

## What are ambulance crews' experiences of using a mechanical chest compression device for out of hospital resuscitation?

<b>RESEARCH REFERENCE NUMBERS</b>	
<b>Sponsor Reference:</b>	TBC
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<b>Host Trust Reference</b>	TBC
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### **KEY STUDY CONTACTS**

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### **LIST OF ABBREVIATIONS**

CPR	Cardiopulmonary Resuscitation
CCARU	Critical Care and Cardiac Arrest Response Unit
GNAAS	Great North Air Ambulance Service
HEMS	Helicopter Emergency Medical Service
HRA	Health Research Authority
MCCD	Mechanical Chest Compression Device
MERIT	Medical Emergency Response Incident Team
NEAS	North East Ambulance Service NHS Foundation Trust
NHS	National Health Service
PIS	Participant Information Sheet
RCT	Randomised Controlled Trial
R&D	Research and Development
ROSC	Return of Spontaneous Circulation

### **STUDY SUMMARY**

Study Title	What are ambulance crews' experiences of using a mechanical chest compression device for out of hospital resuscitation?
Internal reference number (or short title)	Qualitative - Mechanical Chest Compression Devices
Study Design	Qualitative paradigm with a constructivist, deductive framework

Study Participants	Operational NHS ambulance crew staff
Planned Sample Size	12-32 for focus groups (4 focus groups x 3-8 participants in each)
Follow up duration	None
Planned Study Period	September 2019 to June 2020

## **FUNDING**

<b>FUNDER(S)</b>	<b>FINANCIAL SUPPORT GIVEN</b>
Stryker - Jolife AB/Stryker Lund, Sweden, Scheelevagen 17, 223 70 Lund	£1500

The funder manufactures one of the types of mechanical chest compression devices and has had no influence in the design of the study. The funding will cover costs of a transcription service, compensating participants for their time taken to participate and dissemination of the results. It has been made explicit to the funder that outputs from this study will refer to other types of mechanical chest compression devices, not just theirs; the funder has continued to still provide support. The protocol has also evolved since the initial funding contract was written. Stryker have been advised of these changes and advised there is no requirement for a revised funding contract to be supplied. The agreement with the funder includes that they have copies of the protocol and any amendments, the ethical and other regulatory approvals, a quarterly update, access to and a right to use the anonymised deliverables (excluding raw data) generated by this study for commercial and non-commercial purposes.

## **STUDY TIMELINE AND MILESTONES**

September 2019	Commence project
September-November 2019	Submit and gain HRA and ambulance service R&D approvals
November-December 2019	Submit and gain Northumbria University Ethics approval
December 2019	Advertise and recruit to focus groups
January-February 2020	Conduct focus groups

February-March 2020	Transcribe focus group discussion
March-April 2020	Analyse focus group discussion
April-June 2020	Write up study

## **SCIENTIFIC BACKGROUND AND RATIONALE**

Around 30,000 people in the United Kingdom receive out of hospital resuscitation for cardiac arrest annually (Hawkes et al., 2017) with only around one in ten surviving to hospital discharge (NHS England, 2018). CPR, comprising chest compressions and ventilations, is one of the vital treatments for this condition (British Heart Foundation, 2014) with higher quality CPR (i.e. that which meets the current guidelines recommended by the Resuscitation Council (UK), 2015) being linked to higher incidence of survival (Stiell et al., 2012). Physiologically, chest compressions increase coronary perfusion pressure, also making it more likely that defibrillation will revert a shockable rhythm and culminate in a ROSC (Achleitner et al., 2001; Cobb et al., 1999; Paradis et al., 1990). The maintenance of high quality CPR is particularly difficult in the dynamic pre hospital environment with difficulties well documented (Gates et al., 2015; Perkins et al., 2015) and variations in CPR quality may have a role in poor outcomes (Abella et al., 2005). Although chest compressions have traditionally been provided by hand (manually), they only provide around 30% of cardiac output (Vincent, 2003). Recently there has been the introduction of mechanical chest compression devices (MCCD) (Wik, 2000).

The efficacies of MCCD continue to be an area of development and interest with manikin studies indicating that the use of such devices improves consistency and quality of compressions when compared to manual (Sunde, Wik, & Steen, 1997). Several human RCTs have also been conducted, with different end points; Hallstrom et al. (2006), had a primary outcome of survival to 4 hours post ROSC but was terminated early because of a trend towards lower survival to discharge and worse neurological outcomes in the group who received mechanical compressions; Rubertsson et al. (2014) studied survival to 4 hours post ROSC as their primary outcome; Wik et al. (2014) studied survival to discharge and Perkins et al. (2015) examined survival to 30 days post ROSC. Another, a pilot study, primarily sought figures for a power calculation (Smekal et al., 2011). There were differences in the designs between these above RCTs. However all found no difference in survival outcomes between those patients treated with manual or mechanical compressions.

