Which patients received a ReSPECT form, what was documented and what were the patient outcomes? A protocol for a retrospective observational study investigating the impact of the COVID-19 pandemic on the implementation of the ReSPECT process

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ABSTRACT

Introduction: Recommended Summary Plan for Emergency Care and Treatment (ReSPECT) is a UK advance care planning (ACP) initiative aiming to standardise the process of creating personalised recommendations for a person’s clinical care in the future emergency and therefore improve person-focused care. Implementation of the ReSPECT process across a large geographical area, involving both community and secondary care, has not previously been studied. In particular, it is unknown whether such implementation is associated with any change in outcomes for those patients with a ReSPECT form. Implementation of ReSPECT in the Bristol, North Somerset and South Gloucestershire (BNSSG) Clinical Commissioning Group (CCG) area overlapped with the first UK COVID-19 wave. It is unclear what impact the pandemic had on the implementation of ReSPECT and if this affected the type of patients who underwent the ReSPECT process, such as those with specific diagnoses or living in care homes. Patterns of clinical recommendations documented on ReSPECT forms during the first year of its implementation may also have changed, particularly with reference to the pandemic.

To determine the equity and potential benefits of implementation of the ReSPECT form process in BNSSG and contribute to the ACP evidence base, this study will describe the characteristics of patients in the BNSSG area who had a completed ReSPECT form recorded in their primary care medical records before, during and after the first wave of the COVID-19 pandemic; describe the content of ReSPECT forms; and analyse outcomes for those patients who died with a ReSPECT form.

Methods and analysis: We will perform an observational retrospective study on data, collected from October 2019 to 12 months. Data will be exported from the CCG Public Health Management data resource, a pseudonymised database linking data from organisations providing health and social care to people across BNSSG. Descriptive statistics of sociodemographic and health-related variables for those who completed the ReSPECT process with a clinician and had a documented ReSPECT form in their notes, in addition to their ReSPECT form responses, will be compared between before, during and after first COVID-19 wave groups. Additionally, routinely collected outcomes

STRENGTHS AND LIMITATIONS OF THIS STUDY

This is the first study to examine the implementation of the Recommended Summary Plan for Emergency Care and Treatment (ReSPECT) process, a national advance care planning (ACP) initiative, across a large geographical area, approximately one million patients living in the Bristol, North Somerset and South Gloucestershire region of the UK.

Use of data from a linked dataset allows not only a description of how the ReSPECT process was implemented as the COVID-19 pandemic progressed but also an analysis of any difference between measured healthcare outcomes for those who died with a ReSPECT form and those who died without one.

Due to the nature of routinely collected data, missing data are a potential problem. To address this, codes have been carefully selected to reflect the most reliably recorded data and sensitivity analyses were performed as appropriate.

Individual general practitioner practices may opt not to contribute data. Local studies that have previously used the same approach to obtain data have reported low opt-out numbers. However, if the number of practices opting out becomes significant, we will contact each practice individually to understand their concerns and explore how our study could be modified to their satisfaction.

The impact of COVID-19 and the subsequent increased public and professional emphasis on ACP is likely to be reflected in the study findings, and this has implications for understanding the effects of the pandemic on ACP initiatives.
for patients who died in our study period will be compared between those who completed the ReSPECT process with a community clinician, hospital clinician or not at all. These include emergency department attendances, emergency hospital admissions, community nurse home visits, hospice referrals, anticipatory medication prescribing, place of death and if the patient died in preferred place of death.

**Ethics and dissemination** Approval has been obtained from a National Health Service Research Ethics Committee (20/YH/0185). Findings will be disseminated to policy decision-makers, care providers and the public through scientific meetings and peer-reviewed publication.

**INTRODUCTION**

The Recommended Summary Plan for Emergency Care and Treatment (ReSPECT) process has been developed by a national working group composed of professional healthcare organisations, regulatory bodies and patient representatives working in conjunction with the Resuscitation Council UK. It is intended as a standardised solution to inconsistent practices of advance care planning (ACP) and do not attempt cardiopulmonary resuscitation (DNACPR) documentation, and implementation has already taken place across various regions of the UK. The ReSPECT process involves discussion between patients, their carers and clinicians and results in a ReSPECT form being completed by a clinician recording patient preferences for treatment, beyond simply documenting cardiopulmonary resuscitation (CPR) decisions.

The authors of a study detailing the development of the ReSPECT process commented that ‘robust evaluation of the effectiveness of ReSPECT in achieving its overall goals will be essential’, and this evidence base is still being built. The National Institute of Health Research has funded a mixed-methods evaluation of early adopting healthcare organisations, regulatory bodies and patient representatives working in conjunction with the Resuscitation Council UK educational material clarifying the ReSPECT form is not simply a replacement for DNACPR forms, later consultant interview studies (2019–2020) found that CPR was still dominating ReSPECT conversations and that, again, these conversations were mainly taking place with acutely unwell patients.

