

BMJ Open

BMJ Open is committed to open peer review. As part of this commitment we make the peer review history of every article we publish publicly available.

When an article is published we post the peer reviewers' comments and the authors' responses online. We also post the versions of the paper that were used during peer review. These are the versions that the peer review comments apply to.

The versions of the paper that follow are the versions that were submitted during the peer review process. They are not the versions of record or the final published versions. They should not be cited or distributed as the published version of this manuscript.

BMJ Open is an open access journal and the full, final, typeset and author-corrected version of record of the manuscript is available on our site with no access controls, subscription charges or pay-per-view fees (<http://bmjopen.bmj.com>).

If you have any questions on BMJ Open's open peer review process please email info.bmjopen@bmj.com

BMJ Open

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

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2021-060253
Article Type:	Protocol
Date Submitted by the Author:	17-Dec-2021
Complete List of Authors:	McDermott, Adam; Bristol Medical School, Centre for Academic Primary Care Woodall, Claire; Bristol Medical School, Centre for Academic Primary care Chamberlain, Charlotte; Bristol Medical School, Population Health Sciences Selman, Lucy; Bristol Medical School, Population Health Sciences Pocock, Lucy; Bristol Medical School, Centre for Academic Primary Care
Keywords:	PRIMARY CARE, PALLIATIVE CARE, Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

SCHOLARONE™
Manuscripts

1
2
3
4 **A protocol for a retrospective observational study investigating the**
5 **impact of the Covid-19 pandemic on the implementation of the**
6 **ReSPECT process: which patients received a ReSPECT form, what**
7 **was documented, and what were the patient outcomes?**
8
9
10
11
12
13
14
15

16 Corresponding Author Affiliation

17
18 Dr Adam McDermott - Centre for Academic Primary Care, Bristol Medical School, Canynge
19 Hall, 39 Whatley Rd, Bristol, BS8 2PS, UK – adam.mcdermott@bristol.ac.uk
20
21
22
23

24 Contributing Author Affiliations

25
26 Dr Claire A Woodall - Centre for Academic Primary Care, Bristol Medical School, Canynge
27 Hall, 39 Whatley Rd, Bristol, BS8 2PS, UK
28
29

30 Dr Charlotte Chamberlain – Population health Sciences, Bristol Medical School, Canynge
31 Hall, 39 Whatley Rd, Bristol, BS8 2PS, UK
32
33

34 Dr Lucy Selman – Population health Sciences, Bristol Medical School, Canynge Hall, 39
35 Whatley Rd, Bristol, BS8 2PS, UK
36
37

38 Dr Lucy Pocock - Centre for Academic Primary Care, Bristol Medical School, Canynge Hall, 39
39 Whatley Rd, Bristol, BS8 2PS, UK
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Abstract

Introduction

ReSPECT (Recommended Summary Plan for Emergency Care and Treatment) is a UK Advance Care Planning initiative, aiming to standardise the process of creating personalised recommendations for a person's clinical care in a future emergency, and therefore improve patient outcomes. Despite this, implementation across an entire healthcare area and any subsequent outcomes have not yet been studied. Therefore, it is unclear if patients with a ReSPECT form benefit from the positive outcomes associated with good advance care planning. The implementation of ReSPECT in the Bristol, North Somerset and South Gloucestershire (BNSSG) area overlapped with the first UK COVID-19 wave.

This study will describe the characteristics of patients in the BNSSG area who completed the ReSPECT process before, during, and after the first wave; describe the content of ReSPECT forms; and analyse outcomes for those patients who died with a ReSPECT form. This is to determine the equity of the ReSPECT form implementation process and the benefits to patients and their local services.

Methods and Analysis

We will perform an observational retrospective study on data, collected from October 2019 for 12 months. Data will be exported from the Systemwide Dataset, a pseudonymised database linking data from organisations providing health and social care to BNSSG patients. Descriptive statistics of sociodemographic and medical variables for those who completed the ReSPECT process, in addition to their ReSPECT form responses, will be compared between pre-, during- and post-first COVID-19 wave groups. Additionally, routinely collected outcomes for patients who died in our study period will be compared between those who completed the ReSPECT process in the community, hospital or not at all.

Ethics and dissemination

Approval has been obtained from an NHS 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.

Strengths and limitations of the study

- This is the first study to examine the implementation of the ReSPECT form, a national Advance Care Planning initiative, across an entire healthcare area - approximately one million patients who interact with community and secondary care 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 form was implemented as the COVID-19 pandemic progressed, but also analysis of any difference between measured healthcare outcomes for those who died with a form and those who died without one.
- Due to the nature of analysing routine data, some records may be missing or incorrect. Codes have been selected which reflect the most reliably recorded data, based on local knowledge and expertise, and sensitivity analyses performed as appropriate.
- The impact of COVID-19 and the subsequent increased public and professional emphasis on advance care planning is likely to be reflected in the study findings and this has implications for understanding the effects of the pandemic on ACP initiatives

Introduction

The 'Recommended Summary Plan for Emergency Care and Treatment' (ReSPECT) process has been developed by a national working group comprised of professional healthcare organisations working in conjunction with the Resuscitation Council UK.¹ It is intended as a national solution to inconsistent practices of Advance Care Planning (ACP) and Do Not Attempt Cardio-Pulmonary Resuscitation (DNACPR) documentation. It was developed as part of a large public consultation, and aims to be acceptable to patients and clinicians, evidence based and able to record patient preferences for treatment beyond simply documenting Cardio-Pulmonary Resuscitation (CPR) decisions. It is being implemented nationally in a staggered approach.