Despite the anticipatory times around the conduction of the above RCTs, these underwhelming results have played a part in the debate about MCCD use stalling. Whilst these patient centred outcomes are of utmost importance to the people suffering a cardiac arrest there is another neglected, but important element and that is of the qualitative experiences of ambulance crews using

such devices. From the researcher's experience, and discussion with other colleagues, the use of a MCCD at an out of hospital resuscitation can be of great benefit. There are a lot of tasks, both practical and cognitive that need to be coordinated. This is alongside monitoring, and giving feedback if required, on the all important quality of CPR that is being provided. The use of a MCCD provides consistent, high quality compressions which meet current guidelines (Poole et al., 2018). It can provide scope to multitask and allow smoother coordination of a resuscitation attempt, potentially indirectly contributing to it. Also, there can sometimes be just a single Paramedic at an out of hospital resuscitation attempt and whilst they are the overall clinical lead at such an incident and assume the role of team leader, they are also the only person who can provide the more advanced skills of cannulation, drug administration and advanced airway management, all whilst gathering information and making clinical decisions. Therefore the use of a device which offloads one of the practical tasks, but one which is of the utmost importance to the resuscitation attempt, can be invaluable.

In addition, whilst the latest Cochrane review on MCCD (Wang and Brooks, 2018), still does not endorse MCCDs for routine use, it includes a subtle change of direction in the wording. It states that MCCD, whilst not superior to manual compressions, is a reasonable alternative to high quality manual compressions where these high quality manual compressions are not possible or dangerous, where the previous review concluded that the evidence is insufficient and that widespread use of mechanical compression devices was not supported (Brooks et al., 2014). This suggests the MCCD debate has not necessarily reached its final conclusion and as MCCD still continue to be used, including by Specialist responses within the local ambulance service, it is a reasonable topic to study.

A BOOLEAN search of the CINAHL database (selected as a starting point for qualitative literature) in both February and October 2019 using the terms mechanical compressions, AND qualitative AND out of hospital yielded no results, suggesting there is a need for this work to be done.

It is also important to establish clinicians' viewpoints of interventions, particularly new ones. A second BOOLEAN search of the CINAHL database in October 2019 using the terms of ambulance crew, AND viewpoints OR opinions AND interventions yielded no results. Changing the term ambulance crew to paramedic yielded 14 results, but none of the results were relevant. As pre hospital research is also a fledgling field it is imperative to include and empower pre hospital clinicians and to highlight research to encourage future participation.

This study will also explore whether the use of MCCD at an out of hospital resuscitation has any effect on, or can facilitate the role of a resuscitation team leader and it will explore whether providing mechanical versus manual chest compressions has an effect on how ambulance crews feel physically and emotionally after an out of hospital resuscitation.

### **Assessment and management of risk**

This overall risk of conducting this study is low. Participants will read an information sheet before participating in the study and the content of the questions and focus of conversation will be made

explicit, therefore meaning there will be nothing unexpected that the participants are asked. It will be made clear to participants, before participating that the focus groups will be audio recorded.

Participants will be asked about their experiences of using MCCD and because of this subject topic, participants will therefore be talking about instances when they have attended out of hospital resuscitations, some of which will have concluded with resuscitation being ceased. This could potentially be an emotive subject. The researchers will be vigilant for anyone becoming upset or distressed during this study. Although this study is being conducted online therefore making the detection of a participant's distress more difficult; the researcher will be vigilant to anyone showing any non verbal or verbal signs of distress, such as tone of voice, emotionally laden words, external signs of distress such as crying, or a change in their style of participation in the discussion. All participants will be reassured they can leave the conversation, the focus group and/or the study at any time. Should any participant become upset or distressed during the focus group they will be given time either during, if they feel comfortable to, or separate to the focus group to talk through their feelings with a study team member who would arrange onward support if necessary. This support would be from a NEAS Clinical Care Manager and/or NEAS Occupational Health Department.

Participants will be offered a £20 voucher to compensate for their time, and show appreciation of their participation.

## **RESEARCH QUESTION, AIMS AND OUTCOMES**

### **Research question**

What are ambulance crews' experiences of using a mechanical chest compression device for out of hospital resuscitation?

