PROTOCOL

Evaluation of the Recommended Summary Plan for Emergency Care and Treatment

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NHS University Hospitals Birmingham NHS Foundation Trust

WARWICK CLINICAL TRIALS UNIT

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TABLE OF CONTENTS PAGE

LIST OF FIGURES PAGE

LIST OF ABBREVIATIONS/GLOSSARY

Abbreviation	Explanation
CAG	Confidentiality Advisory Group
CI	Chief Investigator
CPR	Cardiopulmonary resuscitation
CRF	Case Report Form
CTU	Clinical Trials Unit
DMC	Data Monitoring Committee
DNACPR	Do not attempt cardiopulmonary resuscitation
ECTP	Emergency Care (and) Treatment Plan
EQUATOR	Enhancing the QUAlity and Transparency Of health Research network
GCP	Good Clinical Practice
HRA	Health Research Authority
HS &DR	NIHR Health Service and Delivery Research Programme
ICF	Informed Consent Form
ICNARC	Intensive Care National Audit and Research Centre
IRAS	Integrated Research Application System
ITS	Interrupted Times Series
MRC	Medical Research Council
NCAA	National Cardiac Arrest Audit
NCEPOD	National Confidential Enquiry into Patient Outcome and Death
NIHR HSDR	National Institute for Health Research, Health Services and Delivery Research programme
PI	Principal Investigator
PPI	Patient & Public Involvement
PoLST	Physician Orders for Life Sustaining Treatments
REC	Research Ethics Committee
ReSPECT	Recommended Summary Plan for Emergency Care and Treatment
R&D	Research and Development
RCN	Royal College of Nursing

RC(UK)	Resuscitation Council (UK)
ROSC	Return of Spontaneous Circulation
SOP	Standard Operating Procedure
SSC	Study Steering Committee
UFTO	Universal Form of Treatment Options
UP	Unwell Patients
WCTU	Warwick Clinical Trials Unit

1. BACKGROUND

Cardiopulmonary resuscitation (CPR) is a highly invasive medical treatment associated with potentially serious complications (multiple rib fractures, sternal fractures, damage to internal organs).[1] When CPR is provided to someone with minimal comorbidities and a reversible cause of their cardiac arrest it can be lifesaving.[2] Conversely if CPR is applied as someone approaches the end of their natural life it has little chance of success and deprives them of a dignified death. Do not attempt cardiopulmonary resuscitation (DNACPR) decisions were introduced in the 1970's to provide a mechanism through which CPR may be withheld in the event of cardiac arrest which occurs as part of the process of natural death.[3] Current guidelines, published by the Resuscitation Council (UK)[4] and General Medical Council[5] explain that a DNACPR decision may be made:

(i) At the request of a patient
(ii) If CPR has no realistic prospect of success
(iii) Where the burdens of treatment outweigh the benefit.

Although the concept of DNACPR is relatively straight forward, independent reviews (National Confidential Enquiry into Patient Outcome and Death;[6] Premature Deaths of People with Learning Disability;[7] Parliamentary Health Select Committee Report[8] and a NIHR HSDR Scoping review[9] have identified substantial problems with the process of DNACPR decision-making and implementation.

Key findings from these reviews identified:

- A reluctance or fear in both patients and doctors to discuss CPR, leading to failures to involve patients in decision-making [10, 9, 11, 12]
- Poor communication with patients, and those important to them [9, 13-15]
- Variable levels of understanding of the ethical considerations in clinical decision-making [9]
- CPR decisions being made in an ad hoc manner, with variation across different care settings, within similar care settings (e.g. hospitals, care homes, general practices) and among individual clinician [10, 16]
- Unjustified DNACPR decisions being made for people with physical and mental disabilities [7, 17]
- Variation in the method of recording CPR decisions, and inconsistency in which methods of recording are accepted in different geographic regions and by different organisations within those regions, making good communication problematic [18, 19]
- People being subjected to CPR attempts that will be of no benefit or are contrary to their wishes [6, 9, 14]
- Conflation of the term 'DNACPR' which is meant only to apply to resuscitation, to limitations on other elements of care and treatment [9, 20, 21]
- Evidence that those with DNACPR decisions receive poorer care than those with similar

conditions and backgrounds without such decisions in place [10, 22, 23]

Emergency care treatment plans

The term Emergency Care Treatment Plans (ECTPs) is used as a summary term to describe the process by which a resuscitation decision is considered with the patient alongside overall treatment goals and other treatment choices. It encompasses the broad principles of approaches variously described as limitation of treatment, limitation of care, treatment escalation plans, Universal Form of Treatment Options, Personal Emergency Plans.

Recent UK surveys indicate[18, 19, 25] that between 12-20% of acute hospitals and community services have introduced some style of ECTP that has either replaced or sits alongside the DNACPR form.

Evaluations of emergency care treatment plan implementation

Originally developed in Oregon over 10 years ago, the Physician Orders for Life Sustaining Treatments (POLST) has now been rolled out to 26 states in the USA. POLST breaks end-of-life care interventions into categories of care (CPR, medical interventions, artificial hydration and nutrition) and presents patients with corresponding clear choices: comfort measures only, supportive non-invasive treatments; full treatment. Qualitative and quantitative evaluations have shown the system improved communication, [25, 26] and implementation of end of life preferences and patient satisfaction. [27-31]

The Universal Form of Treatment Options (UFTO) was co-designed by co-investigators Fritz and Fuld with a multi-professional and patient user group [32] and has been implemented in Cambridge University Teaching Hospital and the West Suffolk Hospital in the UK, as well as several international sites. The resulting system incorporates other treatment decisions alongside the resuscitation decision. In a single centre, mixed-methods, before-and-after study which included contemporaneous controls it was found that the use of the UFTO system was associated with a 23.3%, (95%, confidence interval 7.8-36.1) reduction in harms (measured by the global trigger tool). [22] A concurrent qualitative evaluation involving interviews with clinicians and ward observation indicated that the UFTO system provided clarity of goals of care and reduced negative associations with resuscitation decisions.

Clinicians at Gloucester NHS Foundation Trust developed and evaluated the Unwell Patient (UP) escalation pathway and form. This form similarly incorporates the resuscitation decision in the context of other treatments such as referral to intensive care. Internal evaluation of this form identified broad clinician and patient support and a reduction in the proportion of cases of resuscitation terminated for futility (17% to 5%) and an increase in overall cardiac arrest survival (17 to 28%). (Personal communication David Gabbott).

Development of the National Recommended Summary Plan for Emergency Care and Treatment (ReSPECT)

Our HS&DR Scoping review [9] of DNACPR decisions in the NHS found evidence of variation and sub-optimal practice in relation to DNACPR across health care settings. There were deficiencies in considering, discussing, and implementing the decision, as well as widely recognised, unintended consequences of DNACPR decisions being made on other aspects of patient care. Integrating DNACPR decisions within overall treatment plans was identified as a key clinical priority along with developing tools to support clinicians and patients in decision-making. The dissemination event for the project was co-chaired by Dr Wee, the National Clinical Director for End of Life Care and Barry Williams (PPI research team member). Over 100 clinicians, patients, patient representative groups and representatives from the Department of Health, attended the event which identified widespread support for the development of a national process to contextualise resuscitation decisions with overall treatment plans. Following the meeting the Resuscitation Council (UK) and Royal College of Nursing established a working group [33] with the remit to work collaboratively and build on major work already undertaken in order to develop a national form to record anticipatory decisions about CPR and other life-sustaining treatment. This work has been highlighted as a key part of the Governments response to the Health Select Committee Report on End of Life Care.

The ReSPECT working group has representation from patients, professional organisations (Royal Colleges, British Medical Association) regulatory bodies (General Medical Council, Nursing Midwifery Council), the Care Quality Commission, NHS organisations (Acute, Community and Ambulance Trusts) and patient and public members. https://www.resus.org.uk/consultations/respect/

A prototype form for recording a summary of an emergency care and treatment plan and associated information and guidance leaflets to support discussions and completing such plans was developed and has been revised following a national stakeholder consultation early in 2016. The revised documentation supports what is now known as the ReSPECT process (Recommended Summary Plan for Emergency Care and Treatment). The purpose of the ReSPECT process is to help patients and their doctors and nurses to discuss, agree and record recommendations about the types of care and treatment that the patient would or would not want them to consider for them in a medical emergency. This is important, because in lots of medical emergencies a person is not able to communicate or make decisions for themselves. Making a plan in advance helps to make sure that each person gets the care and treatment that is right for them. ReSPECT records a summary of the discussion, relevant health information and the agreed recommendations about treatment. It will be used to guide doctors and other healthcare professionals looking after the person in a future emergency situation when the person cannot make decisions for themselves.

A successful usability pilot was conducted during summer/autumn 2016. It is anticipated that the form and accompanying materials will be made available in early 2017.

1.1 Need for this research

Health need: Decisions about resuscitation are undertaken hundreds of times each day in NHS hospitals. Getting the process wrong can have profound consequences. Withholding resuscitation when it would work will cost lives. Giving resuscitation where it will clearly not work can cause pain and distress in the moments before death. Misinterpreting a DNACPR decision and inappropriately withholding other treatments will also cause harm. Failing to engage effectively with patients and their families will generate dissatisfaction, loss of trust, conflict and complaints.

Expressed need: A central criticism of the independent enquiry into the Liverpool Care Pathway (More Care Less Pathway) was the absence of evaluation early in the national adoption process. The need to introduce and evaluate an ECTP, such as ReSPECT, has been specifically identified by a national stakeholder group including representatives from NHS England, Patient Organisations, Policy makers and clinicians. This need and the urgency for such work was highlighted in the Health Select Committee report published in March 2015.

Sustained interest / intent: Patient-centred healthcare is a central tenet of the new NHS. Patient involvement in discussions and decisions about their health and care, including end of life care is specifically highlighted as a priority in the NHS Constitutions (Section 3a). As the population continues to age, and individuals survive longer than previously, often with increasing comorbidities, the importance of getting the process of making these decisions, including advance decisions, right will gain even greater prominence in the years ahead.

Capacity to generate new knowledge: Whilst international studies and our early pilot work at a small number of NHS hospitals suggests great potential for gains from the use of ECTP, the impact of their implementation across the NHS requires prospective evaluation.

Organisational focus: This project is focused on evaluating the effects of widespread implementation of ReSPECT, the ECTP developed by a national working group, chaired by the Resuscitation Council (UK) and Royal College of Nursing. It will determine, how, when and why a ReSPECT is made in clinical practice and what effect they have on patient care.

Generalisability: The evaluation described in WP 1 and 3 will take place in six Acute Trusts purposely sampled for diversity according to volume of admissions, approach to ReSPECT implementation, performance according to CQC banding, and social class and ethnic mix of populations served. Work package 2 will use data from the National Cardiac Arrest Audit which has >70% national coverage. This project focuses on implementation in the acute hospital setting in the expectation that most decisions, at least initially will be taken in this setting and provide the opportunity to observe the transferability of decisions between healthcare settings.

Building on existing work: This project builds on the findings from our previous HSDR work. This identified: resuscitation is still performed where it has little or no chance of success; patient and family involvement in decision-making in DNACPR decisions is sub-optimal;

DNACPR decisions are often conflated to mean 'not for active treatment' and decisions generate ethical challenges for health care professionals at each stage in the process.

Our early pilot work explored the use of overall treatment plans and suggests they improve decision-making and patient involvement leading to better outcomes for patients. The need for ECTP with concurrent evaluation was rated as the number one research priority at the national patient, public, clinician and policy maker event we hosted in October 2014.

The project will provide an opportunity to conduct a robust prospective evaluation of a large-scale change in NHS policy and practice. It is focused on resuscitation decisions and advance care planning; providing information about the consequences of this policy change on the three main areas identified as most important by patients and clinicians and highlighted by independent enquires. We will also consider how our finding may be transferable to other initiatives and any wider uses of our methodological approaches.

2. STUDY SUMMARY, CONSIDERATIONS AND PROCEDURES

This section presents an overview of the evaluation study, its ethical considerations and procedures across the four work packages (WP). Details of the individual WP's are followed in sections 3 (WP1), 4 (WP2), 5 (WP3) and 6 (WP4).

This study is a multi-centre mixed-methods evaluation of the use of the new national ReSEPCT process for adults being admitted to acute hospitals to determine how, when and why they are used and what effects they have on patient care.

The study consists of four work packages (WP) with the following objectives:

WP 1a: A qualitative study of the decision-making process using observation, mini-interviews with decision-making clinicians and patients/family members to explore how and why judgments are made.

WP 1b: To explore the ethical basis and the experience of the patient / family in the decision-making process.