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.² The National Institute of Health Research (NIHR) has funded a mixed-methods evaluation of early adopting acute National Health Service (NHS) hospitals and there are currently several published studies and reports of the implementation of ReSPECT in NHS organisations.³

The results have so far been mixed. Early audits undertaken in 2017 at the Heart of England NHS trust indicated low numbers of patients with ReSPECT forms, poor completion of non-DNACPR areas of the form and low levels of documentation regarding patient or family involvement.⁴⁻⁶ These results contrast with a later report published in 2018 by the NHS Forth Valley Trust.⁷ This report found much higher rates of form completion (including non-DNACPR recommendations), patient and family involvement, and also patient and family satisfaction. Additionally, patients with a ReSPECT form were less likely to be admitted to hospital and more likely to die at home than those without a form. These positive findings were also demonstrated by a 2019 study at the University Hospital Birmingham Trust which showed a doubling of patients with documented treatment escalation plans (from 43% to 86.6%) after the trust introduced ReSPECT.⁸

These mixed results could be partly explained by differences in training and familiarity with ReSPECT as most of the positive studies collected part or all of their data from 2018 or later, in contrast to the less positive studies that collected data mainly in or before 2017. It has also been shown that consultants from early adopting hospitals prioritised ReSPECT discussions for patients who were rapidly deteriorating and therefore focussed on DNACPR decisions.⁹ However, training and familiarity may not be the entire explanation as despite the subsequent release of Resuscitation Council UK educational material clarifying that 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.^{10,11}

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 led ACP discussions are associated with a decrease in the likelihood of patients dying in hospital compared to those patients who had ACP discussions with other healthcare professionals.¹²

1
2
3 A 2019 ReSPECT study which did look at the use of ReSPECT in the community found that
4 GPs discussed plans beyond CPR, such as possible hospital admission and symptom
5 management.¹³ Although it was noted that GPs were still not using the ReSPECT process
6 entirely in line with the original aims, with their focus being on primary care related
7 decisions such as preferences for hospital admission without consideration to specific
8 hospital-based interventions.¹³
9
10

11 The existing literature recommends further work to adequately train clinicians in the
12 ReSPECT process, specifically regarding the breadth of its desired aims and improved patient
13 and family involvement in decisions and their documentation. This has informed the
14 development of Version 3 of the ReSPECT form (2020).¹⁴ Further recommendations include
15 that future studies specifically explore the interplay of the ReSPECT form between primary
16 and secondary care settings, which are considered in this study.¹³
17
18
19
20
21
22

23 **Implementation of ReSPECT in a UK region**

24 In the Bristol, North Somerset and South Gloucestershire (BNSSG) area, the ReSPECT
25 process was launched in October 2019.¹⁵ Shortly after this launch the COVID-19 pandemic
26 began, which has presented the NHS with unprecedented national challenges. The first UK
27 cases were diagnosed in late January 2020 and, as of 8th December 2021, there have been
28 170,001 deaths in the UK due to COVID-19.¹⁶ Patients most vulnerable to COVID-19 are the
29 elderly and those with chronic health conditions.¹⁷ These groups have significant overlap
30 with those patients that the NHS Forth Valley report identified as being appropriate for the
31 ReSPECT process.⁷ In the weeks preceding the first rapid increase of COVID-19 cases in the
32 UK, the NHS emphasised the importance of ACP. For clinicians, NICE guidance was updated
33 with COVID-19 rapid guidelines which stated that clinicians should discuss ACP with patients
34 at risk of deterioration due to COVID-19.¹⁸ For patients, document templates such as the
35 'My COVID-19 Advance Care Plan' were produced.¹⁹ The result of this increased focus on
36 ACP is evidenced by a survey of UK palliative care services, with 37.9% reporting that they
37 had been providing more direct ACP and 58.5% reporting an increase in advising others
38 about ACP.²⁰ This increased emphasis and usage of ACP has also been seen in other
39 countries during the pandemic.^{21,22}
40
41
42
43
44

45 It is currently unclear how the pandemic has affected the implementation of the ReSPECT
46 process both in the BNSSG area and nationally. The Royal College of General Practitioners
47 has stated that the pandemic may have made certain aspects of the sensitive conversations
48 around ACP more difficult, such as the reduction in face-to-face consultations, and others
49 easier, for example some patients feeling an increase in the relevance of ACP for
50 themselves. This is a view substantiated by a 2020 evidence synthesis report.^{23,24} It is also
51 unknown how many ReSPECT forms have been completed during the pandemic, who were
52 receiving them and what recommendations were being documented. This is particularly
53 important as there have been concerns in both the media and various healthcare
54 organisations that ACP and DNACPR documents have been "applied in a blanket manner to
55 whole groups" such as care home residents.^{25,26}
56
57
58
59
60

