific articles are published, in case a participant wishes to withdraw their consent. We anticipate that this will be a maximum of 12 months after the end of the study, and we will securely delete this personal data earlier if possible. All personal identifiable data will be securely stored in a password protected folder on the University of Warwick server and accessed only by authorised study personnel. We will retain all other study data on the University of Warwick server for at least ten years from the date of any publication based upon this study, in line with the University's Research Data Management Policy:

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

Only Dr Christopher Smith will have access to this data, if required, after peer-reviewed publication. He will be responsible for its storage and eventual deletion. Encryption programmes provided by the University can securely remove this data and we will seek advice from IT Services about the best way to do this at that time.

6. STUDY ORGANISATION

6.1 Sponsorship arrangements

The University of Warwick will sponsor this project.

6.2 Collaborators

This project is a collaboration between the University Hospitals Coventry and Warwickshire NHS Trust, University of Warwick, Welsh Ambulance Service NHS Trust and SkyBound Rescuer.

6.3 Patient and public involvement

We have two PPI representatives in this project. They will be active members of the research team, participating in group meetings and communications. Their time and efforts are fully costed. They will have an important role in reviewing all aspects of the project where we interact or share information with participants.

In particular, they have reviewed this protocol document and all review patient-facing documents (participant information leaflets, consent documents). They will be present at the cardiac arrest simulations (work package 2) to help with study participants and to provide real-time feedback on our study processes. They will contribute to (and co-author) peer-reviewed publications and all other outputs from the project.

Mark Holt resuscitated his own father in an isolated location but, thankfully, there was an AED at the site. He successfully defibrillated his father (after using an AED for the very first time), who was conscious by the time the ambulance arrived. He survived with no brain injury. Mark works as a Registered Nursing Associate in the NHS. He therefore has seen and participated in unsuccessful resuscitation attempts and knows how devastating this can be. He has a keen interest in making AEDs more equitably available to the population.

Mary O'Sullivan works as a data manager. She has experience of working on commercial and academic research projects, but not in the field of cardiac arrest. She has no experience of performing CPR or using an AED. She partnered successfully with us as a PPI member during our previous simulation work (19) and we are delighted that she has chosen to join us for the next phase of our work. She is an ideal person to provide technical input to project documents whilst retaining a crucial perspective as an untrained bystander: she will ensure that project materials are clear and precise for participants and that we do not overly burden them in both interviews (work package 1) and simulated out-of-hospital cardiac arrests (work package 2).

6.4 Ethical and regulatory approvals

We are seeking NHS Research Ethics Committee (REC) and Health Research Authority (HRA) approvals for this project, and this protocol accompanies an Integrated Research Application System (IRAS) application.

Interview participants (work package 1) are NHS service users, being recruited because they intervened at an out-of-hospital cardiac arrest and likely interacted with an NHS ambulance service on a 999 call and/or at the scene. No flying will take place without permissions from the CAA.

6.5 Indemnity and insurance

NHS indemnity covers NHS staff, medical academic staff with honorary contracts, and those conducting the trial. 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.

Drone-specific issues

SkyBound Rescuer has operational authorisations from the UK CAA to fly unmanned aircraft, with a flying weight of less than 25kg. SkyBound Rescuer will provide drone pilot(s), who will be fully licensed and accredited.

SkyBound Rescuer has Public Liability Insurance (worldwide) for up to £10 million for the duration of this project. An Operational Safety Case detailing all activities in this project has been submitted to the CAA, and no flying will take place without their express approvals.

The drone has two cameras. The first is a 'First Person View' camera that is always forwards facing and so cannot identify people or personal information on the ground. The second is downward facing and allows the drone operator to see that the lowering zone is clear of people and obstructions. The camera resolution is such that individual people and personal information (e.g. number plates, house numbers) are **not** identifiable.

6.6 Study timeline

This project is funded for 18 months. **Appendix 4** shows a GANTT chart detailing the study timeline.

6.7 Administration

The NIHR have issued a research contract to University Hospitals Coventry and Warwickshire (UHCW) NHS Trust, who have arranged collaboration agreements with WAST and with University of Warwick. The University of Warwick have administered the relevant commercial subcontract with SkyBound Rescuer.

6.8 Funding

This project has received funding from Competition 47 of the NIHR RfPB scheme (ref: NIHR204382). We will also receive funding for Excess Treatment Costs from Health and Care Research Wales (HCRW).

6.9 Essential documentation

We will store all study material in an encrypted, password-protected folder on secure servers at the University of Warwick in line with the University of Warwick SOP 11 (Essential Documentation: Creation and Maintenance of Trial Master and Investigator Site Files), and with advice from the Quality Assurance Team at Warwick Clinical Trials Unit.