An additional explanation for why the ReSPECT form has not yet been shown to have fully achieved its aims may be due to most of these studies taking place in hospital settings. This may be especially important as it has been shown that general practitioner (GP)-led ACP discussions are associated with a decrease in the likelihood of patients dying in hospital compared with those patients who had ACP discussions with other healthcare professionals. A 2019 ReSPECT study which did look at the use of ReSPECT in the community found that GPs discussed plans beyond CPR, such as possible hospital admission and symptom management. Although it was noted that GPs were still not using the ReSPECT form entirely in line with the original aims, with their focus being on primary care-related decisions such as preferences for hospital admission without consideration of specific hospital-based interventions.

In light of these conflicting results, the existing literature recommends further work to adequately train clinicians in the ReSPECT process, specifically regarding the breadth of its desired aims and improved patient and family involvement in decisions and their documentation. This has informed the development of V.3 of the ReSPECT form (2020). Further recommendations include that future studies specifically explore the interplay of the ReSPECT form between primary and secondary care settings, which are considered in this study.

**Implementation of respect in a UK region**

In the Bristol, North Somerset and South Gloucestershire (BNSSG) Clinical Commissioning Group (CCG) area, the ReSPECT process was launched in October 2019. Shortly after this launch, the COVID-19 pandemic began, which has presented the NHS with unprecedented national challenges. The first UK cases were diagnosed in late January 2020 and, as of 5 April 2022, there have been 186,921 deaths in the UK due to COVID-19. Patients most vulnerable to COVID-19 are the elderly and those with chronic health conditions. These groups have significant overlap with those patients that the NHS Forth Valley report identified as being appropriate for the ReSPECT process.

In the weeks preceding the first rapid increase
of COVID-19 cases in the UK, the NHS emphasised the importance of ACP. For clinicians, National Institute for Health and Care Excellence guidance was updated with COVID-19 rapid guidelines stating that clinicians should discuss ACP with patients at risk of deterioration due to COVID-19.18 For patients, document templates such as the ‘My COVID-19 Advance Care Plan’ were produced.19 The result of this increased focus on ACP is evidenced by a large patient population, specifically the approximately one million patients served by the BNSSG CCG.

It is not clear how the pandemic affected the implementation of the ReSPECT process both in the BNSSG area and nationally. The Royal College of General Practitioners suggested that the pandemic made certain aspects of sensitive ACP conversations more difficult due to the reduction in face-to-face consultations. Conversely, these conversations may have been easier, with some patients seeing an increased relevance in ACP for them or their loved ones. This is a view substantiated by a 2020 evidence synthesis report.23 24 It is also unknown how many ReSPECT forms have been completed during the pandemic, who were receiving them and what recommendations were being documented. This is particularly important as there have been concerns in both the media and various healthcare organisations that ACP and DNACPR documents have been ‘applied in a blanket manner to whole groups’ such as care home residents.25 26

It should also be considered that irrespective of the pandemic, all published studies on the ReSPECT form have included small samples and the majority have been secondary care orientated. This study is the first to explore the implementation, use and outcomes of all documented ReSPECT forms (from primary and secondary care) for a large patient population, specifically the approximately one million patients served by the BNSSG CCG.

There are two unknowns that contribute to the rationale for this study. First, the implementation of the ReSPECT process in the BNSSG area was started 4 months before the pandemic began. In this period, it is reasonable to assume that clinicians were still adapting to the new process. As the pandemic began, it is also likely that clinicians’ usage of the ReSPECT form changed due to both gained experience and necessity. We will explore which patients were receiving a ReSPECT form during the first year of implementation and any changing patterns over the year. We will also explore the equity of which patients had a documented ReSPECT form such as the proportion of those with a cancer diagnosis or those in a care home or similar communal residence. Additionally, the impact of the ReSPECT process on patient outcomes in emergency and ‘end-of-life’ situations during the pandemic has not yet been investigated. Therefore, through investigation of the ReSPECT form implementation and its outcomes, we hope to inform future ReSPECT form usage in the BNSSG area, future implementation processes across the UK, and contribute to the evidence base for any subsequent effects on the patient outcomes.

Aims

The aims of this study were to describe the characteristics of patients in the BNSSG CCG area who had a ReSPECT form recorded in their primary care medical records before, during, and after the first wave of the COVID-19 pandemic and to analyse any differences in outcomes for those patients who died with a community-completed ReSPECT form, a hospital-completed ReSPECT form or without a ReSPECT form.