1
2
3 It should also be considered that irrespective of the pandemic, all published studies on the
4 ReSPECT form have included small samples and the majority have been secondary care
5 orientated. This study is the first to explore the implementation, use and outcomes of all
6 documented ReSPECT forms (from primary and secondary care) for a large patient
7 population, specifically the approximately one million patients served by the BNSSG CCG.
8 Therefore, there are two rationales for this study. Firstly, the pandemic has coincided with
9 the implementation of the ReSPECT form in the BNSSG area and is likely to have affected
10 the rollout and use of the ReSPECT form during the UK's first COVID-19 wave. Additionally,
11 the impact of the ReSPECT process on patient outcomes in emergency and EoL situations
12 during the pandemic have not yet been investigated.
13
14
15
16
17
18

19 **Aim**

20 To describe the characteristics of patients in the BNSSG area who had a ReSPECT form
21 completed before, during, and after the first wave of the COVID-19 pandemic and to analyse
22 any differences in outcomes for those patients who died with a community-completed
23 ReSPECT form, a hospital-completed ReSPECT form, or with those who died without a
24 ReSPECT form.
25
26
27
28
29

30 **Objectives**

- 31 1. To quantify how many ReSPECT forms were completed before, during and after the first
32 peak of COVID-19
- 33 2. To determine any changes in clinical and demographic characteristics of patients receiving
34 ReSPECT forms during these periods
- 35 3. To identify any changes in patterns of priorities, recommendations and DNACPR decisions
36 documented on ReSPECT forms during these periods
- 37 4. To measure any differences in routinely collected outcomes for those patients who died
38 after completing a ReSPECT form in the community, in hospital, or those who died without
39 a ReSPECT form. These outcomes are: ED attendances, emergency hospital admissions,
40 district nurse home visits, hospice referrals EoL 'Just In Case' medication packs prescribed
41 and if the patient died in their preferred place of death (if documented).
42
43
44
45
46
47
48
49

50 **Methods**

51 **Study overview and setting**

52 This is a quantitative study with two phases which will both take place within the Bristol,
53 North Somerset and South Gloucestershire area:
54
55
56

- 57 1. Implementation Phase – An observational cross-sectional study of all patients for
58 whom a ReSPECT form was completed between October 2019 and October 2020.
59 We will evaluate the number of ReSPECT forms completed across all general
60

practices and secondary care settings in the BNSSG 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 completing ReSPECT forms along with any shifting patterns in the priorities, recommendations and DNACPR decisions documented.

2. Outcomes Phase – A retrospective cohort study of all patients who died between October 2019 and October 2020. We will compare any differences between routinely collected outcomes for those patients who died after completing a ReSPECT form in the community, in hospital, or who died without a ReSPECT form. These outcomes will be: Emergency Department (ED) attendances, emergency hospital admissions, district nurse visits, hospice referrals, EoL ‘Just In Case’ medication packs prescribed (and how long before death) and whether the patient died in their preferred place of death (if documented).

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

This data will be collected from the System Wide Dataset (SWD) retrospectively from October 2019 to October 2020. The SWD provides information about healthcare use across primary, community and secondary care to help inform research and commissioning. The SWD is built using data collected from the following sources: BNSSG CCG, Gov.uk, Police.uk, National Health Application and Infrastructure series (NHAIS), the Community Services Dataset and OneCare Ltd. OneCare is a local GP federation that contributes data from GP practice EMIS records to the SWD. GP practices will be able to opt out of this study’s data collection if they wish.

The BNSSG area represents a diverse population, from both urban and rural areas.²⁷ In 2017 the BNSSG population was approximately 951,000, with a median age of 36, just below the national median age of 40.4.²⁸ 9.8% of the BNSSG population 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%.²⁹ BNSSG is a relatively affluent area with only 16% of its population living in the most deprived national quintile (the national average being 20%).^{27,30}

Inclusion criteria:

- All patients aged 18 and over with completed ReSPECT form.

Exclusion criteria:

- Patients under 18 years old.
- Patients without a completed ReSPECT form.

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 this study's advisory group (composed of various ReSPECT stakeholders from local commissioning and research bodies):

Sociodemographic	Medical	ReSPECT
Practice code	Cognitive impairment	Date of ReSPECT form completion
Gender	Cancer diagnosis?	Setting in which the form was completed (Primary vs Secondary)
Age	Electronic Frailty Index	Clinical Priorities
Residence type	Charlson Score	Clinical Recommendations
LSOA		Preferred place of death
		Preferred place of death discussed with family
		Patient has capacity and was involved in the process?
		Who was involved in the process if the patient didn't have capacity?
		DNACPR decision in place?