WP 2: An interrupted time series analysis using repeated measures of process and survival outcomes for in-hospital cardiac arrests covering two years before and two years after ReSPECT implementation

WP 3: A descriptive summary of patient characteristics according to ReSPECT treatment choice and evaluation of whether a DNACPR decision, made in the context of an overall treatment plan are independently associated with risk of patient harm.

WP 4: Focus groups with General Practitioners to evaluate how ReSPECT is working across the acute/primary care boundary. A description of the context for implementation from regular meeting between sites, researchers and the ReSPECT National Working Group, responsible for

developing the process. A narrative synthesis of the key findings of the study and future research priorities from the patient, clinician and policy maker perspective, effectively disseminated to ensure that key messages are integrated into future development work on ReSPECT.

2.1 Intervention to be evaluated

The intervention described below is not being implemented as part of this study. The study is evaluating the impact of the intervention as it is used in routine clinical practice.

Emergency care treatment plans (ECTPs) contextualise 'do not attempt cardiopulmonary resuscitation' in relation to other treatments. The focus of emergency care treatment plans differs from DNACPR in that it focuses on which treatments will be given rather than solely on which treatments will be withheld. ECTPs are designed to promote patient centred healthcare and patient involvement in decision-making.

This study aims to evaluate an Emergency Care and Treatment Plan (ECTP) approach as it is adopted and implemented in acute NHS hospitals. The ECTP approach being evaluated for this study is known as the ReSPECT process (Recommended Summary Plan for Emergency Care and Treatment) and it is being developed by a national working group, chaired by the Resuscitation Council (RCUK) and the Royal College of Nursing (RCN). The process is supported by documents, (a form to record the recommended guidance, following discussion between a patient and their clinician, information leaflets, guidance for clinicians) will be launched in early 2017 and it will be up to individual NHS organisations and other healthcare providers to adopt it and implement it (see Appendix 1).

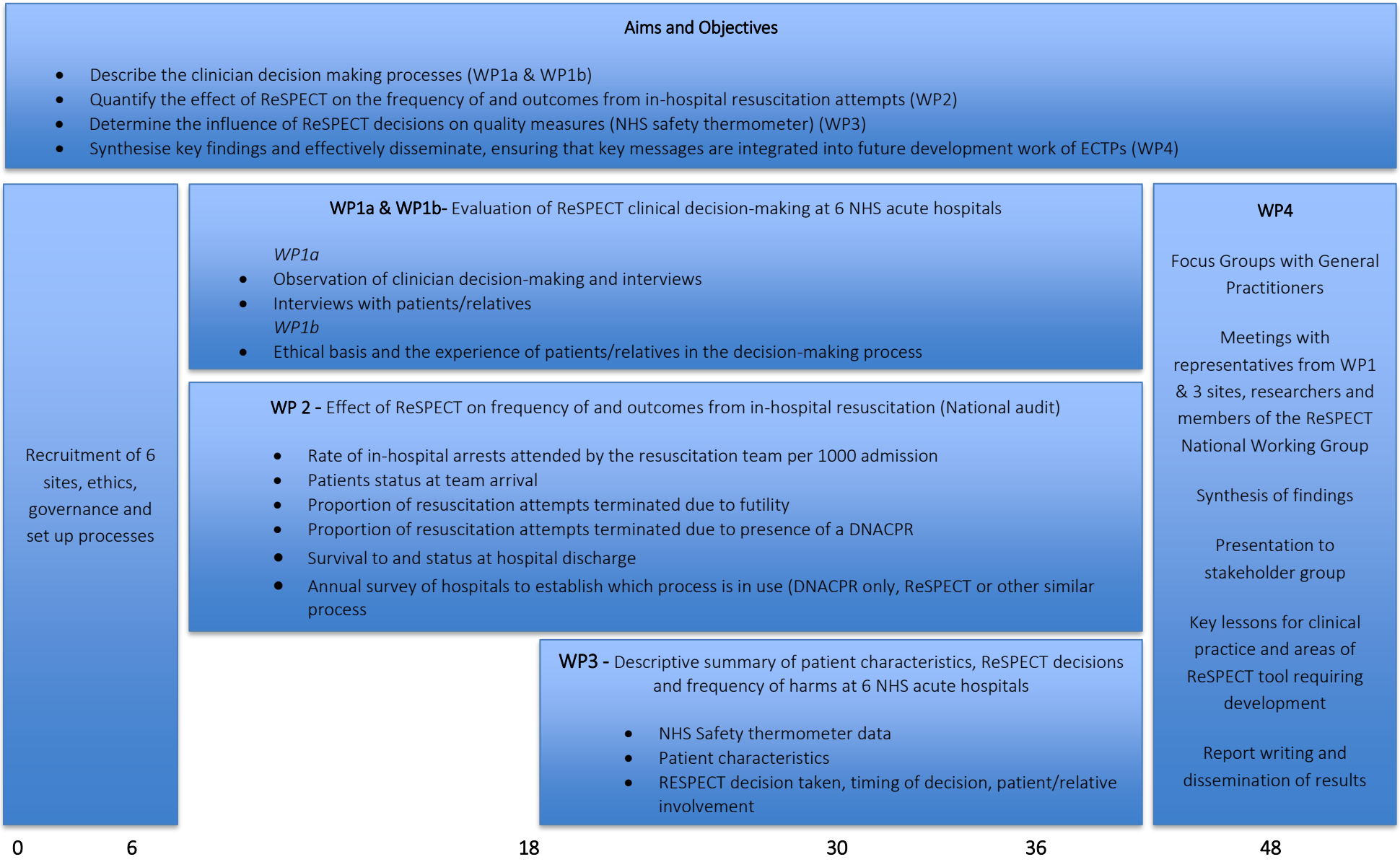
The current working version of an ReSPECT form contains several elements (1) clinical guidance on interventions that may or may not be recommended and two broad treatment priorities from the patients perspective (i) focus on life sustaining treatment (ii) focus on symptom control (2) a decision about resuscitation status (for resuscitation or do not attempt resuscitation) (3) summary of communication with patient and who was involved in decision-making (4) where in the medical records full details of discussions are documented

A training / implementation package is being developed for simultaneous launch by the national working group. It is envisaged that changes in a patients' circumstances (e.g. acute admission to hospital, the presence of a new, life limiting diagnosis, acute deterioration overall decline in functional status) will prompt consideration of emergency care treatment plan choices. Experience with the UFTO system indicates that around 70% of in-patients will have a ReSPECT process completed at the time of hospital admission of which approximately 20% will also have a DNACPR decision.

In this research we recognise that the intervention being evaluated may be under specified and that a form cannot achieve change by itself – human agency is involved. The form could be seen as analogous with the checklist in the Michigan sepsis study which resulted in a large and sustained reduction (up to 66%) in rates of catheter related bloodstream infection. [34]

However the Michigan study was subsequently shown to be a compound intervention involving not just the form but a cultural change intervention. [35] Introducing the ReSPECT is also likely to be associated with other actions. Part of our plan is therefore to capture how the ReSPECT was implemented in the sample sites in field notes (WP1) and through summary data collected at regular meetings between site representatives, researchers and members of the ReSPECT National Working Group (WP4).

Figure 1 ReSPECT Evaluation flow diagram



2.2 Recruitment summary

Six sites for WP1 and WP3 will be recruited through co-applicant's networks, e.g. contacts from the ReSPECT working group, colleagues within clinical networks. Random selection is not required. It is essential that the hospital has a commitment to implementing the new ReSPECT system soon after its release by the RCUK. We will endeavour to select sites to ensure a diversity of hospitals (e.g. university affiliated, district general), and populations (e.g. areas including diverse ethnicity or rural and urban) served. This is because the purpose of the study is to evaluate the impacts of the ReSPECT system itself, which requires it to be implemented well and before data collection is scheduled to commence.

2.3 Ethical Considerations

The study will be conducted in accordance with the NHS Research Governance Framework and the principles of Good Clinical Practice. As the study may involve some patients who by the nature of their underlying illness lack capacity, the requirements of the Mental Capacity Act (2005) will be observed. The study will comply with relevant Warwick CTU Standard Operating Procedures and all data will be stored securely and held in accordance with the Data Protection Act (2018).

Some of the work described in this protocol crosses the interface between research and service evaluation / quality improvement. The research design is that of a mixed-methods observational study, where we will attempt to derive generalizable new knowledge. The "intervention" under evaluation (ReSPECT) has been adopted by the NHS organisations involved in this project and so is not in itself a research intervention. We will share site specific summary findings directly with the Trusts which they may choose to use for quality improvement purposes.

The main ethical challenges relate to informing participants about the nature of the study, obtaining consent and ensuring confidentiality for clinicians and patients is maintained. The degree of patient, relatives and staff involvement and intrusiveness of the research varies between work packages. We propose consent models that we believe are proportionate to what is being asked of research participants in the different stages of the research study. Our approach to obtaining consent in this study is informed by the findings from the HRA consultation on simple and efficient trials, prior work in this field and discussion with our patient and public partnership group.

The research involves four main activities, which are ordered to reflect the invasiveness of the research. The four activities are:

(1) Interviewing clinicians, patients and relatives

(2) Observation of clinicians engaged in making ReSPECT recommendations

(3) Accessing clinical records

(4) Use of anonymised data from the National Cardiac Arrest Audit.

1) Interviewing clinicians, patients and relatives (WP1 and WP4)

The consent process for interviews will follow standard models for obtaining written informed consent. Written, informed consent to participate will be obtained from clinicians, patients and family members who agree to participate in interviews.

Approaching patients and family members around the time a ReSPECT discussion has occurred raises concerns about intrusion of privacy and causing further distress to patients and family who will already be anxious. We will be guided by the clinical team caring for the patient and supporting the patient / family as to whether it is appropriate to approach them and the timing of any approach. The approach would be from the clinical team in the first instance. When a patient's relative acts on behalf of a patient who lacks capacity during the ReSPECT process we will seek to obtain their consent to be interviewed as part of the study. As these interviews will include information about, or reference to, the patient we plan to ask the relative to sign a personal consultee declaration that in their view if the patient had capacity he or she would not have objected to their relative taking part in the interview. Any initial interview will be tailored to the needs of the individual patient or family member would be brief and it would be made clear that the interview could be stopped at any time, if the participant wished. The researcher will have experience of and/or training in interviewing patients or families experiencing distressing situations.

To facilitate participation of people who do not speak English or who are deaf and able to use sign language we will endeavour to conduct the interview with translator who is not a member of hospital staff.

2) Observation of clinicians engaged in making ReSPECT recommendations (Protocol WP 1)

We will seek written informed consent from clinicians prior to observing their involvement in ReSPECT recommendations. Clinicians will be allowed, without giving a reason, to withdraw from a period of observation at any time and without prejudice.

When a clinician is being shadowed by a researcher, the focus of the researcher's observation is the clinician. However, the researcher will be present when the clinician interacts with a patient or member of the patient's family. At the start of any such interaction the clinician will introduce the researcher to the patient/family member and anyone else present, and seek their permission for the researcher to remain, explaining that the researcher is there to observe the clinician. If the patient/family member or anyone else present does not want the researcher present the researcher will withdraw. This is a similar approach that was successfully developed with patient and public partners in our related study (HS&DR Project: 13/10/14 – Gate Keeping in Intensive Care, REC reference 15/WM/0025). The patient/family member can change their mind at any point without giving a reason and without prejudice.

It is not possible to obtain individual consent from all patients and their families or anyone else present for the presence of a researcher conducting observation within a particular clinical area e.g. hospital ward / emergency department. However, the study researchers will ensure that information about the study is displayed in all areas that the researcher is likely be working and he/she will be clearly identified as an observer.

To contextualise our observations of how ReSPECT is used in clinical interactions, we will conduct additional observations of ward environments where clinicians engage with the ReSPECT form and where they discuss the ReSPECT process and form with one another. This data collection may be outside times where the study researcher is shadowing the clinicians, and will involve observations as well as informal conversations with clinical staff members such as nurses, junior doctors, and consultants. Information about the observation study is already provided through posters displayed in the wards; however, we will provide ward staff with additional leaflets about the study, to be distributed to them by the ward manager prior to the first observation. These leaflets will inform ward staff that observations and informal conversations will be taking place, that the study has been approved, and that they are not obligated to participate. Consent will be obtained from the relevant ward manager prior to the extended observations taking place. When the researcher will initiate or participate in informal conversations with staff members, the researcher will obtain and document verbal consent from the participating staff members to write up these conversations, or any part thereof (in quoted or paraphrased form), as field notes, to be used in data analysis. Verbal consent is appropriate in research situations where the researcher and the participants (in this case, nurses, junior doctors, and other clinical staff members) are of similar professional standing. Obtaining verbal consent would allow us to maintain continuous transparency about the fieldwork process and ensure that clinical staff members consent to each informal conversation, while minimising disruption to the informal conversation and observation process. To ensure that participants can easily contact the researcher to withdraw their consent, the researcher will give her University of Warwick business card, which includes her email address and other contact information, to each clinical staff member who participates in an informal conversation.