### **Primary aim**

The primary aim of the project will be to collect and report ambulance crews' experiences of using MCCD for out of hospital resuscitation attempts.

### **Secondary aims**

To explore how ambulance crews feel about being asked their opinions on new pieces of equipment

To explore whether the use of MCCD has any effect on, or facilitates the team leader role at an out of hospital resuscitation attempt

To explore whether providing mechanical versus manual chest compressions has an effect on how ambulance crews feel physically and emotionally after an out of hospital resuscitation attempt.

### **Expected outcomes**

The expected outcomes of this work will be to add to the scant qualitative evidence base on ambulance crews' experiences of MCCD for out of hospital resuscitation and explore how ambulance

crews feel about being asked about new pieces of equipment. It will also explore the team leader role at an out of hospital resuscitation and whether the use of MCCD has any effect on, or facilitates this team leader role. Lastly this study will explore whether there is a difference in how ambulance crews feel physically and emotionally after an out of hospital resuscitation when manual or mechanical chest compressions have been provided.

By being involved it will hopefully highlight how important, and required, it is for ambulance crews to be involved in pre hospital research.

There may also ultimately be benefits for patient by exploring whether MCCD can play a part in out of hospital resuscitation.

## **STUDY METHODOLOGY**

The methodology will be a qualitative paradigm with a constructivist, deductive framework.

Participants will be invited to take part, alongside other colleagues, in an online focus group, around the subject of their experiences of using mechanical chest compression devices during out of hospital resuscitation.

The initial plan was to conduct these focus groups face to face. However, since the initial protocol was written the UK government's advice about social distancing in response to COVID-19 has presented. Therefore there has been an adaptation to move to online focus groups. This change is supported by the Sponsor.

A focus group is a group discussion with others (Kitzinger, 1995). The intention is to conduct 4 focus groups, with 3-8 participants in each. The focus groups will have a semi structured approach, to allow freedom for experiences to be shared, whilst maintaining a degree of control over the format and direction of conversation. The data collection tool of focus groups was chosen as ambulance crews are familiar with discussing and debriefing cases in a collective group discussion.

A topic guide for the focus groups will be designed, based on the literature, and core concepts identified by an expert group of users of MCCD and those familiar with focus groups. It is important to note that there may be iterative development and evolution of the topic guide for each focus group, depending on outputs from the previous one(s). Therefore the topic guide developed so far is an initial version.

Should there be hesitation from the participants about embracing the discussion of the focus group there will be a standby activity of ranking statements about the use of MCCD, so as to encourage participation and discussion.

The focus groups will be audio recorded and participants will be aware of this when volunteering to participate; the poster advertising the study, the PIS and consent form all make it explicit that by consenting to participate, the participants are agreeing to be audio recorded.

The reasons for the recording of the focus group are multiple; to expedite the transcription of the focus groups (this is converting the spoken word from the focus groups into a written format) for it then to be coded in a timely manner, to allow the researcher to get fully immersed in the focus group, rather than being distracted by recording the conversation and to also collect rich both verbal and nonverbal communication. The transcription company selected is NJC Secretarial ([www.njcsecretarial.com](http://www.njcsecretarial.com)) and use of a third party for the transcription was chosen to expedite the focus group transcription and allow timely coding of the data.

Consideration was giving to allowing participants to not consent to being recorded, yet still participate. However there was concern this would lead to lack of flow of the transcription and coding, as this/these participants' contribution would have to be recorded manually. As restrictive as this appears and may constitute a threat to inclusivity of the study, a decision was made to make it explicit to the participants that they are being recorded, in order to protect the quality of the data, assure informed consent and equity of experience.

For the focus group consent form, participants will also agree to their discussion points being included in the final MSc submission and subsequent publications. All submissions and publications will ensure anonymity of the participants.

## **STUDY SETTING**

The focus groups will be conducted online. This is a change to the original plan of face to face focus groups and was necessary given restrictions imposed by the UK government in response to the COVID-19 pandemic.

## **PARTICIPANTS AND ELIGIBILITY CRITERIA**

Inclusion criteria in brief

- Aged 18 and over
- NEAS employee
- Employed as operational ambulance crew member, irrespective of title



- Have experienced an out of hospital resuscitation where MCCD was used, irrespective of type of device or their level of involvement

To expand on the above, participants will be any operational ambulance crew employees of NEAS who have had any experience of being involved in an out of hospital resuscitation where a mechanical chest compression device was used. Therefore purposive sampling will be used to recruit participants who meet this criteria.