Table 1. Sociodemographic, Medical and ReSPECT form data to be collected

Outcomes

Primary

1. The rate of ReSPECT form completion across three time periods:
 - Before the first wave - 1st October 2019 (the introduction of the ReSPECT form in the BNSSG area) to 31st January 2020.¹⁵
 - During the first wave - 1st February (the first cases of COVID-19 in the UK along with rising awareness) to 31st May 2020.^{16,31,32}
 - After the first wave - 1st June (a significant easing of restrictions following the first national lockdown and a decrease in the COVID alert level) to 30th September 2020.³³

Secondary

1. The demographic, socioeconomic and medical characteristics of patients completing ReSPECT forms across three time periods.
2. 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 programs '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 χ^2 tests. For continuous variables we will use mean averages and standard deviations for summarisation and ANOVA 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 between routinely recorded outcomes for those patients who died after completing a ReSPECT form in the community, in hospital, and those who died without a ReSPECT form.

Data Collection

Data collected for the outcome phase will also be from the SWD.

Inclusion criteria:

- All patients aged 18 and over, who died between 1st October 2019 to 30th 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
- District nurse home visits
- Hospice referrals
- EoL 'Just In Case' medication packs prescribed (and the how long these were prescribed before death)
- Whether patient died in preferred place of death

Outcomes

Primary

1. The difference in secondary care usage (ED attendance and emergency admission) between the three groups (Community ReSPECT form, Hospital ReSPECT form and No ReSPECT form).

Secondary

1. The difference in community care usage (district nurse visits, hospice referrals) between the three groups.
2. The difference in the three groups in regard to frequency of end of life 'Just In Case' medication packs prescribed and how long (days) these were prescribed before death.
3. The difference in the three groups regarding the percentage of patients dying in their documented 'Preferred Place of Death'.

Analysis

Data will be analysed using the statistical programs 'R' and 'STATA'. Logistic regression models (adjusting for age, gender and the Charlson co-morbidity index) will be used to compare the patient care outcomes above between those who received a ReSPECT form in the community, in 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 Patient and Public involvement group, it was agreed by the group that the possible impact of Covid-19 on the implementation of ReSPECT was important to understand. Additionally, they 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.

Ethics and Dissemination

Ethical approval

The BNSSG SWD is a resource that links health and social care data from primary care, acute care, community services, mental health and social care for the one million local population. For a defined set of purposes focusing on Population Health Management and Applied Research, HRA Research Ethics approval has been sought to approve the SWD as a Research Database thereby providing ethical approval for analyses undertaken by University of Bristol using this resource. This approval has currently been approved for COVID-19 urgent analyses (REC Reference Number: 20/YH/0185, Date: 28/07/2020).

Data management

Before patient data is released to the research team it will be pseudonymised by the BNSSG CCG, with each patient record assigned a study ID number. This 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

Upon completion of this study a manuscript 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 manuscript will also help inform future commissioning decisions in the BNSSG area.

Author's Contributions

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

Funding statement

This study will be completed by Dr McDermott whose role is funded the Severn Deanery as part of an Academic Clinical Fellow in General Practice training programme, with LP as primary supervisor. This programme is NIHR-badged.

