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# ReSPECT Evaluation study

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|---|---|---|
| **Submission date**<br>03/08/2017 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[X] Protocol |
| **Registration date**<br>05/09/2017 | **Overall study status**<br>Completed | [_] Statistical analysis plan<br>[X] Results |
| **Last Edited**<br>18/10/2022 | **Condition category**<br>Other | [_] Individual participant data |

## Plain English summary of protocol

Background and study aims
A national group of patients, healthcare professionals and organisations have been working together to develop the Recommended Summary Plan for Emergency Care and Treatment (ReSPECT) process. It aims to respect patient preferences and respect clinical judgment through shared conversations between a person and their healthcare professionals. One of its principal aims is to make sure people understand the care and treatment options that may be available to them and that may work in a medical emergency, and to allow them to make healthcare professionals aware of their preferences. Although the idea of emergency plans sounds good, experience (e.g. the Liverpool Care Pathway) has taught that it is important to test any changes to the way things are done. Therefore, this project plans to study how, when and why these emergency treatment plans are made and the effects they have on patient care. It will use a mixture of methods for collecting information to achieve this aim. The project will look at people coming into hospital, as this is where most decisions will be made initially. The study will involve researchers watching emergency treatment decisions being made in hospital. Doctors, nurses, patients and family members are interviewed to ask them about their experience. This is done to find out when decisions are made and check they are being made consistently and are ethical. National resuscitation audit data is used to see what effect emergency treatment plans have on the number of people having resuscitation and what happens to them afterwards. The study will also look at how emergency treatment plans affect overall patient care. The overall aim of this study is, through our partnership with key national organisations, this study will produce the essential information to inform the future use of emergency plans throughout the NHS.

Who can participate?
Adult patients involved in the ReSPECT process, relatives of adult patients, GP's and NHS trust staff members.

What does the study involve?
This study consists of four work packages with a different sample of participants for each one. The first work package involves observations and interviews with clinicians, patients and relatives and the review of patient clinical records involved in the decision-making for the ReSPECT process. The second work package involves collecting routine audit data on a national scale; therefore, participants will not be required to do anything. This work package also involves distributing a survey on a national scale which requires completion from a member of NHS staff, usually a resuscitation officer, responsible submitting national audit data from their

hospital. The third work package involves collecting information from participant's medical record on a selected data collection date whilst they are an in-patient in hospital. The participant will not be required to do anything unless they wish to opt-out of their data being used. Lastly, the fourth work package will require general practitioner participants to take part in a focus group discussion.

What are the possible benefits and risks of participating?
There are no direct benefits or risks with participating.

Where is the study run from?
1. Heartlands Hospital (UK)
2. University Hospitals Coventry and Warwickshire NHS Trust (UK)
3. Queen Elizabeth Hospital (UK)
4. Manchester Royal Infirmary (UK)
5. Hampshire Hospitals NHS Foundation Trust (UK)
6. Addenbrookes Hospital (UK)

When is the study starting and how long is it expected to run for?
November 2016 to November 2020

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
respect@warwick.ac.uk

### Study website
http://www2.warwick.ac.uk/fac/med/research/hscience/ctu/trials/respect

# Contact information

### Type(s)
Public

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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
REGO-2017-1916

# Study information

### Scientific Title
Evaluation of the Recommended Summary Plan for Emergency Care and Treatment

### Study objectives
The aim of this evaluation study is to determine, in adults admitted to acute NHS hospitals where emergency care and treatment is provided, how, when and why are Recommended Summary Plans for Emergency Care and Treatment plans (ReSPECT) made and what effects do they have on patient care.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Coventry and Warwickshire Research Ethics Committee, 12/06/2017, ref: 17/WM/0134

### Study design
This study will evaluate the ReSPECT process using a mixed-methods approach across four work packages in 6 acute NHS trusts, GP focus groups and using UK wide audit data.