There have historically been two types of mechanical chest compression device used locally; participants will be invited to participate regardless of the type of device they had experience of. Differences in experiences of the two types of MCCD will be an area explored during the focus groups.

Employees of NEAS will have had the opportunity of experiencing the use of the devices previously for a number of reasons; this Trust was one of those contributing to the PaRAMeDIC trial (Perkins et al., 2015) and these devices are still used by the Trust's CCARU response, Specialist Paramedic – Emergency Care and the local HEMS and MERIT service (as provided by GNAAS).

All roles of ambulance crew will be eligible to participate. It is a deliberate decision to not limit the inclusion of the study to Paramedics for a number of reasons; all operational members of an ambulance crew are included in providing care at an out of hospital resuscitation, as only Paramedics can provide the more advanced skills of airway management, circulatory access and drug therapy, the task of providing CPR and chest compressions often fall to the none-paramedic and thirdly, it is imperative that ambulance crews are involved in providing feedback and insight into how new interventions work, not least to empower them and promote the development of pre-hospital research.

Participants will be included whether they had active or passive involvement with the device. Active involvement is where the participants was responsible for the decision to, and physical deployment of, the device (this would be in the context of being one of the Paramedics who recruited patients to the PaRAMeDIC trial (Perkins et al., 2015), current CCARU staff members and Specialist Paramedics – Emergency Care). Passive involvement is defined as any Paramedic, Advanced Technician or Clinical Care Assistant who was involved in an out of hospital resuscitation where a mechanical chest compression device was used, yet they weren't involved in being responsible for its use.

It is acknowledged that some participants will not have had active involvement of MCCD for a few years (as recruitment to the PaRAMeDIC trial ended in 2013) but, whilst accepting this limitation, it is deemed important to still include these participants, to gain a breadth of experiences. Generalist ambulance crews, as well as those responding as part of the specialist CCARU and Specialist Paramedic-Emergency Care response will be invited to participate, so as to again uncover a breadth of

experiences, whilst accepting the limitation that these Specialists will have had more recent use of MCCDs.

Those who meet the inclusion criteria will be invited to attend a mixed composition focus group formed from the above groups.

#### Exclusion criteria

- Not a NEAS employee
- No experience of using MCCD at an out of hospital resuscitation
- Unwilling to provide consent to participate
- Unwilling to provide consent to be audio recorded

## **STUDY PROCEDURES**

### Recruitment

The focus groups will be advertised by posters displayed on ambulance stations, by email via the weekly 'Summary' trust email, through cascading to relevant teams from each Clinical Care Manager (who are responsible for a cluster of stations and staff), Trust social media accounts and by word of mouth by the researcher.

Although the poster will inevitably be seen by those who did not have experience of using MCCD, the poster will include the inclusion criteria of needing to have had previous experience of MCCD to take part.

If interested, potential participants will be directed to an email address to contact for more information, where they will then be provided with the PIS. Participants will be encouraged to read the PIS, ask any questions before then deciding whether they want to participate. Participants will not be coerced to take part in this study; they will be encouraged to make the decision to take part only if they want to. Participants will be emailed a copy of the consent form prior to the focus groups date. This is explained further below.

Convenience sampling based on availability for the focus group dates will then be used to filter numbers, if required, and then by order of volunteering. Also, to ensure a breadth of experience across both generalist and specialist ambulance crew staff, if there are an excess number of volunteers in comparison to the anticipated maximum 8 participants per focus group, numbers will be filtered to ensure equal numbers of generalist and specialist roles. Thought has been given to this, as to whether to separate generalist and specialist roles but a decision made to combine them, as the construction of the ambulance service and its response to out of hospital resuscitations are that generalist and specialist responses often work, and are debriefed, together; already breaking down the barriers of jointly discussing cases.

The focus group discussion will take place online and participants will only be required to participate once. The focus group will last 1-2 hours and participants will have another opportunity to ask questions before then being invited to confirm their consent verbally, prior to the commencement of the focus group discussion.

After the focus group discussion ends, participants will be given another opportunity to ask any questions and be emailed a debrief sheet explaining the purpose of the work, where they will be able to find out the results and how they can withdraw from the study, should they wish to.

All participants of the focus group will be offered a £20 Amazon gift voucher to compensate for their time and participation. These vouchers will be paid for by funding from Stryker.