Competing interests

None declared

References

1. Hawkes C, Fritz Z, Deas G, Ahmedzai S, Richardson A, Pitcher D et al. Development of the Recommended Summary Plan for eEmergency Care and Treatment (ReSPECT). *Resuscitation*. 2020;148:98-107. doi: 10.1016/j.resuscitation.2020.01.003.
2. Fritz Z, Slowther A, Perkins G. Resuscitation policy should focus on the patient, not the decision. *BMJ*. 2017;;j813. doi: 10.1136/bmj.j813.
3. NIHR Funding and Awards Search Website [Internet]. Fundingawards.nihr.ac.uk. 2020 [cited 28 August 2020]. Available from: <https://www.fundingawards.nihr.ac.uk/award/15/15/09>
4. Davies M, Couper K, Jeyes L, Slater P, Speakman J, Arolker M et al. Successful implementation of the ReSPECT (Recommended Summary Plan for Emergency Care and Treatment) process in a large UK based NHS Trust. *Resuscitation*. 2017;118:e95-e96. doi :<https://doi.org/10.1016/j.resuscitation.2017.11.013>
5. Trethewey S, Morlet J, McDonald D, Dowling D, Davies M, Perkins G. Evaluation of ReSPECT forms in critical care: A clinical audit. *Resuscitation*. 2017;118:e93. doi: <https://doi.org/10.1016/j.resuscitation.2017.11.007>
6. Eli K, Hawkes CA, Fritz Z, Griffin J, Huxley CJ, Perkins GD, et al. Assessing the quality of respect documentation using an accountability for reasonableness framework. *Resuscitation Plus*. 2021;7:100145. doi: 10.1016/j.resplu.2021.100145.
7. Clinical Outcomes Group Forth Valley. A Quantitative and Qualitative Evaluation of the ReSPECT (Recommended Summary Plan for Emergency Care and Treatment) Process in Forth Valley Scotland's first ReSPECT pilot: A Case for Change [Internet]. 2019. Available from: <https://ihub.scot/media/6171/respect-report-final.pdf>
8. Jeyes L, Hall M, Slater P, Broderick K, Couper K, Perkins G. The impact of implementation of ReSPECT (recommended summary plan for emergency care and treatment) on the making of treatment escalations in patients with do not attempt cardiopulmonary resuscitation decisions. *Resuscitation*. 2019;142:e62-e63. doi: <https://doi.org/10.1016/j.resuscitation.2019.06.151>
9. Eli K, Ochieng C, Hawkes C, Perkins G, Couper K, Griffiths F et al. Secondary care consultant clinicians' experiences of conducting emergency care and treatment planning conversations in England: an interview-based analysis. 2020. doi: 10.1136/bmjopen-2019-031633.
10. Resuscitation Council UK Statement on the role of the ReSPECT Process during COVID-19 [Internet]. Resus.org.uk. 2020 [cited 28 August 2020]. Available from: https://www.resus.org.uk/sites/default/files/2020-06/COVID%20ReSPECT%20Guidance%2023042020_0.pdf
11. Eli K, Hawkes C, Ochieng C, Huxley C, Baldock C, Fortune P et al. Why, when and how do secondary-care clinicians have emergency care and treatment planning conversations? Qualitative findings from the ReSPECT Evaluation study. *Resuscitation*. 2021;162:343-350. doi: 10.1016/j.resuscitation.2021.01.013
12. Nicholas R, Nicholas E, Hannides M, Gautam V, Friede T, Koffman J. Influence of individual, illness and environmental factors on place of death among people with neurodegenerative diseases: a retrospective, observational, comparative cohort study. *BMJ Supportive & Palliative Care*. 2021;6:bmjpspcare-2021-003105. doi: 10.1136/bmjpspcare-2021-003105.
13. Huxley C, Eli K, Hawkes C, Perkins G, George R, Griffiths F et al. General practitioners' experiences of emergency care and treatment planning in England: a focus group study. *BMC Family Practice*. 2021;22(1). doi: 10.1186/s12875-021-01486-w.
14. Resuscitation Council UK Introduces version 3 of ReSPECT form [Internet]. Resuscitation Council UK. 2020 [cited 18 August 2021]. Available from: <https://www.resus.org.uk/about-us/news-and-events/resuscitation-council-uk-introduces-version-3-respect-form>
15. Remedy – ReSPECT. BNSSG CCG [Internet]. 2019 [cited 20 October 2021] Available from: <https://remedy.bnssgccg.nhs.uk/adults/end-of-life-care-and-hospice/respect/>
16. Coronavirus (COVID-19) in the UK [Internet]. Coronavirus.data.gov.uk. 2020 [cited 8th December 2021]. Available from: https://coronavirus.data.gov.uk/?_ga=2.207192858.866620603.1597831851-1162254990.1597831851
17. Cascella M, Rajnik M, Aleem A, Dulebohn S, Napoli R. Features, Evaluation, and Treatment of Coronavirus (COVID-19) [Internet]. Ncbi.nlm.nih.gov. 2021 [cited 20 October 2021]. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK554776/>
18. NICE. COVID-19 rapid guideline: managing symptoms (including at the end of life) in the community [Internet]. 2020. Available from: <https://www.nice.org.uk/guidance/ng163/resources/COVID19-rapid-guideline-managing-symptoms-including-at-the-end-of-life-in-the-community-pdf-66141899069893>
19. NHS England. Advance care planning guidance and template [Internet]. 2020. Available from: <https://www.england.nhs.uk/coronavirus/publication/advance-care-planning-guidance-and-template/>
20. Bradshaw A, Dunleavy L, Walshe C, Preston N, Cripps R, Hocaoglu M et al. Understanding and addressing challenges for advance care planning in the COVID-19 pandemic: An analysis of the UK CovPall survey data from specialist palliative care services. *Palliative Medicine*. 2021;35(7):1225-1237. doi: 10.1177/02692163211017387.
21. Lapid M, Koopmans R, Sampson E, Van den Block L, Peisah C. Providing quality end-of-life care to older people in the era of COVID-19: perspectives from five countries. *International Psychogeriatrics*. 2020;32(11):1345-1352. doi: 10.1017/S1041610220000836.
22. Cascella M, Rajnik M, Aleem A, Dulebohn S, Napoli R. Features, Evaluation, and Treatment of Coronavirus (COVID-19) [Internet]. Ncbi.nlm.nih.gov. 2021 [cited 20 October 2021]. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK554776/>
23. Anticipatory Care Planning in a COVID landscape [Internet]. Rcgpp.org.uk. 2020 [cited 20 October 2021]. Available from: <https://www.rcgp.org.uk/about-us/rcgp-blog/anticipatory-care-planning-in-a-COVID-landscape.aspx>
24. Selman L, Lapwood S, Jones N, Pocock L, Anderson R, Pilbeam C et al. What enables or hinders people in the community to make or update advance care plans in the context of Covid-19, and how can those working in health and social care best support this process? [Internet]. 2020 [Cited 20 October 2021]. Available from: <https://www.cebm.net/covid-19/advance-care-planning-in-the-community-in-the-context-of-covid-19/>
25. Lacobucci G. COVID-19: Don't apply advance care plans to groups of people, doctors' leaders warn. *BMJ*. 2020;369:m1419.
26. Joint statement on advance care planning [Internet]. Rcgpp.org.uk. 2020 [cited 20 October 2021]. Available from: <https://www.rcgp.org.uk/about-us/news/2020/april/joint-statement-on-advance-care-planning.aspx>