(3) Accessing clinical records (Protocol WP 1 and WP 3)

We are seeking approval from the Confidentiality Advisory Group to use section 251 of the NHS Act 2006 to access medical records. Patients will be given the opportunity to opt out of this part of the study by the provision of information leaflets and posters explaining the study. We present the potential risks, mitigations and benefits of this approach below.

The main risk for copying and extracting data from clinical records relates to a breach of trust / confidentiality through access to clinical records. We are mitigating the risk by (1) only reviewing sections of the record relevant to the research question (2) collecting the minimum amount of data to address this research question (3) anonymising copied/extracted data (4)

making use of routine audit data where possible (5) ensuring staff collecting the data will have a duty of confidentiality through a contract with the hosting NHS Trust. It is possible (although unlikely, given the existing duty of clinicians to consult patients), that an awareness of this research activity may prompt patients to raise questions about their overall treatment.

The direct benefits for individual research participants are limited to raising a general awareness about ReSPECT amongst clinical staff and patients. There will also be benefits for future patients through a better understanding of how ReSPECT is working in the NHS.

Considering the risks, mitigations and benefits we assess the overall risks from this as low to negligible.

The research requires the research team to access the following information from the patients' clinical records

i) Information recorded on the ReSPECT form

ii) Clinical justification for a ReSPECT recommendation

iii) General information about the patient (Full information is provided in protocol section 5.3). The types of information required is e.g. demographic information, severity of illness measures and laboratory results.

This information will be linked by hospital based research staff to hospital held information on:

iv) NHS Safety Thermometer data for each individual patient

v) Overall outcome for each individual patient (length of hospital stay, survival to discharge, discharge location type)

Information will be copied or extracted from the ReSPECT form and clinical records by NHS research staff. This will be linked with information from the NHS Thermometer measurements and outcome information (length of stay, survival, discharge location type).

NHS staff will anonymise the data set before it is securely returned to the central research team at Warwick Clinical Trials Unit for analysis.

A record of who the participant identification numbers have been allocated to will be kept at the research site in order to enable withdrawal of participants after the data has been collected and before the dataset is locked for analysis. In the event a patient requests their data not to be included after it has been collected but before the data is analysed, we will treat this as if it were a withdrawal and their data will be removed from the data set.

Our approach seeks to balance respect for the patients right to information in their medical record being treated confidentially, a public interest in obtaining an unbiased sample to

achieve a valid research outcome and consideration of practicable alternatives to obtaining consent. This part of the data collection is the subject of our application to the Confidential Advisory Group (CAG).

We consider the use of assumed consent model (sometimes called opt-out consent) as proportionate to (1) the level of risk involved (2) the burden to patients / relatives of going through a process of written informed consent (3) the cost to the public purse of clinical staff approaching patients for written informed consent.

Information leaflets about the study will be distributed to patients / relatives prior to the data collection date by the NHS site staff. Posters about the data collection and where to get more information will be displayed in participating units and wards. The leaflet will include information about the study, what information is being collected, that it will be anonymised before leaving the NHS site and securely transferred to the central research team for analysis. It will also include contact details for further information and how an individual can opt out of the study. The opt-out approach was developed with patient and public partners and implemented successfully in previous studies (Early Mobilisation to prevent Hospital Acquired Pneumonia) REC code 13/WM/003 (UKCRN 139921 code).

4) Use of anonymised data from the National Cardiac Arrest Audit (Work Package 2)

Anonymous information will be sent securely by the National Cardiac Arrest Audit (NCAA) Team to the research team at Warwick. NCAA hold this information under CAG approval ECC 2-06(n)/2009. Permission to access the data required for this study has been provided by the NCAA management committee.

Table 1 summarises the different approaches to consent planned for the study.

	Written consent	Verbal consent	Section 251 NHS Act 2006
WP 1A observation	Clinicians (shadowed)		
WP 1A informal conversation		Clinical staff members	
WP 1A interviews	Clinicians / Patients / Relatives		
WP 1b			Anon patient data
WP 2			Anon Patient data

WP 3			Anon Patient data
WP 4	Clinicians		

Hospital level consent

Trust level approval for participation in the study (and sharing of documents relevant to the system approach to implementing respect) will be provided through site specific approval processes.

System wide evaluation of cardiac arrest outcomes is a key objective of the National Cardiac Arrest Audit. Participating units already provide information about clinical services and case mix at hospital level. We will extend this by asking questions about resuscitation services, and the use of the use of emergency care treatment plans.

2.4 Data Collection

Several modalities will be used for the collection of research data across the different work packages (Table 2). Full information is provided in the detailed description covering each work package.

Table 2 summarises the main approaches by each work package

	Observation	Interviews	Case note review	Audit data	Focus group
WP 1 A	X	X			
WP 1 B			X		
WP 2				X	
WP 3			X	X	
WP 4					X

Confidentiality: Any researcher(s) from the study research team needing access to patient records to support the data collection at sites will apply for a research passport/letter of access. When reporting the findings of the study, participants (hospitals, patients and relatives, clinical staff) who consent or chose not to opt out of the medical case note review will be assigned a unique participant identification number. All results and findings reported will be anonymised, to ensure no individuals can be identified in the study. Participating hospitals' identities will only be reported with their agreement and specific data relating to each hospital will be reported anonymously using a case identifier.

2.5 Data Management

Data collected during the study will be handled and stored in accordance with the 2018 Data Protection Act and Warwick Clinical Trial Unit Standard Operating Procedures.

No personal identifiable data will be transferred between hospital sites and the University of Warwick. The detailed data management processes in the descriptions of each work package that follows.

Data collected from the National Cardiac Arrest Audit will be transferred securely. Information sent will be anonymised at a patient level. A unique identifier will be assigned to each case and hospital to allow NCAA to address any data queries without providing patient identifiable information to the research team.

Disclosure of confidential information

If during data collection a participant raises any issue which may jeopardise the safety of the participant, the researcher will follow local Trust safeguarding processes, usually reporting the issue to the unit or ward manager. Similarly if the participant becomes distressed or ill during an interview or observation the researcher will report this to their clinical team. Participant information sheets will include information about the disclosure of such information. If the researcher identifies an issue which raises concerns regarding professional misconduct that could result in a significant risk of harm to patients generally the researcher will discuss this with the work package lead. If the work package lead agrees that there is a cause for concern they will inform the Trust in accordance with local Trust policy on raising concerns.

2.5.1 Databases

The study database will be developed by the Programming Team at WCTU. All specifications (i.e. database variables, validation checks, screens) will be agreed between the programmer and appropriate study staff. Whenever possible information will be entered directly in to the database at each site.

2.5.2 Data storage

All essential documentation and study records will be stored by WCTU in conformance with the applicable regulatory requirements and access to stored information will be restricted to authorised personnel. Any paper data forms, field notes, meeting notes, or other documents will be stored in a lockable filing cabinet in a secure room, to which access is restricted to authorised personnel. Electronic data will be stored in a secure area of the computer with access restricted to staff working on the study. Any data that are transferred out of the secure environment (for example for statistical analysis, ICNARC, NCAA) will adhere to WCTU SOPs.

2.5.3 Data access and quality assurance

Study participants will be assigned a unique study identifier. Each site will maintain a confidential and secure list of patient identifiable information (name, date of birth, identification number) for the purposes of audit / quality assurance.

Once the study has been completed the records will be destroyed according to WCTU and or local site SOPs. The CI and the WCTU administrator (or staff they delegate this role to) will have access to the final study data set from all four work packages. Access requests from both co-investigators and external parties will be considered by the CI. A formal process will be developed by the study team to facilitate such requests and decisions. Any data shared will be anonymised and transferred as per WCTU SOPs with data sharing agreements in place.

2.5.4 Archiving

Study documentation and data will be archived for at least ten years after completion of the study. Research sites will archive documentation following their local policies.

2.6 End of the Evaluation Study

The study will officially end on the last day of funding, although dissemination of results will continue beyond that date.

Since this study is not implementing any intervention, it is unlikely to be stopped prematurely, unless funding is ended early. If several or all of the research sites in WP1 and 3 withdraw the ReSPECT process during data collection this could result in these aspects of the study ending prematurely or partially completed, unless replacement sites can be found within the time constraints of the project. The Research Ethics Committee will be notified in writing if the study has been concluded or terminated early.

3. WORK PACKAGE 1 – QUALITATIVE STUDY OF DECISION MAKING PROCESSES

3.1. Objectives

To describe the decision-making process including how, when and why judgments are made, their ethical basis and patients/family understanding and experience of the process.

This work package has two parts – (1a) a case study evaluation of ReSPECT decisions in clinical practice and (1b) a review of written records.

3.2 Work Package 1a: Case study of ReSPECT decisions in clinical practice

3.2.1. Study design for WP1a

This observation and interview study will seek to answer the following questions:

1. How, when and why are clinicians making ReSPECT decisions in the acute hospital setting?

2. What happens when a patient brings a ReSPECT or similar document from the community to hospital?

3. How is the ReSPECT system used within the process of decision-making?

4. To what extent is the patient, and where appropriate family members, involved in the decisions?

5. How do patients/family members experience the decision-making process and their subsequent care?

6. What influences the ReSPECT decision-making process, including considerations of ethics (or not), and why?

7. From the clinician perspective, what are the perceived impacts of the ECPT process on clinical decision-making and patient care including their ethical dimensions and what changes are needed to improve ReSPECT decision-making?

8. From the perspective of clinicians working with acute admissions, what changes are needed to improve ReSPECT decision-making, including ethical dimensions of the decisions?

3.2.1.1 Research approach for WP1a

We will undertake case studies of acute medical and surgical admissions. Our approach to assessing decision-making is based on a model that we are already using successfully in another HS&DR funded study (13/10/14) on the ethical dimension of decision-making related to ICU admissions. We will study acute admissions in NHS Trusts where ReSPECT has been introduced and the associated training has been rolled out so we are studying normalised practice rather than the implementation process although we will include details of the implementation process using the COM-B ('capability', 'opportunity', 'motivation' and 'behaviour') model [36] in the case study description to contextualise the study setting. Normalisation [37] of the use of ReSPECT by the acute admissions teams is likely to occur rapidly as there will be opportunity for them to use them many times in any one 12 hour take. We will take a realist approach to the identification of the index event – the first admission to a participating hospital during a period when we are actively collecting data. [38] However, different people may perceive the same event in different ways. Capturing and understanding differences in perception of an event requires a relativist [39] epistemological approach. The realist and relativist approaches are commonly brought together within case studies as described by Yin [40] and in the realist evaluation approach. [41, 42] The use of the ReSPECT process (or not) and all the actions associated with its use (for example, talking to the patient and/or family about treatment goals, discussion with colleagues at a post take ward round about completion of a ReSPECT process, completing the ReSPECT form, writing about the discussion in patient notes, and associated learning and reflection) will be central to our data collection as we seek to understand how ReSPECT plays a part in the processes of decision-making about treatment escalation. We will

draw on organisational theory on 'entanglement' of objects (such as ReSPECT) with social practices and the organisational and individual learning from using these objects. [43] This recognises ReSPECT as an 'object-actor' within social practices in that the object influences how individuals (human actors) think, behave and organise themselves. For example, the requirement for the clinician to ask a patient what they want from treatment in order to categorise the patient on the ReSPECT form will change how the clinician talks to the patient (or family where appropriate). It may also change both patient's and clinician's thinking about the level of certainty/uncertainty they can live with or prefer to live with – patients and clinicians may be wary of being clearly categorised.

3.2.2 Recruitment of individual participants for WP1a

Recruitment of clinical teams: In advance of clinician recruitment we will visit hospitals to present information about the study to clinical staff. We will then seek individual informed written consent from each clinician who agrees to be shadowed and interviewed.

Interviews with patients, or where appropriate, family members: Following the initial approach with the clinician, the researcher will hand either the patient or family member if patient is too unwell/clearly does not have capacity, a brief information sheet about the study saying the researcher may approach them later to ask if they would be prepared to be interviewed. Following the observations, the researcher will review the types of cases observed where they have handed the patient or family member the brief information sheet. They will identify which patients or family members they would like to approach according to the stratification sampling frame. The researcher will return to the patient's ward/unit and check with the nursing staff whether the patient is well enough and/or when the best time would be to be to approach the patient or family member with further study information and to seek consent to interview. Where a patient or family member expresses interest in participating in the study, the researcher will then seek written informed consent prior to the interview.

If we recruit fewer patients or relatives than the 14 originally planned at each site we will identify and approach additional patients on the wards where we conduct observations who have experience of the ReSPECT conversation. Failure to recruit from the observation period may be because insufficient ReSPECT conversations are conducted during the clinician observation sessions, or most of the patients observed are too unwell to take part in an interview.