Objectives

- To quantify how many ReSPECT forms were completed before, during and after the first peak of COVID-19 and the clinical and demographic characteristics of patients with a documented form.
- To describe any changes in clinical and demographic characteristics of patients with a ReSPECT form added to their notes during these periods.
- To identify any changes in patterns of priorities, recommendations and DNACPR decisions documented on ReSPECT forms during these periods.
- To measure any differences in routinely collected outcomes for those patients who died with a ReSPECT form that was completed either in the community or in hospital or who died without a ReSPECT form. These outcomes are emergency department (ED) attendances, emergency hospital admissions, district nurse home visits, hospice referrals, prescription of anticipatory medication and if the patient died in their preferred place of death (if documented).

METHODS

Study overview and setting

This is a quantitative study, conducted in two phases, which will take place within the BNSSG CCG area:

- Implementation phase—an observational cross-sectional study of all patients for whom a ReSPECT form was completed between 1 October 2019 and 30 September 2020. We will evaluate the number of ReSPECT forms completed across all general practices and secondary care settings in the BNSSG CCG area before, during and after the first COVID-19 wave. Across these time periods, we will describe any changes in clinical and demographic patterns of patients with ReSPECT forms, along with any shifting patterns in the priorities, recommendations and DNACPR decisions documented.
- Outcomes phase—a retrospective cohort study of all patients who died between 1 October 2019 and 30 September 2020. We will compare any differences between routinely collected outcomes for those patients who died with a ReSPECT form completed in the community, those who completed a ReSPECT form in the hospital or those who died without a ReSPECT form. These outcomes will be
ED attendances, emergency hospital admissions, community nurse visits, hospice referrals, prescription of anticipatory medication (and how long before death), place of death and whether the patient died in their preferred place of death (if documented). Only deceased patients are included in this phase as their patient journey is ‘complete’ and any difference in outcomes is likely to give a fully representative picture.

Implementation phase
Design
We will undertake an observational cross-sectional study of those patients with ReSPECT forms. This will provide the number of ReSPECT forms completed within the study population, along with patient demographics, medical conditions and ReSPECT form details.

Data collection
These data will be collected from the Public Health Management (PHM) data resource (also known as the System Wide Dataset), retrospectively from 1 October 2019 to 30 September 2020. The PHM data resource is used for various purposes by the CCG, one of those being population health management. The PHM data resource routinely collects administrative health and social care data from primary care, secondary care, community services, mental health and adult social care for the local population in the BNSSG area. For a defined set of purposes focusing on population health management, BNSSG CCG may choose to commission named providers to analyse, for a limited time, effectively anonymised minimised extracts of these data. This particular study is being undertaken for the purposes of reviewing, evaluating and transforming current health and care service provision across and within the population. Our study team (as a named provider) works as a data processor under a project-specific data sharing agreement (DSA), which is designed in reference to the overarching data protection and impact assessment.

The PHM dataset consists of two tables: attributes and activity. The first table contains information regarding patient characteristics, such as demographic information (age and sex), clinical information (long-term conditions), socioeconomic information (deprivation index), as well as other data like smoking status and social status. The second table contains information regarding patient contacts such as point of delivery (eg, secondary care, inpatient and elective), specialty (eg, dermatology), provider, dates, times and cost. More details of its contents can be found in the Github online repository.

The BNSSG area represents a diverse population from both urban and rural areas. In 2017, the BNSSG population was approximately 951,000, with a median age of 36, just below the national median age of 40.4. Of the BNSSG population, 9.8% have black and Asian ethnicity. This is slightly below the national average of 14.6% but represents a large amount of local variation, with Bristol above the national average at 16%. BNSSG is a relatively affluent area with only 16% of its population living in the most deprived national quintile (the national average being 20%).

Inclusion criteria
► All patients aged 18 and over with a completed ReSPECT form in their primary care medical record.

Exclusion criteria
► Patients under 18 years old.
► Patients without a completed ReSPECT form in their primary care medical record.

All data collected will be pseudonymised. In addition to the number of ReSPECT forms completed, we will also collect data on specific variables. These variables were determined in consultation with the study advisory group (composed of stakeholders from local commissioning, clinical and academic organisations). Sociodemographic variables were specifically chosen to describe our population within our dataset limitations. One such limitation is ‘ethnicity’, which is poorly documented within local electronic patient records. The ‘medical conditions’ variables were chosen due to their perceived relevance to clinicians in identifying patients who would benefit from the ReSPECT process. The ‘ReSPECT and end of life’ variables were chosen, again within the limitations of our data, to specifically fulfil our aims of exploring patterns of priorities, recommendations and outcomes of the ReSPECT form. These will be collected from electronic patient records using general sociodemographic codes, medical condition codes and ReSPECT form-specific codes as detailed in table 1.