- 1
 - 2
 - 3
 - 4
 - 5
 - 6
 - 7
 - 8
 - 9
 - 10
 - 11
 - 12
 - 13
 - 14
 - 15
 - 16
 - 17
 - 18
 - 19
 - 20
 - 21
 - 22
 - 23
 - 24
 - 25
 - 26
 - 27
 - 28
 - 29
 - 30
 - 31
 - 32
 - 33
 - 34
 - 35
 - 36
 - 37
 - 38
 - 39
 - 40
 - 41
 - 42
 - 43
 - 44
 - 45
 - 46
 - 47
 - 48
 - 49
 - 50
 - 51
 - 52
 - 53
 - 54
 - 55
 - 56
 - 57
 - 58
 - 59
 - 60
27. Norman J, Thompson C. Single System and CCG plan 2019/20 [Internet]. Bristol: Bristol, North Somerset and South Gloucestershire Clinical Commissioning Group; 2019. Available from: https://bnssgccg-media.ams3.cdn.digitaloceanspaces.com/attachments/govbody_7May19_item6.4.pdf
28. Population estimates for the UK, England and Wales, Scotland and Northern Ireland - Office for National Statistics [Internet]. Ons.gov.uk. 2021 [cited 20 October 2021]. Available from: <https://www.ons.gov.uk/peoplepopulationandcommunity/populationandmigration/populationestimates/bulletins/annualmidyearpopulationestimates/mid2020>
29. Diversity in the UK - Diversity UK [Internet]. Diversity UK. 2021 [cited 20 October 2021]. Available from: <https://diversityuk.org/diversity-in-the-uk/>
30. Case for Change - Addressing the Health and Wellbeing Gap [Internet]. Bristol.gov.uk. 2017 [cited 20 October 2021]. Available from: <https://www.bristol.gov.uk/documents/20182/34748/Case+for+Change+-+Addressing+the+Health+and+Wellbeing+Gap+2017+%28BNSG%29/c4765bc1-0c3d-5db4-bd03-36ce6395b1bd>
31. Coronavirus [Internet]. Google Trends. 2020 [cited 20 October 2021]. Available from: <https://trends.google.com/trends/explore?geo=GB&q=%2Fm%2F01cppy>
32. The United Kingdom – Communicating COVID-19 [Internet]. COVID19.philemerge.com. 2020 [cited 28 August 2020]. Available from: <https://COVID19.philemerge.com/the-united-kingdom/>
33. Timeline of UK government coronavirus lockdowns [Internet]. The Institute for Government. 2021 [cited 20 October 2021]. Available from: <https://www.instituteforgovernment.org.uk/charts/uk-government-coronavirus-lockdowns>

BMJ Open

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

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2021-060253.R1
Article Type:	Protocol
Date Submitted by the Author:	13-Apr-2022
Complete List of Authors:	McDermott, Adam; Bristol Medical School, Palliative and End of Life Care Research Group / Centre for Academic Primary Care Woodall, Claire; Bristol Medical School, Centre for Academic Primary care Chamberlain, Charlotte; Bristol Medical School, Palliative and End of Life Care Research Group, Population Health Sciences Selman, Lucy; Bristol Medical School, Palliative and End of Life Care Research Group, Population Health Sciences Pocock, Lucy; Bristol Medical School, Palliative and End of Life Care Research Group / Centre for Academic Primary Care
Primary Subject Heading:	General practice / Family practice
Secondary Subject Heading:	Epidemiology, Palliative care
Keywords:	PRIMARY CARE, PALLIATIVE CARE, Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, EPIDEMIOLOGY

SCHOLARONE™
Manuscripts

1
2
3
4 1 **A protocol for a retrospective observational study investigating the**
5 2 **impact of the Covid-19 pandemic on the implementation of the**
6 3 **ReSPECT process: which patients received a ReSPECT form, what**
7 4 **was documented, and what were the patient outcomes?**
8
9
10
11
12
13
14
15

16 10 Corresponding Author Affiliation

17
18 11 Dr Adam McDermott - Palliative and End of Life Care Research Group / Centre for Academic
19 12 Primary Care, Bristol Medical School, Canynge Hall, 39 Whatley Rd, Bristol, BS8 2PS, UK –
20 13 adam.mcdermott@bristol.ac.uk
21
22 14
23
24 15

25 16 Contributing Author Affiliations

26
27 17 Dr Claire A Woodall - Centre for Academic Primary Care, Bristol Medical School, Canynge
28 18 Hall, 39 Whatley Rd, Bristol, BS8 2PS, UK
29
30 19