A member of the site research team will create a list of patients with a ReSPECT form completed or validated during this admission. They may use their hospital system, if their system records ReSPECT form completion, to extract a list of patients on the ward(s) where clinician observations have been conducted or they will ask the lead nurse for a locally held list. If they are unable to create a list in either of these ways, a member of the site research team will screen patient records on the ward(s) to identify patients with a ReSPECT form completed or validated during this admission. Patients admitted with ReSPECT forms completed in community settings (e.g. by a GP), will be noted on the list. The site research team will also

make a record if there is documentation in the patient records stating the patient lacks capacity to the extent they could not consent to take part in a research interview.

The researcher conducting the interviews will identify potential participants (either patients or family members for those unable to give consent) based on the purposive sampling frame developed for WP1a. Prior to approaching any identified patients, the researcher will consult with the clinical staff to check whether the patient is well enough to be approached and whether they have capacity to give informed consent to take part. If they do not have capacity, the researcher will ask the clinician to approach a family member, if available. The clinician will ask the patient or family member if they are willing for the researcher to talk to them about the study. If they agree, the clinician will introduce the researcher and the researcher will give the potential participant an information sheet and arrange for the researcher conducting the interviews to return once the potential participant has had sufficient time to make an informed decision about whether or not to take part (usually 24 hours). When the researcher returns, they will first check with clinical staff that patients are well enough to discuss participation. The researcher will approach those patients who are well enough, or family members, in order to answer questions about the research and seek written informed consent should the patient or family member wish to take part.

Interviews with implementation leads: The researcher will ask the PI to help identify and approach the site's ReSPECT implementation lead or someone with significant involvement in the implementation process. The researcher will provide the implementation lead with an information sheet about the research and answer any questions they have regarding it. If they agree to be interviewed the researcher will obtain written consent prior to the interview, which will be audio recorded and transcribed for analysis.

3.2.3 Withdrawals and Exclusions for WP1a

Clinician or patient participants can withdraw from the study at any time without prejudice. Unless a participant explicitly withdraws their consent, they should be followed-up wherever possible and data collected as per the protocol until the end of the study.

The participants in WP1a will be given contact details for the research team who they may contact at any time after they have been recruited until the data is analysed to inform the team they wish to withdraw consent. The team will establish whether they wish to withdraw all data contributed to the study or for any further planned data collection. Their wishes will be recorded in the Study Master File using their study ID only and their data removed from the study. If their data is part of an observation involving other participants, they will be specifically asked whether this data can continue to be used. If they withdraw their consent for this data remaining in the study the work package team will make an assessment on whether to remove the whole observation or simply the data about their contribution to interactions. The researchers and the co-applicants responsible for WP1 will discuss the situation and decide whether an additional participant at that site or another site should be included. This decision will be informed by various factors including the stage of data collection at the site and the impact of the loss of the data on the findings. A record of any withdrawals will be made at the

site, if the data has not yet been returned to the study team, or in the Study Master File following transfer.

3.2.4 Data collection for WP1a

Collation of documents: Local policies guidelines on ReSPECT use, the implementation process used when it was introduced and interviews with implementation leads will be collated and summarised as contextual information for data collection.

Observational study: The observational study will be conducted consecutively in each of the six recruited hospitals by a researcher based in that hospital for a period of approximately 2-3 weeks. Prior to commencing the study at each site, we will visit the hospital to find out about on-take rotas and timetable sessions of observation. Where completion of ReSPECT processes is infrequent during on-take admissions and post-take ward rounds we will discuss with clinicians when the best time to observe them completing ReSPECT processes is and agree an observation schedule with them. Sometimes ReSPECT discussions may be more opportunistic and the researcher and clinician will arrange a way for the clinician to alert the researcher that they are going to conduct a ReSPECT conversation (e.g. telephoning or bleeping the researcher). We will conduct observations with at least three acute medicine (with different teams), one surgery and one orthopaedic team at each site. This will ensure diversity of practice is observed within each hospital. Within each session of observation (usually 4-6 hours within any 24 hours) a researcher will shadow the clinician most likely to complete ReSPECT forms. These will form our cases. Approximately 7 clinicians per site will be observed, usually this will be once each, but depending on the pattern of completion of ReSPECT processes the 4-6 hour observation may be split into shorter sessions with the clinician's agreement. We expect up to eight discussions to complete ReSPECT forms will be observed with each clinician. Shadowing will cease after a maximum of eight ReSPECT discussions to limit the burden of participation on the clinician and to allow sufficient time for clinician will be available over the subsequent 24 hours for interview (see below). Session timetabling will be reviewed during the observation period to ensure observations are spread across the week. Observation will continue until data saturation is reached, we have observed a range of ReSPECT processes (medical, surgical, orthopaedic) across the study sites and initial analysis suggests we have reached data saturation for each specialty/site. We will continue to observe until we also have sufficient cases for sampling for interviews (see below).

In preparation for observation, posters about the project will be displayed in all areas of the hospital where admitting clinicians usually work e.g. corridors, family waiting areas, common rooms, admissions units, ward entrances and wards alerting health professionals, patients, and families to the presence of an observer. The observer will be identified by wearing a clinical 'scrubs' type uniform, or a t-shirt printed with the University of Warwick logo, that is clearly marked 'researcher' and photo-ID badge.

While shadowing clinicians the researcher will observe clinician decision-making, the recording

of decision-making and what seems to influence the process. They will ask clinicians about local practice and terminology used. While shadowing, they will be present during clinical care but this is not the focus of their observation.

During observation the researcher will talk informally with the clinician being shadowed and other health care staff encountered, to clarify what they observe and ask why it is happening the way it is. Field notes will be taken about the admission process, decisions made about treatment including the ReSPECT decision category, the involvement of patient and/or family in decision-making, the use of the ReSPECT form, when, where and by whom decisions were made and recorded.

Observing the completion of ReSPECT forms may involve attending post-take ward rounds, other ward rounds or other discussions between clinicians and their patients/family member(s). Field notes will be typed up and expanded by the researcher soon after each observation session. An identifying number will be used for referring to clinicians in hand written and typed field notes. The identities of patients will not be recorded in the field notes. A hard copy list of the names of clinicians and their IDs when not being used will be kept in the locked cabinet at the hospital until the project is complete and will then be destroyed.

In addition to observations related to the shadowing of clinicians, we will conduct observations and informal conversations with clinical staff in clinical and staff-only areas of the hospitals, as needed. This data collection may be conducted outside the times when we are shadowing the clinicians. This additional time for observations and informal conversations will provide contextual data on how ReSPECT is used, including descriptions of the ward environments where clinicians engage with the ReSPECT form and where they discuss the ReSPECT process and form with one another. As part of these observations, we may take photographs involving the ReSPECT form; these photographs will document, for example, where the form is stored, advertised, and placed within the wider structure of the ward. All photographs will be of the ReSPECT form, posters, and surrounding material objects. We will not take any photographs of patient data or of people. In addition, the researcher will initiate and / or participate in informal conversations with clinical staff members such as nurses, junior doctors, and consultants. The researcher will obtain verbal consent from the participating staff members to write up these conversations, or any part thereof (in quoted or paraphrased form), as field notes, to be used in data analysis. All field notes will anonymise participants and exclude or alter identifying information; pseudonyms will be used throughout, and the clinical staff members' names will not be recorded.

Sampling for interviews: We take a stratified sample of cases for interviews according to the ReSPECT treatment choices. We will oversample for cases where the patient has been observed to bring to the hospital a ReSPECT completed outside of the hospital or other similar document (e.g. DNACPR form). These cases will enable us to explore the community-hospital interface relevant to the ReSPECT form. We will sample for interviews until data saturation is

reached for each of the ReSPECT decision treatment options (Focus on Life Sustaining Treatment, Focus on Symptom Control and whether the patient is for cardiopulmonary resuscitation (CPR) or not). In all decision groups we will ensure a diversity of patients has been included (medical/surgical/orthopaedic, age, gender) before we cease sampling. Where possible, interviews with the same patients or family members discussed in the clinician interviews (see below) will be conducted. We will aim to interview up to about 14 patients or family members at any one site and up to 80 over all sites, but exact numbers will be determined by data saturation. Data saturation may be reached relatively quickly for the Focus on Life Sustaining Treatment group who are for CPR as the decision-making about treatment escalation for these patients may be relatively straightforward (e.g. young man with bone fracture or young woman with ectopic pregnancy) (estimate 15-20 cases across all sites). In the other ReSPECT treatment groups where decisions may not be so straight forward, data saturation is likely to require more interviews (estimate 20-30 cases across all sites). We will undertake an initial analysis of interview data while still 'in the field' so we are able to determine when data saturation has been reached.

Interviews: Semi -structured interview schedules will be developed and refined with input from the lay advisory group. The interviews will be designed to encourage the participants to talk about their experiences of the ReSPECT decisions making process, initially with minimum prompting. As the interview progresses, prompts will be used to elicit data relevant to all our research questions. In the later stages of the interview, the interviewer will alter their interview approach to engage in discussion with the participant about ReSPECT decision-making, as it is through this type of data that we can identify ethical dilemmas that participants face but may find difficult to describe. Where possible all interviews will be audio recorded to capture as much data as possible, but where this is not practical or the interviewee refuses permission, field notes will be taken. For each sampled case, we aim to interview the clinicians involved in the admission and care of the patient, the patient and where appropriate a family member. Family member interviews will be sought if the patient is too unwell to participate in an interview or has cognitive impairment or other reason why interview would be difficult. Based on our previous experience of interviews we expect a rate of agreement to be interviewed by patients of as much as 80%. With patients/family members when a patient is seriously ill, we estimate no more than 50% agreement to interview as the patient and family are usually distressed and the family very busy. Interview data from all interviews will be confidential and care will be taken not to convey any sense to interviewees of what other interviewees said about the same event.

Interviews with admitting clinicians: Interviews about cases will be scheduled within the 48 hours following an observation period while the admissions are fresh in the clinician's memory. During the interview the admitting clinician will be asked to talk aloud their process of decision-making for between 1 and 3 of the observed cases: what they took into account; factors that influenced their decision such as age, resource availability, patient views, previous ReSPECT; any dilemmas they faced; and their use (or not) of the ReSPECT. They will also be asked to

reflect on how the decision-making process and ReSPECT could be improved (estimate 20 min interview for each observation period covering between 1 and 3 cases. These numbers will be reviewed as data collection progresses). Following the empirical ethics approach [46], the clinician interviews will add some challenging questions, aimed at starting discussions about ethical issues that have been identified in the interviews we conducted in the two first study sites. For cases where no ReSPECT is in place at the time of the interview, the researcher will check with ward staff after 48 hours if a ReSPECT has subsequently been put in place and seek an interview with the clinician who completed the ReSPECT.

Longitudinal data collection: After the completion of data collection in all six sites, we will review the WP1a data collected, with particular focus on comparing sites where data were collected during the early stages of ReSPECT implementation (within the first year) and sites where data were collected during later stages of ReSPECT implementation (two or more years after initiation of implementation). If we identify notable differences between these two groups, we will return to the sites where data were collected during the early stages of implementation to conduct repeated data collection, including all the elements described above. This will enable a longitudinal comparison of data collected in the same sites within the first year of ReSPECT implementation and 2.5 or more years after. This comparison will allow us to contextualise our findings, and any differences therein, with regard to stages of implementation.

3.2.5 Data Management for WP1a

Consent will be taken and observational and interview data will be collected by researcher(s) from the co-ordinating study team or local site research team. The researcher from the co-ordinating study team will also collect contextual information.

Audio recordings will be transcribed and anonymised. Names and contact details of participants will be recorded on a separate database and stored in a locked filing cabinet. Audio recordings will be transferred from site to the university securely using encryption either on the audio recorder, or by downloading the recording to an encrypted laptop. The recordings will be transferred to secure university servers for secure storage and copies on the audio recorder and / or laptop deleted. Transfer to any transcription services will be done via a secure system and according to WCTU data transfer SOPs and a data sharing agreement. Hand written field notes will be kept in a locked filing cabinet. Field notes recorded electronically will be on an encrypted laptop while the researcher is at the site and then uploaded to secure university servers when they return to the office. Photographs will be downloaded to an encrypted laptop and transferred to secure university servers for secure storage, with the copies on the camera, phone, and / or laptop deleted. All qualitative data will be uploaded into NVivo software which will be used to assist data management.

3.2.6 Data analysis for WP1a

Data management and quality checks: Audio recordings will be transcribed and anonymised.

Names and study ID allocation for participants will be recorded separately on an electronic database and stored securely by local study teams. All qualitative data will be uploaded into NVivo software which will be used to assist data management. Coding will be undertaken by independent researchers for 30% of transcripts and any inconsistency discussed to ensure consistency.