6.10 Intellectual Property

The project will be using and testing SkyBound Rescuer's background IP, as outlined in this table:

Description of Background IP	Owner	Nature of Restriction	Risk to Research & Outcomes
SkyBound Coordinator platform: software platform that manages the end-to-end process of data-driven public safety drone missions	SkyBound Rescuer	Nil	Nil
SkyBound Requestor platform: software portal to request a drone mission	SkyBound Rescuer	Nil	Nil
SkyBound Remote Viewer Portal: portal for remote viewers to monitor the drone's feed and location and interact with the live feed	SkyBound Rescuer	Nil	Nil
SkyBound Manager platform: software platform that catalogues/manages ground risks, air risks, installation, and maintenance for a drone network	SkyBound Rescuer	Nil	Nil
Training standards & materials for using each SkyBound platform	SkyBound Rescuer	Nil	Nil
5-Phase BVLOS methodology: a step by step process for achieving BVLOS permission from the CAA	SkyBound Rescuer	Nil	Nil
Mission planning algorithm for drone defib deliveries, inc. flight parameters & configuration details produced by SBR research	SkyBound Rescuer	Nil	Nil
Design spec for an automated drone defib delivery system	SkyBound Rescuer	Nil	Nil
CONOPs and Operations Manuals for public safety drone applications	SkyBound Rescuer	Nil	Nil

Foreground IP is owned by the Contractor except for: the Operational Safety Case for Beyond Visual Line of Sight which will be owned by SkyBound Innovations Ltd.

Research Data is owned or controlled by the Contractor. The contractor will put into place data sharing arrangements as necessary so that relevant Foreground IP arising as a result of this project can be used by collaborators for the purposes of dissemination, education and as a basis for future related research.

7. DISSEMINATION AND IMPACT

Our audiences are patients and the public, clinicians, and policy makers (including NHS and UK ambulance service leaders). We will involve all study team members, including our PPI members, to:

- produce written summaries and infographics for both lay and professional audiences
- Disseminate our findings via open-access peer-reviewed publications (one for the findings of each work package), podcasts, blogs, national and international conference presentations and social media
- Use public relations teams from the University of Warwick, WAST, regulatory agencies and SkyBound to assist in dissemination of our findings according to their current procedures
- Engage policy makers through our existing relationships with key organisations (e.g. International Liaison Committee on Resuscitation, European Resuscitation Council, Resuscitation Council UK, British Heart Foundation).

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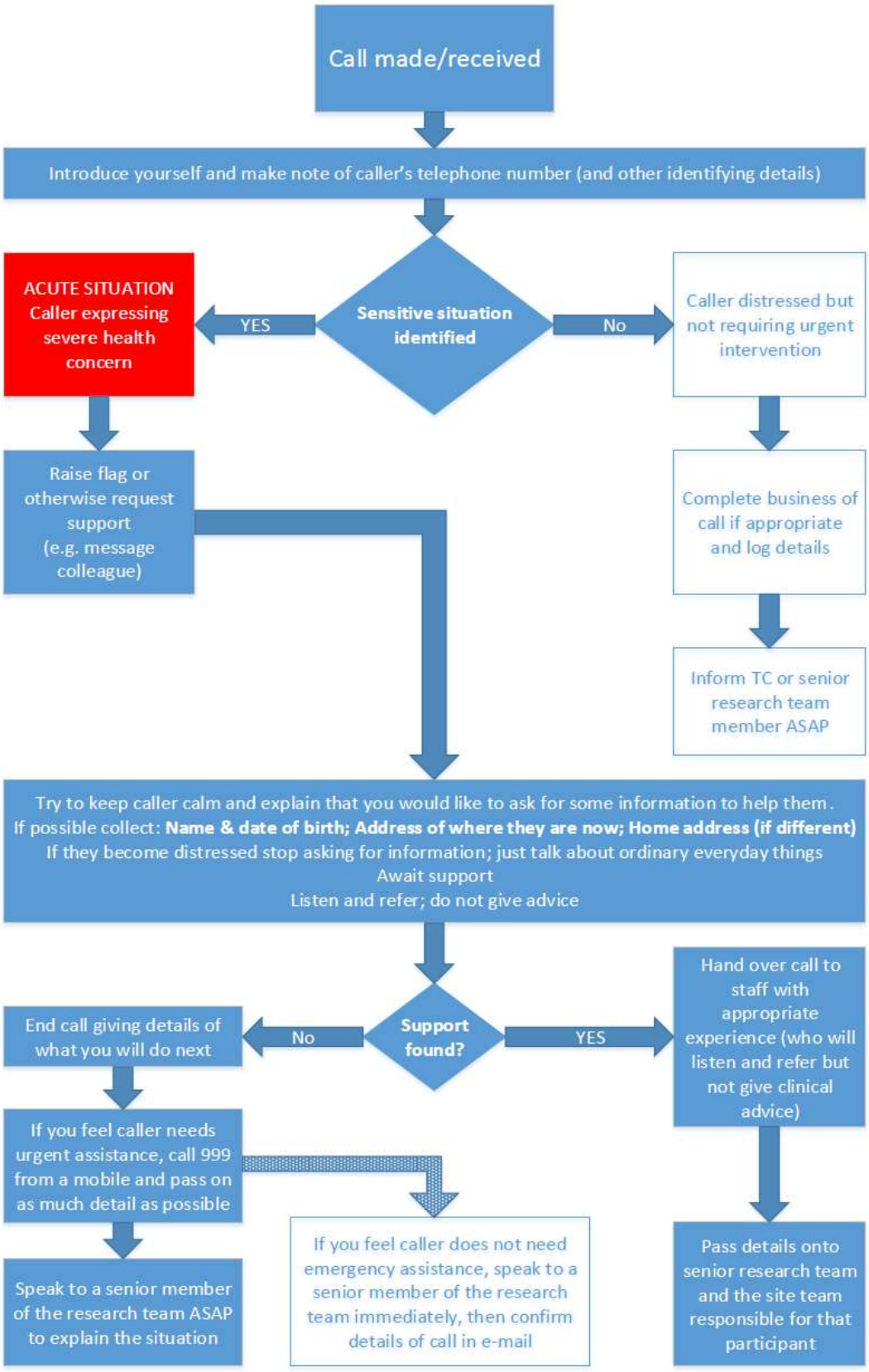
9. APPENDICES