31 20 Dr Charlotte Chamberlain – Palliative and End of Life Care Research Group, Population
32 21 Health Sciences, Bristol Medical School, Canynge Hall, 39 Whatley Rd, Bristol, BS8 2PS, UK
33
34 22

35 23 Dr Lucy Ellen Selman – Palliative and End of Life Care Research Group, Population Health
36 24 Sciences, Bristol Medical School, Canynge Hall, 39 Whatley Rd, Bristol, BS8 2PS, UK
37
38 25

39 26 Dr Lucy Pocock - Palliative and End of Life Care Research Group / Centre for Academic
40 27 Primary Care, Bristol Medical School, Canynge Hall, 39 Whatley Rd, Bristol, BS8 2PS, UK
41
42 28
43
44 29
45 30
46
47 31
48
49 32
50
51 33
52 34
53
54 35
55 36
56
57 37
58 38
59
60 39

40 **Abstract**

42 **Introduction**

43 ReSPECT (Recommended Summary Plan for Emergency Care and Treatment) is a UK
44 Advance Care Planning initiative, aiming to standardise the process of creating personalised
45 recommendations for a person's clinical care in a future emergency, and therefore improve
46 person-focused care. Implementation of the ReSPECT process across a large geographical
47 area, involving both community and secondary care, has not previously been studied. In
48 particular, it not known whether such implementation is associated with any change in
49 outcomes for those patients with a ReSPECT form.

51 Implementation of ReSPECT in the Bristol, North Somerset and South Gloucestershire
52 (BNSSG) Clinical Commissioning Group (CCG) area overlapped with the first UK COVID-19
53 wave. It is unclear what impact the pandemic had on the implementation of ReSPECT and if
54 this affected the type of patients who underwent the ReSPECT process, such as those with
55 specific diagnoses or living in care homes. Patterns of clinical recommendations
56 documented on ReSPECT forms during the first year of its implementation may also have
57 changed, particularly with reference to the pandemic.

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

67 **Methods and Analysis**

68 We will perform an observational retrospective study on data, collected from October 2019
69 for 12 months. Data will be exported from the CCG Public Health Management data
70 resource, a pseudonymised database linking data from organisations providing health and
71 social care to people across BNSSG. Descriptive statistics of sociodemographic and health-
72 related variables for those who completed the ReSPECT process with a clinician, and had a
73 documented ReSPECT form in their notes, in addition to their ReSPECT form responses, will
74 be compared between pre-, during- and post-first COVID-19 wave groups. Additionally,
75 routinely collected outcomes for patients who died in our study period will be compared
76 between those who completed the ReSPECT process with a community clinician, hospital
77 clinician or not at all. These include: emergency department attendances, emergency
78 hospital admissions, community nurse home visits, hospice referrals, anticipatory
79 medication prescribing, place of death, and if the patient died in preferred place of death

82 **Ethics and dissemination**

83 Approval has been obtained from a National Health Service Research Ethics Committee
84 (20/YH/0185). Findings will be disseminated to policy decision-makers, care providers and
85 the public, through scientific meetings and peer-reviewed publication.

Strengths and limitations of the study

- This is the first study to examine the implementation of the ReSPECT process, a national Advance Care Planning (APC) 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 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 is a potential problem. To address this, codes have been carefully selected to reflect the most reliably recorded data and sensitivity analyses performed as appropriate.
- Individual GP 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 advance care planning is likely to be reflected in the study findings and this has implications for understanding the effects of the pandemic on advance care planning initiatives.

120 **Introduction**

121 The 'Recommended Summary Plan for Emergency Care and Treatment' (ReSPECT) process
122 has been developed by a national working group comprised of professional healthcare
123 organisations, regulatory bodies and patient representatives, working in conjunction with
124 the Resuscitation Council UK.¹ It is intended as a standardised solution to inconsistent
125 practices of Advance Care Planning (ACP) and Do Not Attempt Cardio-Pulmonary
126 Resuscitation (DNACPR) documentation and implementation has already taken place across
127 various regions of the UK. The ReSPECT process involves discussion between patients, their
128 carers, and clinicians and results in a ReSPECT form being completed by a clinician recording
129 patient preferences for treatment, beyond simply documenting Cardio-Pulmonary
130 Resuscitation (CPR) decisions.

131
132 The authors of a study detailing the development of the ReSPECT process commented that
133 "robust evaluation of the effectiveness of ReSPECT in achieving its overall goals will be
134 essential" and this evidence base is still being built.² The National Institute of Health
135 Research (NIHR) has funded a mixed-methods evaluation of early adopting acute National
136 Health Service (NHS) hospitals.³ There are also currently several published studies and
137 reports of the implementation of ReSPECT in NHS organisations. The results have, so far,
138 been mixed.