Data coding and analysis: Data analysis will be driven by the research questions. Research questions 1-4 require a time ordered mapping of the process of decision-making. [44] Research questions 5-8 requires an interpretive approach [45] and analysis to capture the ethical dimensions. [46] We will initially code data about the decision-making process and use of ReSPECT (or not), and for other themes relevant to the research questions and identified in the data. The decision-making process for each case will be summarised along with other relevant data (e.g. type and severity of illness) based on observation, clinician interview and patient/family interview. Comparison will be made between these different data sources and consistencies and inconsistencies noted. Comparison will then be made across cases to understand how the decision-making processes vary. The results of this analysis will then be used to inform the further interrogation of the data to answer the research questions. We will involve the project lay advisory group in data analysis and its interpretation. Our ethical analysis will take a different approach. We will follow the method of grounded moral analysis described by Dunn et al. [47] This approach initially characterizes the ethical dynamics of the practice (in this case ReSPECT decision-making) described by those participating in the practice (clinicians and patients) and exposes these to ethical analysis. Relevant ethical theories and arguments are used to make sense of the individuals' experiences and attitudes (in this case their reasoning leading to ReSPECT decisions). Emergent ethical perspectives then inform further sampling and data collection (observation and interview questions). The results of such an analysis will identify the ethical dimensions of the decision-making process and suggest the type of support clinicians may need (for example, information about legal issues, and support for coping with uncertainty or ethical dilemmas).

3.3 Study Design for Work Package 1b: Review of written records

This review of a purposive sample of patient records will seek to answer the following questions:

1. Is the recorded decision-making process for a ReSPECT transparent?

2. Is the reasoning process recorded for a ReSPECT ethically justifiable?

3. Are recorded decision-making processes for ReSPECTs consistent across patients and clinicians?

Our previous research identified that there is great variability in DNACPR decision-making. Uncertainty is intrinsic to most clinical decisions [48] and this was one source of variability in decision-making. Added to this was variable levels of understanding of ethical issues and of

ability to incorporate ethical considerations into clinical decision-making. [9] The wide range of health professionals across our focus groups shared a common feeling of ethical discomfort about DNACPR decision-making as it currently happens in practice. This ethical discomfort arose from difficulties in interpreting specific ethical principles such as duty of care or respect for autonomy in the particular context of resuscitation decisions, and from the need to balance conflicting duties and interests in situations of uncertainty and time constraint. One aim of ReSPECT should therefore be to support clinicians in considering the ethical reasoning underpinning ReSEPCT decisions. By embedding the DNACPR decision in a wider conversation and decision-making process about treatment options ReSPECT should prompt clinicians to involve patients and their families (respecting autonomy) and explicitly consider the overall care of the patient including the harms and benefits of a range of treatment options. It should also improve consistency of process, including reasons for decisions, across different contexts and patient populations, improving equity of care. Any evaluation of ReSPECT will need to include an assessment of whether these aims are achieved.

We are not aware of any standard instruments for evaluating the quality of ethical decision-making in clinical practice or for evaluating interventions to improve ethical decision-making. Studies of interventions to support ethical decision-making have usually used clinicians' views on the effect of the interventions on their practice to evaluate its impact. [49] A persuasive and pragmatic candidate for a standard by which to assess ethical decision-making is the Accountability for Reasonableness Framework (AFR) which focuses on the process of decision-making rather than a specific moral theory. The framework was developed in the context of resource allocation decisions in health care but can be applied to other types of health care decision. [50] The AFR has four requirements, decisions must be transparent; based on reasons stakeholders can agree are relevant; revisable in the light of new evidence and arguments; and that there should be an appeals process. Other authors have highlighted the requirement for priority setting decisions by clinicians (including ICU admissions) to be transparent (AFR requirement 1) and ethically justifiable (AFR requirements 2 and 3). [51, 52] The use of such a framework as an evaluation tool requires refining and specifying, particularly in relation to requirement 2 (relevant reasons). Assessing the quality of ethical decision-making using a framework such as AFR would ideally be achieved by direct observation of the decision-making process. However observational studies will include small numbers of clinicians and would not enable us to evaluate consistency and transparency of process across a large number of decisions. As part of a current HS&DR funded project on decision-making around admissions to ICU (HSDR 13/10/14) we are developing an evaluation tool that can be applied to the relevant section of a patient's record to assess the impact of interventions (such as a ReSPECT form) on ethical decision-making. We plan to use this tool with a sample of patient records in the six hospitals where ReSPECT evaluation will take place in addition to observation and ethical analysis of the decision-making process (WP1a).

3.3.1 Method for WP1b

We will pilot and evaluate the performance of the evaluation tool, originally developed in HSDR project 13/10/14, in a sample of records as it may need adapting to reflect the different decision-making context.

For the main analysis we will purposively sample patient records according to type of ward, ReSPECT decision choice (Focus on Life Sustaining Treatment/ Focus on Symptom Control and CPR decision) age of patient, emergency or elective admission. This sampling will allow us to focus on records where the recorded decision is more likely to be complex and ethically challenging for clinicians. We will continue sampling until we are confident that there are no new changes in the pattern of consistency, transparency, and ethical reasoning

We anticipate that the tool will provide a categorisation framework [54] for assessing transparency and ethical reasoning, and will use a configurational comparative method for assessing consistency across records.

3.3.2 Data Collection for WP1b

Sampling of records for the pilot and main study

Pilot: We will collect information about the ReSPECT process and the ReSPECT form from clinical records. We anticipate this will be up to about 20 records.

Main study: For the main analysis an NHS researcher will purposively sample patient records according to type of ward, ReSPECT decision choice, age of patient, emergency or elective admission using a sampling frame developed form the pilot sample. This sampling will allow us to focus on records where the recorded decision is more likely to be complex and ethically challenging for clinicians. An initial sample of twenty records will be selected from the first participating Trust and analysis of these records will inform further sampling at the next Trust with analysis and sampling continuing in an iterative process across all six participating Trusts until we are confident that there are no new changes in the pattern of consistency, transparency, and ethical reasoning.

Data collection for both pilot and main studies: For each set of records an NHS researcher will identify the section of the records relating to the discussion about ReSPECT and any decision made, and will copy data from this section of the record, and the ReSPECT form, having removed any patient identifiers such as name, address and NHS number. The pseudo-anonymous records will then be transferred to the research team for analysis.

3.3.3 Data Analysis for WP1b

Using the developed and tested assessment tool, we will categorise each clinical record copied according to the degree to which our criteria of transparency and ethical justification are met. Our database will include the category for each clinical record and supporting data - usually

one or two sentences from the clinical record or ReSPECT form. We will describe our findings using descriptive statistics. Consistency of decision-making will be assessed through configurational comparative methods. [54, 55] This involves the comparison of configurations of attributes of cases and their supporting data. The criteria used for each categorisation of transparency and ethical reasoning will form the attributes. Comparative analysis will be undertaken comparing each case with each other case. The comparative analysis will be undertaken independently by two analysis teams and the results compared and discussed. We will continue collecting data until no further change in the level of consistency is identified.

3.3.4 Data management for WP1b

Patient records selected for WP1b will have the relevant sections copied and be anonymsied by NHS research staff before secure transfer from site to the University of Warwick in accordance with Warwick CTU SOPs.

4. WORK PACKAGE 2

4.1 Study Design

4.1.1 Objective

To quantify the effect of the introduction of ReSPECT on frequency of and outcomes from, in-hospital resuscitation attempts.

4.1.2 Rationale

A key concern of patients and relatives who contacted an end-of-life support line during our scoping review was that they would be subjected to resuscitation when it had little to no chance of success. [9] The National Confidential Enquiry into Patient Outcomes and Death (NCEPOD) report identified that resuscitation decisions were often not considered in patients admitted to hospital. [6] A key reason for this was their binary nature (for resuscitation or DNACPR) which does not allow decisions to be contextualised with other treatments. This meant that a large proportion of resuscitation attempts were undertaken in those where the NCEPOD reviewers considered a DNACPR decision should have been made prior to the cardiac arrest. These findings are consistent with data from National Cardiac Arrest Audit (NCAA) (2015-16) indicates that 6.5% of resuscitation attempts were terminated after arrival of the resuscitation team as they considered it was futile to continue.

We hypothesise that if the ReSPECT process is successful in allowing resuscitation decisions to be contextualised to overall treatment plans, the proportion of resuscitation attempts terminated by the resuscitation team as they consider resuscitation as futile will decline, the total number of resuscitation attempts will reduce and the proportion of patients, on whom CPR is attempted, surviving to go home from hospital (and their functional status) will improve.

4.2 Recruitment for WP2

Work package 2 will involve the use of anonymised data from the NCAA.

4.2.1 Withdrawals and Exclusions for WP2

WP2 is using routinely collected anonymised audit data form NCAA, so any concerns patients had about their anonymised information being included in the audit, should have been addressed by the organisation collecting the data at the time. Withdrawal will not be possible from the anonymised audit data provided to the study team.

4.3 Data Collection for WP2

NCAA collects data on hospital characteristics and individual patient demographic, resuscitation process and outcome variables for patients who sustain an in-hospital cardiac arrest and receive resuscitation by the hospital resuscitation team (or equivalent). Standardised case identification methods, data definitions, online and manual data validation ensures consistent, high quality data are collected. The NCAA Steering Committee has approved this study and for us to access the data. A sample of data will be transferred to allow the development and testing of statistical code before the final data transfer of the complete anonymised NCAA data set.

Our national audit (2014) indicates that approximately 80% of Acute NHS Trusts use the national DNACPR form (or a modified version) for making resuscitation decisions with the remainder using a system similar to the planned ReSPECT process. Although the new ReSPECT form and supporting documentation will be made available nationally in 2017, the time taken to incorporate into local Trust policies is likely to be variable. To establish baseline systems and time of change to ReSPECT we will contact the NCAA contact at each participating hospital at the start of the study and annually thereafter. The initial survey will establish (i) what system is currently in use at that Trust and how long it been in use (ii) when training for ReSPECT started (iii) when ReSPECT were first implemented (iv) when the entire organisation had adopted the ReSPECT form (v) proportion of patients who have a ReSPECT decision. Freedom of Information request will be made to each hospital, to gain as near complete information as possible in the final year of the study, since the initial survey did not yield a sufficient response rate to enable accurate analysis of the NCAA audit data.

Centres which switch from using a system of DNACPR decisions to ReSPECT between three and nine months of the launch of the national form will form the focus for the interrupted time series analysis. It is possible that some Acute NHS Hospital Trusts will not adopt the ReSPECT form or adoption may be very delayed. In this event such sites will be reported separately as observed counterfactual information.

Work package 2 will also involve an annual survey of acute Hospitals participating in NCAA to establish whether they have or intend to start using the ReSPECT process or not. A member of NHS staff, usually a Resuscitation Officer, responsible for the NCAA data will be asked to

complete the questionnaire.

4.3.1 Outcome measures

Primary: Proportion of resuscitation attempts that are terminated due to futility

Secondary:

(i) Number of in-hospital cardiac arrests attended by the resuscitation team per one thousand admissions
(ii) Patient status at team arrival (dead – resuscitation stopped; resuscitation on-going; ROSC achieved before team arrival; deteriorating (not yet arrested))
(iii) Proportion of resuscitation attempts that are terminated due to presence of a DNACPR (this represents a failure of implementation)
(iv) Vital status at hospital discharge (alive or dead)
(v) Proportion of shockable arrhythmic cardiac arrests
(vi) Cerebral Performance Category at discharge
(vii) Proportion of cardiac arrests to total number of hospital deaths

4.4 Data Management for WP2

WP 2- sites will be identified by a study number only, the data will be sent securely from NCAA in an anonymised format, in accordance with WCTU SOPs and a data sharing agreement between ICNARC, NCAA and the University of Warwick.

The survey to assess use of ReSPECT will be conducted via an electronic survey tool, the sites will have the same study number as the NCAA audit data to allow linkage. The person completing the survey (the person who completes the NCAA audit) will be sent the link to the survey by NCAA and asked to enter their site ID number and/or Hospital name, depending on feasibility. The survey software will be selected or developed by the WCTU programming team to ensure it is secure. If the Hospital name is used NCAA will link the survey data set to their NCAA set to ensure anonymity of the NCAA data set by preventing the co-ordinating study team holding both the name of a hospital and its study ID. NCAA will similarly be asked to link information provided through Freedom of Information Requests to the audit data.