The ReSPECT form has free-text fields in which to record patients’ priorities for care and treatment and the clinical recommendations made by the clinician completing the form. In BNSSG, forms completed in the primary care setting are completed on an electronic patient record template. This template suggests drop-down options for these two items. These are listed in table 2. The last drop-down option for ‘clinical recommendations’ is an option to enter free text. Due to both information governance considerations and limitations of the data, we will only be able to see if this box was ticked but not the free text entered. This is a limitation that will be explored in our study as we will be able to analyse how many forms used the suggested options and how many used free text.

Outcomes
Primary
The rate of ReSPECT form completion across three time periods (ReSPECT forms/4-month period):
► Before the first wave—from 1 October 2019 (the introduction of the ReSPECT form in the BNSSG area) to 31 January 2020.
► During the first wave—from 1 February (the first cases of COVID-19 in the UK, along with rising awareness) to 31 May 2020.
After the first wave—from 1 June (a significant easing of restrictions following the first national lockdown and a decrease in the COVID-19 alert level) to 30 September 2020.  

Secondary
- The demographic, socioeconomic and medical characteristics of patients who have a completed ReSPECT form in their primary care medical record across three time periods.
- The frequency of priority and treatment escalation decision documentation (clinical priorities, clinical recommendations and DNACPR decisions) on ReSPECT forms across three time periods.

Analysis
Data will be analysed using the statistical programmes ‘R’ and ‘Stata’. For those with a completed ReSPECT form during the COVID-19 first wave, summary statistics will be used to describe sociodemographic variables, medical variables and ReSPECT form items (as detailed in table 1). These variables will be described in distinct time periods around the COVID-19 first wave in the UK (as detailed in this phase’s primary outcome). Categorical variables will be summarised using percentages across the three time periods with differences across these time periods being analysed using $\chi^2$ tests. For continuous variables, we will use mean averages and SD for summarisation and analysis of variance tests (or Kruskal-Wallis tests for non-normal data) for differences between time periods.

Outcomes phase
Design
A retrospective cohort study will be undertaken that will allow us to identify any differences in numbers between

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Sociodemographic, medical and ReSPECT data to be collected</th>
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<tbody>
<tr>
<td><strong>Sociodemographic</strong></td>
<td><strong>Medical conditions</strong></td>
</tr>
<tr>
<td>Practice code</td>
<td>Dementia</td>
</tr>
<tr>
<td>Gender</td>
<td>Learning disability</td>
</tr>
<tr>
<td>Age</td>
<td>Cancer diagnosis</td>
</tr>
<tr>
<td>Lives in a nursing or residential home?</td>
<td>Electronic Frailty Index$^{31}$</td>
</tr>
<tr>
<td>Housebound</td>
<td>Charlson Score$^{39}$</td>
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<tr>
<td>Lower super output area$^{40}$</td>
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DNACPR, do not attempt cardiopulmonary resuscitation; ReSPECT, Recommended Summary Plan for Emergency Care and Treatment.

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<tr>
<th>Table 2</th>
<th>Options on electronic patient record template for ‘clinical priorities’ and ‘clinical recommendations’</th>
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<tbody>
<tr>
<td><strong>Clinical priorities</strong></td>
<td>Prioritise sustaining life, even at the expense of comfort.</td>
</tr>
<tr>
<td></td>
<td>Prioritise sustaining life moderately over comfort.</td>
</tr>
<tr>
<td></td>
<td>Prioritise sustaining life slightly over comfort.</td>
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<tr>
<td></td>
<td>Balance between sustaining life and comfort is equal.</td>
</tr>
<tr>
<td></td>
<td>Prioritise comfort slightly over life-sustaining treatment.</td>
</tr>
<tr>
<td></td>
<td>Prioritise comfort moderately over life-sustaining treatment.</td>
</tr>
<tr>
<td></td>
<td>Prioritise comfort, even at the expense of sustaining life.</td>
</tr>
<tr>
<td><strong>Clinical recommendations</strong></td>
<td>Wishes to be kept comfortable at home prioritising symptom control—does not want any active treatments (end-of-life care)</td>
</tr>
<tr>
<td></td>
<td>Wishes to be cared for at home and any discomfort or distress treated effectively—not for hospital admission, but for active treatment in the community (eg, oral antibiotics for infections)</td>
</tr>
<tr>
<td></td>
<td>Wishes to avoid hospital admission, if possible, but would consider admission for urgent treatment if medically advised to do so (eg, broken hip, heart attack, stroke or severe pneumonia) even if these treatments cause discomfort; would not want ventilation or admission to intensive therapy unit</td>
</tr>
<tr>
<td></td>
<td>Wishes to be admitted to the hospital for full investigation and treatment of any new serious health problems, including ventilation and intensive care unit where this is medically recommended</td>
</tr>
<tr>
<td></td>
<td>Please enter plan in free text box.</td>
</tr>
</tbody>
</table>
The difference in the patient groups regarding the