### Consent

Prior to the focus group event the participants will be emailed a copy of the consent form and actively encouraged to ask any questions either by email or phone. Once the participant feels these questions have been answered, participants will be asked to sign two copies of the consent form, retain one, and return the other to the researcher.

Before commencing the discussion of the actual focus group, the researcher will again review that participants understand the purpose of the study and are making an informed decision to take part. Participants will then be asked to verbally re-affirm their consent to participate.

It is recognised this is a pragmatic approach to gaining consent, given the current climate of social distancing, in response to the COVID-19 pandemic.

The researcher taking consent from the participants has recently completed a GCP refresher course. This consent form will include agreeing to be audio recorded.

### Withdrawal criteria

Participants are allowed to withdraw from the study at any time and do not have to provide justification for doing so, as detailed in the Participant Information Sheet and Consent Form. The debrief sheet will give details as to who to contact to withdraw from the study. Should any participant(s) wish to withdraw, any data collected to the point of withdrawal will be retained, as made explicit in the Participant Information Sheet and Consent Form. Participants will be advised to contact the researcher at the earliest opportunity should they wish to withdraw. Participants also have the right to withdraw their consent to the sponsor processing their personal data, in line with guidance published in Northumbria University's Research Ethics and Governance handbook. If consent is withdrawn, processing must stop within 15 days of the withdrawal and confirmation that this is the case should be sent to the participant.

## **DATA COLLECTION**

The data collection tool will be online focus groups. The intention is to conduct 4 focus groups, with 3-8 participants in each. This sample size was decided on taking guidance from academics with expert knowledge in focus groups on the optimum target sample size, as well as authors on the subject (Silverman, 2017)

Demographic data will be collected about the participants; namely their role, length of time working in an operational ambulance crew role and whether their ambulance base is in an urban or rural location. Information will also be collected about the extent of their involvement with MCCD, i.e. whether they were responsible for the deployment of the device or observed it in a passive capacity (or both), which version of MCCD they had experience of, how many times they experienced it and when this experience last was. This information collected is deemed necessary to inform and add context to the analysis of the focus groups content and is the minimum personally-identifiable data. This demographic information will be collected once participants have given their written consent to participate and the details to be collected will be made explicit in the PIS.

A topic guide will be developed for the focus groups, as described earlier.

As mentioned, the focus groups will be audio recorded.

The focus groups will be run by at least two people; one experienced in facilitating a focus group, with the other(s) observing the discussion and making field notes, which will complement the later transcription. There are members within the study team who are experienced at focus group facilitation. There will be field notes recorded by the study team, of non verbal communication, intonation, interaction within the group, time spent on each issue and group dynamics. This can add much depth and quality to the spoken word.

Given the change to online focus groups, these will be conducted using Microsoft Teams, as advised by the host Trust IT department. Participants will be offered support to access and use this programme and is anticipated that participants will then participate in the focus groups by accessing Microsoft Teams from their own devices. Microsoft Teams will be used to facilitate the focus groups only, the audio will be recorded using a separate dictaphone.

## **DATA ANALYSIS**

For the data analysis, the conversations of the focus groups will be listened to by the researcher and transcribed by a third party. The transcripts will be viewed and coded by the researcher, supported by other members of the study team. The reason for the third party transcription service has been explained.

The content of each focus group will be coded and then each participant's individual responses will be coded, first using open coding, then focussed coding, to identify emergent themes before concluding with the categories that have been identified. The method of data analysis will be constant comparison.

Particular attention will be paid to the order of discussion topics that arise, the length of time spent on each subject, whether there is congruence or differences expressed by participants of the group on each subject that arises, non verbal communication and how emotionally laden the words are and whether there are any topics not discussed that had been anticipated. Matrices will be used to record levels of consensus and non verbal communication. There will also be a record of the seating plan of where participants sat.

Trustworthiness and confirmability of the results will be ensured by also having the academic supervisor code a proportion of the data in order to compare and contrast the emergent themes with the researcher's.

## **DATA MANAGEMENT**

### **Data handling and record keeping**

Each participant will be allocated a non-identifying participant ID once informed consent has been obtained. This will be used on all study source documents. This non-identifying code is the only way participants will be referred to in any of the study reports.

Demographic data about the participants will be collected and accessed by researchers and academic supervisor. The recordings of the focus groups will be listened to by the researcher and the third party transcription service. The recordings of the focus groups will be sent to a secure folder on an encrypted platform of the third party transcription service. This folder will be password protected, with password only known by the representative of the third party, and researcher. This transcription service has been contacted, scrutinised and approved in terms of their security and GDPR compliance, by the academic supervisor for this study. A Confidentiality agreement will be in place between the Sponsor and third party transcription service.