4.5 Data Analysis for WP2

4.5.1 Statistical Methods

We will use undertake an interrupted time-series analyses to investigate the impact of ReSPECT implementation on key outcomes in the National Cardiac Arrest Audit, in particular, the proportion of resuscitation attempts that are terminated due to futility. In an interrupted time series, the outcome is observed over multiple equally spaced time periods before and after an intervention that is expected to change either its level or trend. A linear model is fitted to the series of outcomes observed prior to the intervention and another to the period following the

intervention (optionally with the period during which the intervention is being rolled out omitted). These two regression lines are then compared as regards slope (trend) and intercept (level). The counterfactual information for the post-intervention period may be predicted from the model for the pre-implementation period or obtained from observation of the same outcome in groups that are not implementing the intervention. A key advantage of Interrupted time series analysis is that it utilises aggregated rather than individual data (hence we can use existing audit data) and accounts for trends in observed outcomes prior to the intervention.

A statistical analysis plan will be created and approved before the interrupted time series analysis is undertaken.

4.5.2 Analysis

We will use interrupted time-series analyses (ITS) to investigate the impact of Respect implementation on key outcomes in the National Cardiac Arrest Audit, in particular, the proportion of resuscitation attempts that are terminated due to futility. The primary analysis will be a comparison of the group implementing the new ReSPECT form within three to nine months of the national implementation pre- and post-implementation. We anticipate that a period of between three and six months (depending on the speed at which the pilot/phase one is implemented) will need to be omitted from the data used for the interrupted time series analysis in order to ensure comparison of clean pre- and post- intervention periods. This analysis will compare predicted outcomes based on the model fitted to data from the pre-implementation period (i.e. we assume that the trend observed in the pre-implementation period is continued post implementation to estimate outcomes in the post- implementation time period, which is equivalent to assuming the new ReSPECT forms have no effect). As a secondary analysis we will examine actual (contemporaneous) outcomes in hospitals intending to keep using the old DNACPR forms.

197 hospitals contribute data to the NCAA programme in the UK and we will be able to obtain monthly data. By the time we come to perform the ITS analysis we will have at least 2 years (but possibly up to 5 years) of full NCAA data from the pre- implementation period and 1-2 years post-implementation. We will therefore have a minimum of 8 time points in each of the pre- and post- intervention time periods, as required for best performance of the ITS method.

The primary analysis will be performed using the ITSA command within Stata 13 with the Cumby-Huizinga test used to test for autocorrelation and determine the autocorrelation structure (identify the appropriate lag). The regression models will be calculated with Newey-West standard errors to deal with the autocorrelation and possible heteroscedasticity. Estimates of the model parameters (as appropriate) will be reported with associated 95% confidence intervals. Estimates of the trend in outcome during the post intervention period will also be reported with associated 95% confidence intervals. The results will also be presented graphically with observed and fitted data from the pre- and post-intervention periods plotted over time (quarterly) to illustrate the model fit and parameters estimated, with

appropriate counter factual information.

Sensitivity Analyses

We will explore the impact of choosing a longer or shorter implementation period to be omitted from the analysis. This will provide reassurance that the pre- and post-implementation periods are correctly identified. We will also investigate whether outcomes within patient subgroups, defined by hospital type, age, reason for admission, are consistent with our primary results.

Secondary analyses

The same (ITSA) approach will be used to investigate the impact of the intervention on vital status at hospital discharge (% alive), proportion of resuscitation attempts that are terminated due to presence of a DNACPR and proportion of cardiac arrests attended by the team that are shockable. The rate of in-hospital cardiac arrests attended by the resuscitation team per one thousand admissions over time will also be plotted over time to illustrate changes in slope and trend. Data on patient status at team arrival (dead – resuscitation stopped, resuscitation ongoing, ROSC achieved before team arrival, deteriorating (not yet arrested)), Cerebral Performance Category at discharge (Alive-1, Alive-2, Alive-3, Alive-4), the rate of in-hospital cardiac arrests and variance in the proportion of resuscitation attempts that are terminated due to futility over time will also be presented using appropriate descriptive methods.

The annual survey will be analysed descriptively and information about type of system used (e.g. DNACPR, other ECTP system or ReSPECT) and date when ReSPECT was implemented will be linked to the NCAA data to facilitate the ITS analysis using comparison groups described above.

5. WORK PACKAGE 3 –DESCRIPTIVE STUDY OF PATIENT CHARACTERISTICS, RESPECT PLAN CHOICE AND RISK OF HARM

5.1 Study Design

Retrospective observational study

Sampling: Six acute hospitals selected for work package one

Inclusion criteria: Adult in-patients

Exclusion criteria: Paediatrics, Neonates, day case admissions, refusal of consent.

5.1.1 Aim

The overall aim of this work package is to explore how widely ReSPECT is being used amongst patients in hospital and to examine associations between recommendations and patient

characteristics and their outcomes.

Within this broad framework, we will explore if DNACPR recommendations which are made in the context of an overall ReSPECT increase the risk of certain harms when compared with not having a DNACPR order in place.

This work package will also provide a broad understanding about how the ReSPECT process is used in practice.

5.1.2 Objectives

To present a descriptive summary of ReSPECT use in hospitalised patients, explore their relationship with patient characteristics and conduct an analysis of whether a DNACPR decision, made in the context of an overall treatment plan is independently associated with risk of patient harm.

5.1.3 Research Questions

1. What combinations of emergency care and treatment plans are recorded on ReSPECT. How are they related to patient characteristics and overall outcomes of patients?

2. Which patient characteristics predict assignment to particularly emergency care and treatment plans?

3. Which patient characteristics predict assignment to a DNACPR?

4. Do particular patient preferences and emergency care and treatment recommendations predict a DNACPR decision?

5. Is a DNACPR decision an independent predictor of patient harm?

5.1.4 Methods

We will conduct a retrospective case-note review that is synchronised with the routine collection of NHS Safety Thermometer data. In addition information on patient demographics, admission, comorbidities and functional status and ReSPECT decisions (or absence of ReSPECT decisions) will be extracted from clinical records. We will explore the associations between patient characteristics, resuscitation status, care group and risk of harm.

Assessments will be co-ordinated to occur simultaneously with the routinely collected NHS Thermometer Audit data. The majority of NHS Trusts contribute to the NHS Safety Thermometer programme. In the event that a research site does not routinely collect NHS Safety Thermometer data (or the national programme is unexpectedly withdrawn) they will be asked to collect Classic Safety Thermometer data for research purposes.

5.2 Recruitment and withdrawals for WP3

The intention is to assess in-patients across all clinical areas at participating hospital sites. Each in-patient clinical area will be assessed only on one occasion. As described in section 2.3 Ethical Considerations, information collected about a patient will be withdrawn in the event that a patient (or their legal representative or family member) advises the patient would not have wanted to take part in this way when they did have capacity to make their own decisions.

Patients will not only be able to inform the team they do not wish their information to be included in the study prior to data collection, but that they can also contact the team until the data set is locked for analysis to request their data are not used. The local contact will either remove the data from the data set, if data collection is still in progress. If the data set has been returned to the central study team, the local researcher will inform the study team giving the participants study ID and site ID. The study team will remove the data from the data set and record the action in the Study Master File in the appropriate section.

5.3 Data Collection for WP3

The following information will be extracted from the clinical and audit/or records:

(1) Demographics (age, gender, ethnicity, abbreviate home postcode as a proxy for social class), (2) Reason for admission, (3) Co-morbidities: Cognitive impairment (dementia, learning difficulties), Charlson co-morbidity index [56], GO-FAR sore [57] (both of which predict outcome from cardiac arrest), assessment of whether their condition is likely to be fatal (measured by McCabe Scale [58]), (4) ReSPECT (patient preference, emergency care treatment decisions, resuscitation status, capacity, who was involved in the discussions, when, where and by whom was the decision made), (5) NHS Safety Thermometer Audit data, (6) Length of hospital stay, survival to discharge, discharge location.

We will endeavour to ensure that researchers collect baseline data blind to ReSPECT classification. Practically what this means is that the researcher will first extract the baseline data, some of which may need some interpretation. Only when this is complete will they extract ReSPECT classification data which does not require any interpretation.

5.3.1 Outcomes

As our measure of patient harm we will use the data collected for the NHS Safety Thermometer. In participating Acute Trusts this point of care survey collects data on 100% of inpatients for one day each month. Our outcome of interest in the Classic Thermometer is ‘harm free care’ defined as none of the defined adverse events being present on the day of the assessment (pressure ulcers, urine infections in catheterised patients, falls, or venous thromboembolism). These are all events that would be associated with less intense care. If as a consequence of a DNACPR order, there are more of these events we will conclude that more work is needed to prevent iatrogenic harms caused by DNACPR orders leading to a lower level of care.

A second harm measure, the 'Medication Thermometer', is being rolled out in the NHS. This also a point of care survey collecting data on 100% of in-patients for one day each month. Our outcome of interest here is 'drug induced harm'. The survey identifies people who are using a specified list of high-risk medicines. There is then a discussion between a nurse, doctor and a pharmacist to assess if the patient has been harmed and the level of any harm. Harm will be defined as a moderate (or greater) incident which results in a moderate increase in treatment and which caused significant but not permanent harm. We will collect Medication Thermometer data where it is routinely available.

Standardisation of Data collection: NHS Safety Thermometer data will be extracted by NHS audit, clinical or site research staff who have been trained in the use of the tool. We are aware of variation in Thermometer measurements and will develop a training set of standardised cases in to improve consistency. We will work closely with the six sites to ensure the approach is standardised and report on reliability from the standardised cases.

5.4 Data Management for WP3

For WP 3, linking the CRF data and the NHS Thermometer data by patient identifiable data will be done by the research team at the site. Participants will be allocated the same study identifier in both data sets. The data set will be anonymised before secure transfer from site to the University of Warwick according to WCTU SOPs. A record of participant study number and NHS number used to link the participant to the study will be kept in a locked cabinet at the research site until data is locked for analysis at the end of the study or according to local research SOPs before being destroyed.

5.5 Data Analysis for WP3

Descriptive statistics will be used to summarise patient characteristics and outcomes according to patient personal preference, ReSPECT clinical treatment recommendation and resuscitation status. We will use appropriate multiple regression techniques to explore the associations between patient characteristics, resuscitation status (DNACPR or for resuscitation), care group and risk of harm and death. Firstly, by fitting a series of nested models with DNACPR (yes/no) as the dependent variable and patient characteristics and clinical treatment recommendation as indicated on the ReSPECT form) as the independent variables we will assess the influence of patient characteristics at baseline and patient preference on DNACPR decision and establish whether the patient preference adds information beyond that provided by the patient characteristics as regards the DNACPR decision. Secondly, we will use ordered logistic regression with care group ('Focus on Life-Sustaining Treatment' and 'Focus on Symptom Control' and 'No Decision') as the dependent variable and patient characteristics as the independent variables to assess whether patient characteristics influence the choice of care group. Finally, we will use logistic regression (conditional should we be able to match cases to controls), with and without adjustment for patient characteristics, with harm (yes/no, obtained from the NHS Safety Thermometer) as the dependent variable and care group ('Focus on Life-

Sustaining Treatment' and 'Focus on Symptom Control') and DNACPR (yes/no) as independent variables to assess whether focus of care group or DNACPR order independently influence risk of harm.

Sample size: As this is an exploratory analysis a formal sample size calculation is not appropriate.

Nevertheless, for generalisability we need to ensure a reasonable spread of patients/decisions, and in order to model risk of harm we need sufficient harmful events to have occurred. Based on our pilot data we expect 70% of patients to have a ReSPECT decision, of whom 20% will have a DNACPR decision. 20-30% will have no decision, which by default means they would receive resuscitation in the event of cardiac arrest. We therefore intend to enrol 3000 patients in this study (minimum 500 patients per site, six sites). Assuming a "harm rate" of 6.5% (based on 2014 NHS Thermometer data), this will provide 200 incidences of harm for the risk modelling. If possible, for the modelling of harms, we will match cases to controls in order to increase statistical power.

6. WORK PACKAGE 4 - FOCUS GROUPS WITH GENERAL PRACTITIONERS, COLLECTION OF CONTEXTUAL DATA ON IMPLEMENTATION AT SITES, SYNTHESIS OF FINDINGS AND IDENTIFICATION OF AREAS FOR IMPROVEMENT AND FURTHER WORK

6.1 Focus Groups

In addition to data collected in other work packages, we will conduct focus groups with general practitioners in the areas served by the six Trusts included in WP 1 and 3 to establish uptake and attitudes to ReSPECT in the community; focus groups may also include district nurses and other members of community health teams who are involved in the implementation and use of ReSPECT, if appropriate. Focus groups will be run by trained facilitators and will use the approach linked to continued professional development meetings used successfully in our previous NIHR DNACPR project. Where possible they will be audio recorded or detailed field notes taken. We will analyse the data for experiences of the use of the ReSPECT process, what influences its use and why, dilemmas encountered, and clinicians understanding of what happens to the ReSPECT form when a patient is admitted to hospital.