Data collection
Data collected for the outcome phase will also be from

Inclusion criteria
► All patients aged 18 and over who died between 1 October 2019 and 30 September 2020.

Exclusion criteria
► Patients aged under 18 years old at the time of death. All data will be pseudonymised with the following data collected for each patient:
► ED attendances.
► Emergency hospital admissions.
► Community nurse home visits.
► Hospice referrals.
► Anticipatory medication packs prescribed, and the how long these were prescribed before death—these are medication packs prescribed to patients to keep at home when clinicians feel that the patient could quickly deteriorate and develop symptoms related to the terminal phase of life.
► Place of death.
► Whether the patient died in the preferred place of death.

These have been selected based on the views of our advisory board regarding the importance of these outcomes as surrogates of both emergency and end-of-life healthcare use, taking into account any potential limitations of the dataset.

Outcomes
Primary
The difference in secondary care usage (ED attendance and emergency admission) between the patient groups (community ReSPECT form, hospital ReSPECT form and no ReSPECT form).

Secondary
► The difference in community care usage (community nurse visits and hospice referrals) between the patient groups.
► The difference in the patient groups in regard to frequency of anticipatory medication packs prescribed and how long (days) these were prescribed before death.
► The difference in the patient groups regarding the percentage of patients dying in their documented ‘preferred place of death’.

Analysis
Data will be analysed using the statistical programmes ‘R’ and ‘Stata’. Logistic regression models (adjusting for age, gender and the Charlson comorbidity index) will be used to compare the aforementioned patient care outcomes between those who received a ReSPECT form in the community, in the hospital and those who did not have a ReSPECT form.

Patient and public involvement (PPI)
When the aims and objectives of this study were discussed with a local PPI group, it was agreed by the group that the possible impact of COVID-19 on the implementation of ReSPECT was important to understand. Additionally, the group members expressed that it was relevant to patients for this study to investigate which types of patients were receiving the form and if there were any subsequent effects on their healthcare. The group felt that this would help inform healthcare services on where to direct resources to ensure all appropriate patient groups have access to the ReSPECT process. At the conclusion of our data analysis, we will present our results to our PPI group and seek their guidance on dissemination of findings to patients and the public.

ETHICS AND DISSEMINATION

Ethical approval
Human Research Authority Research Ethics approval has been sought to approve the PHM data resource as a research database, thereby providing ethical approval for analyses undertaken by the University of Bristol using this resource. This research ethics committee approval has currently been granted for COVID-19 urgent analyses (REC reference number 20/YH/0185, date: 28 July 2020).

BNSSG CCGs are the controllers of the pseudonymised data with patient opt-outs applied.37 The ethical and governance arrangements for the collection, curation, onward sharing and subsequent processing of these data are formally agreed within DSAs and data protection impact assessments between the primary and secondary care data controllers and the BNSSG CCG.38 In addition, GP practices are provided with a standardised study-specific form by BNSSG CCG. They can reply to this communication to opt out of an individual project before any data are released. GP practices can withdraw their consent at any time. Secondary care data are supplied through NHS digital in line with the Health and Social Care Act 2012. The data flow process for the PHM data resource is shown in more detail in online supplemental appendix 1.

Data management
Before patient data are released to the research team, it will be pseudonymised by the BNSSG CCG, with each patient record assigned a study ID number. These data will be stored securely on the institutional network file store, which will only be accessible with a password.

Dissemination of quantitative patient data findings will be on an aggregate level with no individual patient data being published. Data will be stored for 10 years after completion of the study as per University of Bristol recommendations.

Dissemination of findings
On completion of this study, an article will be prepared. It will also be submitted to a peer reviewed journal for
publication. The results will also be presented at scientific meetings and disseminated through university and social media networks. This article will also help inform future commissioning decisions in the BNSSG area.

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Contributors The study concept and design were conceived to by AMD, LVP, LS and CC. Analysis was planned and will be performed by CAW and AMD. AMD prepared the manuscript with editorial contributions from LVP, CAW, LS and CC.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, conduct, reporting or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

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REFERENCES

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