Appendix 1 – Sensitive Call Action flowchart


Call made/received
Introduce yourself and make note of caller's telephone number (and other identifying details)
Sensitive situation identified
YES
ACUTE SITUATION Caller expressing severe health concern
No
Caller distressed but not requiring urgent intervention
Raise flag or otherwise request support (e.g. message colleague)
Complete business of call if appropriate and log details
Inform TC or senior research team member ASAP
Try to keep caller calm and explain that you would like to ask for some information to help them.
If possible collect: Name & date of birth; Address of where they are now; Home address (if different)
If they become distressed stop asking for information; just talk about ordinary everyday things
Await support
Listen and refer; do not give advice
Support found?
No
End call giving details of what you will do next
YES
Hand over call to staff with appropriate experience (who will listen and refer but not give clinical advice)
If you feel caller needs urgent assistance, call 999 from a mobile and pass on as much detail as possible
Speak to a senior member of the research team ASAP to explain the situation
If you feel caller does not need emergency assistance, speak to a senior member of the research team immediately, then confirm details of call in e-mail
Pass details onto senior research team and the site team responsible for that participant

Appendix 2 – Post-event questionnaire (work package 2)

PARTICIPANT NUMBER_____

You have just retrieved a defibrillator delivered by a drone. Regarding this (please tick the relevant box):

1. I found it unnecessarily complex.

Strongly disagree				Strongly agree
1	2	3	4	5

2. I thought it was easy to do.

Strongly disagree				Strongly agree
1	2	3	4	5

3. I felt very confident doing this.

Strongly disagree				Strongly agree
1	2	3	4	5

4. I would imagine that most people would be able to do this.

Strongly disagree				Strongly agree
1	2	3	4	5

Appendix 3 – Post-event conversation questions (work package 2)

PARTICIPANT NUMBER_____

Age (in years) _____

Gender (M, F, identifies another way – specify) _____

Training in last five years (Yes/No)

CPR only _____

AED only _____

Both _____

Real-world experience in last five years (Yes/No, number of occasions if yes)

CPR only _____

AED only _____

Both _____

Opening question:

- "What are your thoughts on how that went?"

Probing questions (if needed):

- “Did you encounter any difficulties in retrieving the defibrillator?”

- “Is there something that would make it easier for you to retrieve the defibrillator”

Closing question:

- “Is there something else you would like to add to your answers so far?”

Appendix 4 – GANTT chart

	2023								2024									
	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
Work Package 1																		
Protocol development and sponsorship																		
Ethics submission																		
Interview preparation / recruitment																		
Interviews																		
Transcription / data input																		
Data analysis																		
Data synthesis																		
Reporting and publication																		
Work Package 2																		
Protocol development and sponsorship																		
Ethics submission																		
Technical / development work																		
Recruitment																		
Flight days (x4)																		
Data capture and analysis																		
Reporting and publication																		