6.1.1 Recruitment for focus groups

Local site study teams and the local CRN will be asked for assistance with recruiting GPs, district nurses and other members of community health teams who are involved in the implementation and use of ReSPECT, from a variety of practices in the areas served by the 6 NHS Trust sites in WP 1 & 3. Information about the study will be available to the primary care practices and community health teams. We will seek written informed consent from participants prior to the focus group interview. In cases where the focus groups do not align with health professional continuing education needs or infrastructures, participants may be offered payment (£150 per participant) for taking part in a focus group.

6.1.2 Withdrawals and exclusions for focus groups

Focus group participants will be able to withdraw their data from the study prior to analysis, by contacting the study team.

6.1.3 Data Collection for focus groups

We will conduct focus groups with General Practitioners – and, if appropriate, district nurses and other members of community health teams – working in the areas served by the 6 NHS Trust sites in WP1 & 3 to establish uptake and attitudes to ReSPECT in the community. Focus groups will be run by trained facilitators and will use the approach linked to continued professional development meetings used successfully in our previous NIHR DNACPR project. Where possible they will be audio recorded or detailed field notes taken.

6.1.4 Data Management for focus groups

Consent will be taken and observational and interview data will be collected by researcher(s) from the co-ordinating study team. Data will be managed in the same manner as described in WP1 above.

6.1.5 Data Analysis for focus groups

A thematic content analysis will be conducted on the primary and community care focus group data. We will analyse the data for experiences of the use of the ReSPECT forms, what influences their use and why, dilemmas encountered, and clinicians understanding of what happens to the ReSPECT when a patient is admitted to hospital. The resulting findings will also be used in the narrative synthesis.

6.2 Early Adopters meetings

We will conduct regular meetings with representatives from the 6 sites involved in WP1 and WP3, from the national working group, which developed the ReSPECT process, and the research team (Early adopters' meetings). The meetings will involve discussion of sites experiences with implementing ReSPECT and preliminary findings from this study as they become available. This type of discussion has potential to elicit tacit knowledge from participants. Data, such as agreed summaries of key points emerging from the discussions and field notes, will be collected to provide contextual information for the study about site's implementation experiences and any relevant contextual information to supplement that collected by researchers during site visits (e.g. collation of documents see WP1).

6.2.1 Data collection for Early Adopters meetings

Summaries of topics discussed at the meetings between the site representatives, the ReSPECT national working group and the researchers will be made from information captured at the meetings. Summaries of this data relevant to the implementation and context of sites will be used to form contextual descriptions of each site and will be supplemented by contextual data

collected in WP1a from field notes, interviews with ReSPECT implementation leads and relevant documentation.

6.2.2 Data management for Early Adopters meetings

A descriptive summary of the context and implementation of ReSPECT at each site will be produced from field notes and documents collected in WP1, interviews with ReSPECT implementation leads and from data collected in meetings between site representatives, ReSPECT national working group members and the research team. The descriptions will include site demographics, relevant local or national contextual features or events impacting on implementation and the implementation processes used at the site. If the data allows we will also produce a descriptive summary of common experiences and key learning points across all sites.

6.3 Synthesis of findings

The ReSPECT process is intended provide a national system to be used in all healthcare settings to and provide a broader care and treatment plan context in which DNACPR decisions can be made. Concerns about the current DNACPR system have been outlined in the background section. The introduction of ReSPECT intends to address these issues by:

1) Routinising decisions in acute hospitals. This should support clinicians and patients to have difficult conversations including those about CPR, increase numbers of patients with a record of CPR decisions made prior to an emergency situation arising which include patients and family members in the process. With more decisions made routinely they could reduce inappropriate resuscitation attempts. Routinisation may also support clinicians with the process of making ethically challenging decisions about care in emergency situations.

2) Contextualising CPR decisions within broader care and treatment plans should improve care quality and the ethical basis and patient centeredness of decisions. This should reduce the risk of patients with DNACPR decisions receiving poor care and increasing their risk of sustaining an avoidable harm

3) A national system will reduce variability and inconsistency in practice and recognition of decisions within and between organisations and support improved communication.

We will narratively synthesise the findings from each work package to evaluate the extent to which the ReSPECT process has worked to address the issues, explore why they have (or have not) worked and to assess the ethical basis for decisions made using them.

From this synthesis and evaluation we aim to identify recommendations covering:

1. improvements or adaptations needed to be made to the ReSPECT forms or ways it has been used in acute hospitals
2. training needs both in terms of using the form and making ethical decision-making

3. further work/research needed to improve patient experience and outcomes
4. future work / research questions for evaluation in the community setting

Sharing preliminary results of this narrative synthesis and emerging recommendations with the Early Adopters group will provide an opportunity to refine and prioritize recommendations for patients, policy and clinical practice.

7. STUDY ORGANISATION AND OVERSIGHT

7.1 Sponsor and governance arrangements

University of Warwick is the lead sponsor with University Hospitals Birmingham NHS Foundation Trust as co-sponsor.

University Hospitals Birmingham NHS Foundation Trust will manage the financial aspects of the grant and has delegated management of the conduct of the study to the University of Warwick as per the co-sponsorship agreement.

7.2 Regulatory authorities/ethical approval

All required NHS ethical approval(s) for the study will be sought using the Integrated Research Application System.

Before enrolling patients into the study, each study site and co-ordinating team researchers involved must ensure that the local conduct of the study has confirmation of capability and capacity from the relevant NHS Trust Research & Development (R&D) department as well as overarching HRA approval in place. Data collection at sites will not be permitted to commence until written confirmation of HRA approval and R&D capability and capacity is received by Warwick Clinical Trials Unit.

The co-ordinating centre research team will be responsible for communicating substantial protocol amendments to the site research teams, the site R&D offices and any other parties who need to be informed.

7.3 Study Registration

The study will be eligible for inclusion on the CRN Portfolio and will be registered on the ISRCTN.

7.4 Indemnity

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

7.5 Study timetable and milestones

Figure 2 Plan of investigation and timetable

Evaluation of the Recommended Summary Plan for Emergency Care																							
Tasks	Year	Set-up	Year 1				Year 2				Year 3				Year 4								
			Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4					
Liason with HS & DR	Contracting																						
Management group meetings	Study Management Group (SMG)	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx					
Study oversight & patient advisory panel meetings	Study Steering committee (SSC)		x			x			x			x		x			x					
	Patient Advisory Panel		x		x		x		Held in Q4	x		x	SA4	x			x					
Ethics, R&D & HRA Approvals							SA1	SA2			SA3												
WP1 & 3 Site recruitment																							
Site set up								5/6 sites open		5/6 sites open			6th site to open										
WP1 - Case Studies	Development of data collection tools/processes																						
	Data collection - WP1a							On hold, 2/6 sites open	On hold, 2/6 sites open	On hold, 2/6 sites open	2/6 sites completed		4/6 sites completed	5th and 6th sites to open									
	Data collection - WP1b							4/6 sites ongoing	5/6 sites ongoing	4/6 sites completed 1 site ongoing	5/6 sites completed		6th site to open										
	Analysis																						
WP2 - Interrupted Time Series	NCAA Data collection																						
	Survey						x																
	Fredom of information request (to replace annual survey)																						
	Data transfer									Test set tranferred													
	Statistical analysis																						
WP3 - Prospective Case Note review	Development of data collection tools/processes																						
	Data collection - WP3							4/6 sites ongoing	1/6 sites completed 4/6 sites ongoing		5/6 sites completed		6th site to open										
	Analysis																						
WP4 - Narrative synthesis of findings	Early adopters meetings data collection (frequency determined by study progress)					x		x	x	Discontinued													
	Focus groups with General Practitioners						x					x	xxx	xx									
	Synthesis and write up of WP1, 2 & 3																						
	Final narrative synthesis including Stakeholder and PPI feedback																						
Dissemination	Stakeholder conference																						
	Conference presentations																						
Report writing	Final Report and paper writing																						
	Final Report submission																						

Q1: Nov - Jan
Q2: Feb - Apr
Q3: May - Jul
Q4: Aug - Nov

Milestones:

1) Research ethics, regulatory approval, data collection tool complete (WP 1) (6 months)

2) Site set up complete 6 sites, Data collection for WP1 complete at 2 sites (12 months)

3) Data collection for WP 1 complete at 4 sites; Data Transfer for WP 2 complete; WP 3 data collection complete (36 months)

4) Submission of final report (48 months)

7.6 Administration

The study co-ordination will be based at WCTU, University of Warwick.

7.6.1 Essential Documentation

A Study Master File will be set up according to WCTU SOP and held securely at the coordinating centre.

The coordinating centre will provide Site Master Files to all sites involved in the study.

7.7 Study Management Group (SMG)

The Study Management Group, consisting of the project staff and co-investigators involved in the day-to-day running of the study, will meet regularly throughout the project. Significant issues arising from management meetings will be referred to the Study Steering Committee or Investigators, as appropriate.

7.8 Study Steering Committee (SSC)

The study will be guided by a group of respected and experienced personnel and researchers as well as two 'lay' representatives. The SSC will have an independent Chairperson – Professor Bee Wee. Face to face meetings will be held at regular intervals determined by need but not less than once a year. Routine business is conducted by email, post or teleconferencing.

The Steering Committee, in the development of this protocol and throughout the study will take responsibility for:

- Major decisions such as a need to change the protocol for any reason
- Monitoring and supervising the progress of the study
- Reviewing relevant information from other sources
- Informing and advising on all aspects of the Study

7.9 Data Monitoring Committee (DMC)

Since there is no intervention delivered as part of the study a DMC is not required. We are also using a lot of routinely collected audit data (anonymised NCAA for WP2 and NHS Safety Thermometer data for WP3), so issues of safety should have been addressed by organisations collecting the data as part of their audit processes.

8. MONITORING AND QUALITY ASSURANCE OF STUDY PROCEDURES

All research team staff from the co-ordinating centre and the research team at the study sites involved in data collection for WP1 and WP3 will have had GCP training as part of their role. The co-ordinating team will seek confirmation of this training from the sites. PIs and members of the site researcher team will provide a CV to the study co-ordinating team at WCTU.

Training will also be carried out for WCTU administration staff who may answer phone calls from patients or legal representatives and need to deal sensitively with their questions.

WP1: All observations and interviews will be conducted by the co-ordinating team Research Fellow(s). Consent procedures, observation and interview schedules and a process for recording field notes will be developed and reviewed by researchers and co-applicants responsible for this work package, ensuring a consistent, but flexible approach needed for this type of data collection.

Quality assurance during analysis of qualitative data: coding will be undertaken by independent researchers for 30% of transcripts and any inconsistency discussed to ensure consistency.

Members of site research teams collecting and anonymising data from patient records about the ReSPECT process, including the ReSPECT form, will be trained by the study co-ordinating team researchers or study co-ordinator as part of the training for WP3 (see below). They will also check a proportion (c.10% from each site – the exact proportion will be decided once the sampling frame and quota numbers have been finalised) of this data to ensure that it has been anonymised before it was transferred to WCTU/WMS.

WP2: Data quality checks will have been done by the NCAA, according to their protocols, prior to transfer of the clean anonymised data set to University of Warwick for analysis.

WP3: The central team researchers and the study co-ordinator from University of Warwick will work with and train research nurses and the audit staff responsible for collection of the NHS Thermometer data at the six sites to ensure a standardised approach to data collection. A guide to completion of the CRF will be developed and given to each research site. Research nurses will be encouraged to liaise with the central research team about any challenges encountered with data collection. A small random sample of CRFs from each site may be audited by the co-

ordinating centre researchers and/or the study co-ordinator or study administrator to monitor the quality of CRFs. Data entered into the study database will be checked for accuracy in accordance with the WCTU SOPs and study Data Management Plan. The study electronic database will have quality control measures where possible, e.g. will not allow entry of data outside pre-set limits. Quality assurance checks on eligibility, completion of data, and the consent process will ideally be carried out during the data collection period at the site. Any issues identified will be recorded and then raised and discussed with the site research team and action agreed to ensure improved quality of data collection. As data is collected at only one time point at each site and this collection is likely to be completed within a fairly short time period, a pragmatic approach will need to be taken.

The quality of the NHS thermometer data – the study co-ordinating centre researchers and study co-ordinator will develop an approach and then work with trusts to ensure a consistent approach to data collection across sites. Each site is likely to have its own quality checks/processes to ensure it returns the best data to the national audit. The co-ordinating centre study team will work with the local audit departments and use existing local quality assurance processes. Again any process will be pragmatic due to data being collected on in-patients on a particular day at each site and the fact that we are using routinely collected audit data. Once the anonymised data set is returned to WCTU a random sample will be checked to ensure they are anonymised, to check the proportion linked between the CRF data and the NHS thermometer data and to check any variables that are consistently missing across cases, so any problems with the data quality or linkage can be resolved prior to analysis.