### Primary study design
Observational

### Secondary study design
Case series

### Study setting(s)
Hospital

### Study type(s)
Other

### Participant information sheet
Participant information sheets can be accessed here: http://www2.warwick.ac.uk/fac/med/research/hscience/ctu/trials/respect/health/

### Health condition(s) or problem(s) studied
Emergency care treatment escalation plans

### Interventions

This study evaluates the ReSPECT process, it is therefore not an intervention but rather an evaluation of a process already in place. The evaluation is conducted across four work packages with a mixed-methods approach.

WP1a: 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.

## Intervention Type
Behavioural

## Primary outcome measure
The study design is a mixed methods evaluation consisting of qualitative and quantitative methods. WP1 and WP4 use qualitative methods; therefore, they do not have a primary outcome measure.

WP2:
Number of resuscitation attempts that are terminated due to futility is measured using the National Cardiac Arrest Audit Dataset at point of data analysis

WP3:
1. Pressure ulcers is measured using the NHS Classic Safety Thermometer Audit Dataset at point of data collection on specified day
2. Urine infections in catheterised patients is measured using the NHS Classic Safety Thermometer Audit Dataset at point of data collection on specified day
3. Falls is measured using the NHS Classic Safety Thermometer Audit Dataset at point of data collection on specified day
4. Venous thromboembolism is measured using the NHS Classic Safety Thermometer Audit Dataset at point of data collection on specified day
5. Drug induced harm is measured using the NHS Medication Safety Thermometer Audit Dataset at point of data collection on specified day

## Secondary outcome measures

WP2:
1. Number of in-hospital cardiac arrests attended by the resuscitation team per one thousand admissions is measured using National Cardiac Arrest Audit Dataset at point of data analysis
2. Patient status at team arrival (dead – resuscitation stopped; resuscitation on-going; ROSC achieved before team arrival; deteriorating (not yet arrested) is measured using National Cardiac Arrest Audit Dataset at point of data analysis
3. Proportion of resuscitation attempts that are terminated due to presence of a DNACPR (this represents a failure of implementation) are measured using National Cardiac Arrest Audit Dataset at point of data analysis
4. Vital status at hospital discharge (alive or dead) is measured using the National Cardiac Arrest Audit Dataset at point of data analysis
5. Proportion of shockable arrhythmic cardiac arrests is measured using the National Cardiac Arrest Audit Dataset at point of data analysis
6. Cerebral Performance Category at discharge is measured using the National Cardiac Arrest Audit Dataset at point of data analysis

WP3:
1. Demographics (age, gender, ethnicity, abbreviated home postcode as a proxy for social class) are measured using patient notes at point of data collection on specified day
2. Reason for admission is measured using patient notes at point of data collection on specified day
3. Co-morbidities: Cognitive impairment (dementia, learning difficulties), Charlson co-morbidity index, GO-FAR sore
(both of which predict outcome from cardiac arrest), assessment of whether their condition is likely to be fatal is measured by McCabe Scale at point of data collection on specified day
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) is measured using patient notes at point of data collection on specified day
5. NHS Safety Thermometer Audit data at point of data collection on specified day
6. Length of hospital stay, survival to discharge, discharge location is measured using patient notes at point of data collection on specified day

### Overall study start date
01/11/2016

### Completion date
01/11/2020

## Eligibility

### Key inclusion criteria
WP1a:
1. Adult in-patients involved in discussions for the ReSPECT process
2. Relatives of adult patients without capacity, involved in discussions for the ReSPECT process
3. Clinicians completing the ReSPECT process

WP2:
Anonymised patient audit data from National Cardiac Arrest Audit (NCAA) from all participating UK hospitals

WP3:
Adult in-patients in the 6 NHS trust hospitals recruited

WP4:
1. GPs working in practices served by the 6 NHS trust Sites in WP1 and WP3
2. NHS trust staff and members of the National Working Group that developed ReSPECT attending meetings to share experiences of implementing ReSPECT