Transcripts of the focus groups will be viewed and coded by the researcher, supported by other members of the study team. The anonymised data will be coded on host Trust premises, University premises or the researchers' private premises.

The company providing funding support will have access to, and right to use and distribute, any anonymised deliverables (but not raw data) from this study for any commercial and non-commercial purposes, as made explicit in their written contract to support this research work.

The paper based records including the demographic information will be labelled with each participant's pseudonym (a non-identifying letter) only. The consent form is the only document that will include the participant's name and this will be stored separately to other data.

All recordings of the focus groups, accompanying transcriptions and the paper based demographic information will be securely stored on the host Trust's premises in a locked cabinet, within a secure room. Electronic copies of the recordings of the focus groups and digital versions of the transcriptions will be stored on the sponsor's secure, password protected, computer server.

A master list of the participants will be created, and viewed by the researcher only should anyone wish to withdraw. This will be stored in a secure location on the host Trust's premises only accessible to the researcher.

As the coding of the data will be done in various locations, supported by other members of the study team, there will be necessary transport of the data. The anonymised data from the study will be transported to the secure location on the host Trust's premises as soon as practicably possible.

When not in use, i.e. not being analysed, the anonymised data will again be securely stored. Once the coding has been completed, any duplicate copies made of the anonymised transcriptions will be collected back by the researcher and stored securely on the host Trust's premises or computer system. Guidance set out in the sponsor's Research Ethics and Governance Handbook will be followed with regard to security of mobile devices for audio recording.

Research data (any data collected or created by this study) will be retained for 7 years after completion of the academic programme, in accordance with the sponsor's Research Records Retention Schedule. Research data will then be disposed of if necessary, as set out in the University's Research Ethics and Governance Handbook. The data collected in this study will be managed in line with GDPR guidelines.

In the PIS, participants will be informed about the processing of their personal data, where and how long it will be stored for and that in the final submissions and reports they will only be referred to by a pseudonym.

#### Archiving

As set out in the sponsor's Research Ethics and Governance Handbook, appropriate 'whole life' records of the study will be retained. This includes the originals of the recordings, to allow later scrutiny of the transcription and coding, should that be necessary. Data will be retained, then disposed of, as set out in the sponsor's guidance.

## **ETHICAL AND REGULATORY CONSIDERATIONS**

Taking advice from the NHS REC decision tool (<http://www.hra-decisiontools.org.uk/ethics/>) this study does not require NHS REC approval. It will however require Northumbria University ethical

approval. It will require HRA approval as this is NHS research, along with the local ambulance service R&D approval. All approvals will be sought before the start of the study.

Substantial amendments that require review by University Ethics will not be implemented until they grant a favourable opinion, and all correspondence with the Ethics committee will be retained. If the study is ended prematurely, the Researcher will notify the Ethics committee, including the reasons for the premature termination.

Any breach of protocol will be reported directly to the R&D department of the host Trust, as well as the Ethics Committee of the sponsor.

Participants of the focus groups will each receive a £20 gift voucher to compensate for their time and show appreciation of their participation.

#### Data protection and participant confidentiality

The researcher will comply with the requirements of the General Data Protection Regulations (GDPR) 2018 with regards to the collection, storage, processing and disclosure of personal information. In line with GDPR (2018) the information collected is that deemed necessary to inform and add content to the focus group discussion.

Once transcribed, the audio recordings will still be retained to maintain source data should later scrutiny arise. The recordings will be stored securely as described above,

Participants will not be identifiable from the data produced by the study; they will be referred to by, if anything, a non-identifying code. Should a participant accidentally identify themselves, others, any organisation or patient, this confidential information will be removed from the transcription.

#### Financial and other competing interests for the study team and funder

The researcher has no financial or other competing interests that might influence the study design, conduct or reporting.

#### Indemnity

The study sponsor will assume all liability for the study activities.

#### Adverse events

Adverse events will be reported in line with the sponsor's Research Ethics and Governance Handbook

### **DISSEMINATION POLICY**

The rationale for, design and results of the study will be submitted as the dissertation for an academic MSc in Practice Development (Empirical Project) award at the University of Northumbria at Newcastle. The study will also be submitted for publication in relevant peer-reviewed journals and

presented at relevant conferences. A summary report will be presented to the participants, NEAS and Stryker. Host Trust social media may be used to disseminate any outputs from the study.

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