Visits to Sites: As data collection for WP1 is mostly going to be conducted by the co-ordinating centre researcher(s) initiation visits will be staggered to co-inside with the data collection. Each site will need a training visit prior to commencement of data collection for WP3. This training will be recorded on a log to keep who has received training and stored in the trial master file. If data has not yet been collected for WP1 at a site, the training and initiation visit is likely to be combined.

After the initial site visits to each hospital site the study co-ordinator will have regular contact with the sites to identify any problems with compliance with the protocol, training, data collection, or other barriers to progress, and to support sites with the day-to-day management of the study. As well as regular telephone and email contact, and the co-ordinating centre researcher visiting for data collection, a site visit may be arranged if there are particular issues that are best resolved face to face. The study coordinator will check with each site that all Investigator Site File documents are up to date at least once during the study.

9. PATIENT AND PUBLIC INVOLVEMENT (PPI)

This study is based on the output from a joint patient, public, clinician and policy maker

workshop in October 2014 to discuss the use of do not attempt resuscitation decisions in the NHS. (HSDR 12/5001/55) This workshop, chaired by a lay co-investigator Barry Williams, recommended a policy change from standalone DNACPR decisions to one which integrates decisions with overall treatment plans. Key priorities for implementation were to ensure effective communication and shared decision-making, that futile CPR would be avoided without reducing the quality of other aspects of care.

We hosted a follow-up focus group comprising of patients and patients family/friend at which the design and end-points for the study were discussed and refined. The group felt the overall design captured the key priorities from the initial meeting. The use of routinely available information was encouraged. Observation of decision-making was considered feasible provided it was handled sensitively. We had initially proposed to use patient experience questionnaires but these were rejected by the PPI group in favour of the richer perspectives that could be obtained from patient and relative interviews.

Patients and the public will be actively involved in all elements of this research

Strategic oversight: The Study Steering Committee, will have 2 patient and public representatives as full members.

Management: A PPI member will contribute to the day to day running and organisation of the study as a funded co-applicant. He will review patient information resources and contribute to the final report writing and dissemination.

Development of data collection tools/Analysis / interpretation: The members of the Patient Advisory Panel, including members of the initial focus group formed to discuss the study design and have discussed and advised on different consent approaches in this protocol. They have contributed to the development of areas for interview/observation in WP1. They will be involved in analysis of WP 1 and the overall interpretation synthesis of the study findings.

Support for our patient and public partners will be provided through University/User Teaching and Research Action Partnership (UNTRAP) and NHS Research Ambassador Group. UNTRAP provides advice and training for both patients and public and researchers. Any members of the team and management groups who have not already attended or who identify a need to attend such training will be offered the opportunity. We have included costs for UNTRAP involvement in the application.

10. DISSEMINATION AND PUBLICATION

The results of the study will be reported first to study collaborators. The main report will be drafted by the study co-ordinating team, and the final version will be agreed by the Study Steering Committee before submission for publication, on behalf of the collaboration.

The success of the study depends on the collaboration of doctors, nurses and researchers from across the UK. Equal credit will be given to those who have wholeheartedly collaborated in the study.

The study will be reported in accordance with the relevant reporting guidelines (http://www.equator-network.org).

10.1 Dissemination and projected outputs

We believe that the output of this work will have maximal impact through the adoption of a dissemination strategy with three strands. The first will ensure that patients and public are informed of the study results; the second will engage practitioners and health care planners locally to implement the findings and the third will involve consulting with policy makers for maximum impact.

Patients and public: Patient and public understanding of the issues of DNACPR are an essential part of any plans to inform policy. We will produce a 'plain English' summary of the study findings. We will disseminate the findings through the network of lay stakeholder organisations who will be engaged through the project as well as posting on NHS and University websites and social media (e.g. Twitter, Blogs). Through contacts with the Department of Education and Public Health England we will explore other opportunities for bringing to the attention of healthcare users. We will develop a briefing for the press through our NHS communication team in partnership with the National Science Media Centre to promote wider public dissemination.

Practitioners: This project will build on our network of multi-professional healthcare groups that will be used to share our findings. We will submit the key findings from the various work packages to open access, high impact journals with a wide general readership (e.g. BMJ, Lancet, Health Service Journal). We will seek opportunities to present the project findings at National meetings (e.g. Resuscitation Council (UK), Royal College of Physicians, Critical Care Outreach Forum etc.). We will prepare an executive summary suitable for distribution within the main report and distribute through the networks outlined below and work with the Resuscitation Council (UK) to incorporate the key findings into the national e-learning Immediate and Advanced Life Support Course (>100k healthcare practitioners undertake these courses a year).

Policy makers: We will continue engagement with key policy makers (NHS England, Department of Health, Clinical Commissioning Groups) during this body of work with the aim of ensuring the project delivers information of value to any future changes to policy. The project will summarise the key successes and limitations of ReSPECT. It will assist policy makers by providing an evidence base to inform the need for any changes or refinement to policy.

A stakeholder meeting will provide the opportunity to present the findings to policy makers,

managers, patient and public involvement representatives and clinicians. The strategies for dissemination described in the previous section could have the following impacts.

For patients and the public, knowledge about the effects and impacts of the emergency care and treatment plans could be used to enable them on a personal level to become more involved in decision-making about these aspects of care. If emergency care and treatment plans do reduce inappropriate attempts at resuscitation it should increase the number of patients who experience a peaceful death and reduce the effects of coping with a traumatic death for relatives and friends. If patient and relative involvement in decision-making is improved, it should be empowering and reduce the stress in dealing with what are already difficult circumstances. The knowledge about patient experience (or not) generated by the study could be used by individuals and patient and public organisations to inform to public discussion.

For clinicians, the project will provide a summary of the impact of ReSPECT. We will specifically seek out exemplars as best practice to show case how ReSPECTs are best used to support ethical decision-making in partnership with patients and relatives. Clinicians will learn about the impact of ReSPECT on other aspects of care which will hopefully build confidence in the use of ReSPECT.

The results/findings will provide stakeholders with information for decision-making about the continued use of ReSPECT at national and local level. It may also provide information about improving its good impacts or addressing any unintended consequences. It will contribute to health policy by addressing the Health Select Committee's recommendation (March 15) to review DNACPR decision-making in acute hospitals.

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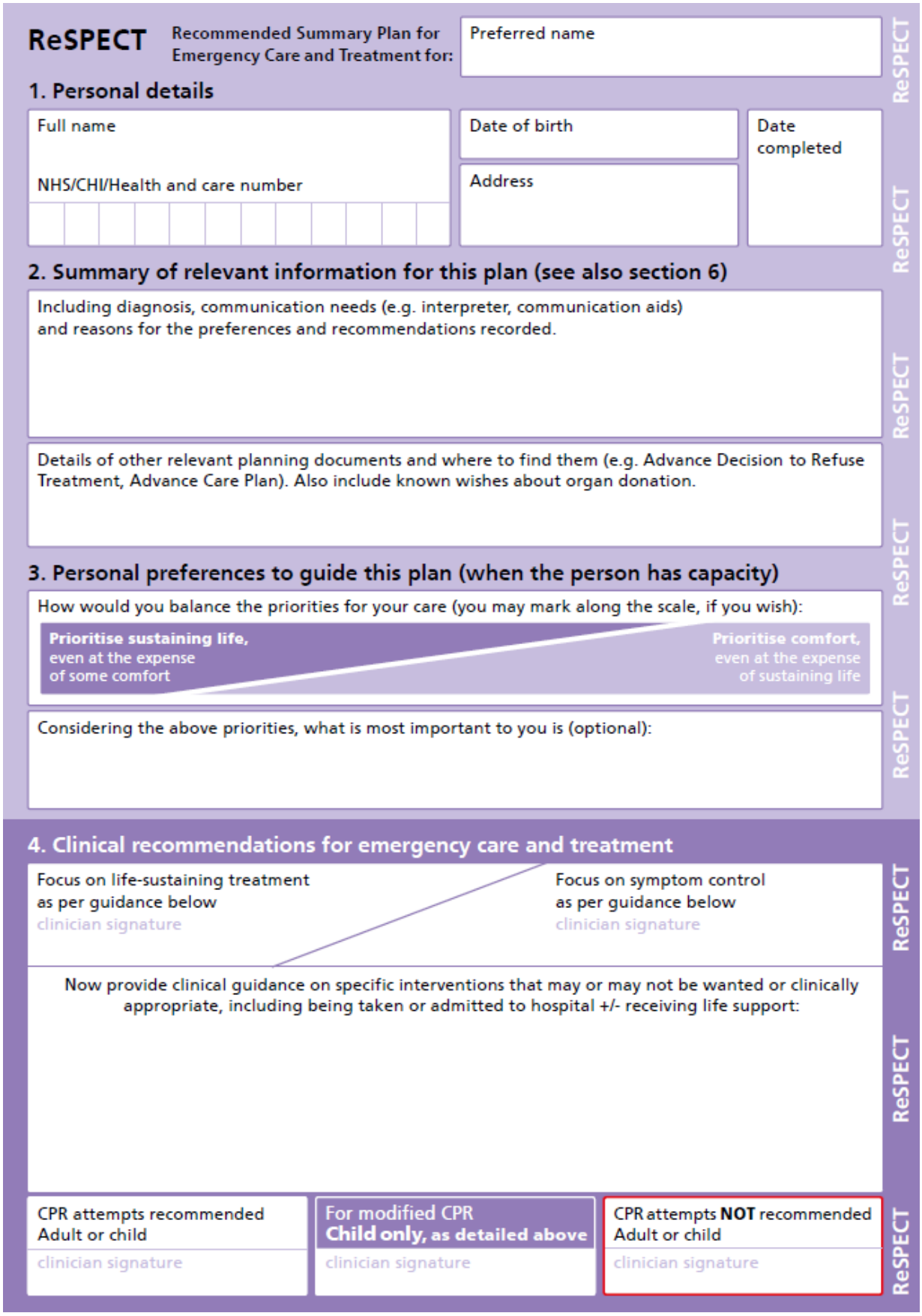
APPENDIX 1 - ReSPECT form



ReSPECT Recommended Summary Plan for Emergency Care and Treatment for:

Preferred name

ReSPECT

1. Personal details

Full name

NHS/CHI/Health and care number

Date of birth

Address

Date completed

ReSPECT

2. Summary of relevant information for this plan (see also section 6)

Including diagnosis, communication needs (e.g. interpreter, communication aids) and reasons for the preferences and recommendations recorded.

ReSPECT

Details of other relevant planning documents and where to find them (e.g. Advance Decision to Refuse Treatment, Advance Care Plan). Also include known wishes about organ donation.

ReSPECT

3. Personal preferences to guide this plan (when the person has capacity)

How would you balance the priorities for your care (you may mark along the scale, if you wish):

Prioritise sustaining life, even at the expense of some comfort

Prioritise comfort, even at the expense of sustaining life

ReSPECT

Considering the above priorities, what is most important to you is (optional):

ReSPECT

4. Clinical recommendations for emergency care and treatment

Focus on life-sustaining treatment as per guidance below

clinician signature

Focus on symptom control as per guidance below

clinician signature

ReSPECT

Now provide clinical guidance on specific interventions that may or may not be wanted or clinically appropriate, including being taken or admitted to hospital +/- receiving life support:

ReSPECT

CPR attempts recommended Adult or child

clinician signature

For modified CPR **Child only, as detailed above**

clinician signature

CPR attempts **NOT** recommended Adult or child

clinician signature

ReSPECT

5. Capacity and representation at time of completion

Does the person have sufficient capacity to participate in making the recommendations on this plan? **Yes / No**

Do they have a legal proxy (e.g. welfare attorney, person with parental responsibility) who can participate on their behalf in making the recommendations? **Yes / No / Unknown**
If so, document details in emergency contact section below

6. Involvement in making this plan

The clinician(s) signing this plan is/are confirming that these recommendations have (circle at least one):

- **A** been recorded after discussion involving this person, who has sufficient mental capacity to participate in making relevant decisions
- **B** where appropriate, been discussed with a person holding parental responsibility
- **C** in the case of a person who does not have sufficient mental capacity to participate in relevant decision-making, been made in accordance with capacity law
- **D** been made without involving the patient (or best interests/overall benefit meeting if the patient lacks capacity)

If **D** has been circled, state valid reasons here. Document full explanation in the clinical record.

Date, names and roles of those involved in discussion, and where records of discussions can be found:

7. Clinicians' signatures

Designation (grade/speciality)	Clinician name	GMC/NMC/ HCPC Number	Signature	Date & time
Senior responsible clinician				

8. Emergency contacts

Role	Name	Telephone	Other details
Legal proxy/parent			
Family/friend			
GP			
Lead Consultant			
Other			

9. Confirmation of validity (e.g. for change of condition)

Review date	Designation (grade/speciality)	Clinician name	GMC/NMC/ HCPC number	Signature