### Participant type(s)
Mixed

### Age group
Adult

### Sex
Both

### Target number of participants
4120

### Key exclusion criteria
WP1:
1. Adult in-patients without a ReSPECT form
2. Neonates, pediatric, day case patients and others refusing consent (WP1a) or who opt-out (WP1b)
3. Clinicians not involved in completing ReSPECT forms

WP2:
N/A

WP3:
Paediatrics, Neonates, day case admissions, patients who opt-out

WP4:
GPs from practices not serving the 6 NHS Trust sites in WP1 and WP3

### Date of first enrolment
08/08/2017

### Date of final enrolment
31/05/2020

## Locations

### Countries of recruitment
England

United Kingdom

**Study participating centre**
**Heartlands Hospital**
Heart of England NHS Foundation Trust
Bordesley Green East
Birmingham
United Kingdom
B9 5SS

**Study participating centre**
**University Hospitals Coventry and Warwickshire NHS Trust**
Clifford Bridge Road
Coventry
United Kingdom
CV2 2DX

**Study participating centre**
**Queen Elizabeth Hospital**
University Hospitals Birmingham NHS Foundation Trust
Mindelsohn Way
Birmingham
United Kingdom
B15 2TH

**Study participating centre**
**Manchester Royal Infirmary**
Manchester Royal Infirmary
Central Manchester University Hospitals NHS Trust
Oxford Road
Manchester
United Kingdom
M13 9WL

**Study participating centre**
**Hampshire Hospitals NHS Foundation Trust**
Aldermaston Road
Basingstoke
United Kingdom
RG24 9NA

**Study participating centre**

**Addenbrookes Hospital**
Cambridge University Hospitals NHS Foundation Trust
Hills Rd
Cambridge
United Kingdom
CB2 0QQ

# Sponsor information

**Organisation**
University of Warwick

**Sponsor details**
Research & Impact Services
University House, Kirby Corner Road
Coventry
England
United Kingdom
CV4 8UW

**Sponsor type**
University/education

**Website**
http://www2.warwick.ac.uk/

**ROR**
https://ror.org/01a77tt86

**Organisation**
Heart of England NHS Foundation Trust

**Sponsor details**
Heartlands Hospital
Bordesley Green East
Birmingham
England
United Kingdom
B9 5SS

**Sponsor type**
Hospital/treatment centre

# Funder(s)

### Funder type
Not defined

### Funder Name
NIHR HS & DR programme (project number 15/15/09)

# Results and Publications

### Publication and dissemination plan
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: 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: 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.).

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.

A stakeholder meeting will provide the opportunity to present the findings to policy makers, managers, patient and public involvement representatives and clinicians.

A PDF link to the study protocol can be found here: http://www2.warwick.ac.uk/fac/med/research/hscience/ctu/trials/respect/studyoverview/

### Intention to publish date
01/11/2021

### Individual participant data (IPD) sharing plan
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 and an electronic database with access restricted to staff working on the study.

Written informed consent will be obtained from participants in WP1a (observations and interviews with clinicians, patients and relatives) and WP4 (focus groups with General Practitioners). WP2 will involve the use of anonymised data collected routinely from NCAA which we have approval from NCAA steering committee to use. WP2 will also involve an annual survey of acute NHS trusts who routinely submit data to NCAA. Completion of the survey indicates their agreement to take part. An opt-out consent process will be used for WP1b and WP3 where participants can choose to opt-out of data being collected from their medical records.

## IPD sharing plan summary

Stored in repository

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Preprint results | Focus group results in preprint | 12/08/2021 | 20/12/2021 | No | No |
| Results article | | 29/06/2022 | 04/07/2022 | Yes | No |
| Protocol file | version 5.0 | 20/06/2019 | 18/10/2022 | No | No |
| HRA research summary | | | 28/06/2023 | No | No |