139
140 Early audits undertaken in 2017 at the Heart of England NHS trust indicated low numbers of
141 patients with ReSPECT forms, poor completion of non-DNACPR areas of the form and low
142 levels of documentation regarding patient or family involvement.⁴⁻⁶ These results contrast
143 with a later report published in 2018 by the NHS Forth Valley Trust.⁷ This report found much
144 higher rates of form completion (including non-DNACPR recommendations), patient and
145 family involvement, and also patient and family satisfaction. Additionally, patients with a
146 ReSPECT form were less likely to be admitted to hospital and more likely to die at home
147 than those without a form. These positive findings were also demonstrated by a 2019 study
148 at the University Hospital Birmingham Trust which showed a doubling of patients with
149 documented treatment escalation plans (from 43% to 86.6%) after the trust introduced
150 ReSPECT.⁸ Overall, the literature demonstrates positive outcomes but also presents
151 conflicting results regarding the completion of forms and variation in patient and family
152 involvement.

153
154 These mixed results could partly be explained by differences in training and familiarity with
155 ReSPECT as most of the positive studies collected part or all of their data from 2018 or later,
156 in contrast to the less positive studies that collected data mainly in or before 2017. It has
157 also been shown that consultants from early adopting hospitals prioritised ReSPECT
158 discussions for patients who were rapidly deteriorating and therefore focussed on DNACPR
159 decisions.⁹ However, training and familiarity may not be the entire explanation as despite
160 the subsequent release of Resuscitation Council UK educational material clarifying that the
161 ReSPECT form is not simply a replacement for DNACPR forms, later consultant interview
162 studies (2019-2020) found that Cardiopulmonary Resuscitation (CPR) was still dominating
163 ReSPECT conversations and that again, these conversations were mainly taking place with
164 acutely unwell patients.^{10,11} An additional explanation for why the ReSPECT form has not yet
165 been shown to have fully achieved its aims may be due to most of these studies taking place

1
2
3 166 in hospital settings. This may be especially important as it has been shown that General
4 167 Practitioner (GP)-led ACP discussions are associated with a decrease in the likelihood of
5 168 patients dying in hospital compared to those patients who had ACP discussions with other
6 169 healthcare professionals.¹² A 2019 ReSPECT study which did look at the use of ReSPECT in
7 170 the community found that GPs discussed plans beyond CPR, such as possible hospital
8 171 admission and symptom management.¹³ Although it was noted that GPs were still not using
9 172 the ReSPECT process entirely in line with the original aims, with their focus being on primary
10 173 care related decisions such as preferences for hospital admission without consideration of
11 174 specific hospital-based interventions.¹³
12 175

13 176 In light of these conflicting results, the existing literature recommends further work to
14 177 adequately train clinicians in the ReSPECT process, specifically regarding the breadth of its
15 178 desired aims and improved patient and family involvement in decisions and their
16 179 documentation. This has informed the development of Version 3 of the ReSPECT form
17 180 (2020).¹⁴ Further recommendations include that future studies specifically explore the
18 181 interplay of the ReSPECT form between primary and secondary care settings, which are
19 182 considered in this study.¹³
20 183
21 184
22 185

23 186 **Implementation of ReSPECT in a UK region**

24 187 In the Bristol, North Somerset and South Gloucestershire (BNSSG) Clinical Commissioning
25 188 Group (CCG) area, the ReSPECT process was launched in October 2019.¹⁵ Shortly after this
26 189 launch the COVID-19 pandemic began, which has presented the NHS with unprecedented
27 190 national challenges. The first UK cases were diagnosed in late January 2020 and, as of 5th
28 191 April 2022, there have been 186,921 deaths in the UK due to COVID-19.¹⁶ Patients most
29 192 vulnerable to COVID-19 are the elderly and those with chronic health conditions.¹⁷ These
30 193 groups have significant overlap with those patients that the NHS Forth Valley report
31 194 identified as being appropriate for the ReSPECT process.⁷ In the weeks preceding the first
32 195 rapid increase of COVID-19 cases in the UK, the NHS emphasised the importance of ACP. For
33 196 clinicians, National Institute for Health and Care Excellence (NICE) guidance was updated
34 197 with COVID-19 rapid guidelines stating that clinicians should discuss ACP with patients at
35 198 risk of deterioration due to COVID-19.¹⁸ For patients, document templates such as the 'My
36 199 COVID-19 Advance Care Plan' were produced.¹⁹ The result of this increased focus on ACP is
37 200 evidenced by a survey of UK palliative care services, with 37.9% reporting that they had
38 201 been providing more direct ACP and 58.5% reporting an increase in advising others about
39 202 ACP.²⁰ This increased emphasis and usage of ACP has also been seen in other countries
40 203 during the pandemic.^{21,22}
41 204

42 205 It is not clear how the pandemic affected the implementation of the ReSPECT process, both
43 206 in the BNSSG area and nationally. The Royal College of General Practitioners suggested that
44 207 the pandemic made certain aspects of sensitive ACP conversations more difficult, due to the
45 208 reduction in face-to-face consultations. Conversely these conversations may have been
46 209 easier, with some patients seeing an increased relevance in ACP for them or their loved
47 210 ones. This is a view substantiated by a 2020 evidence synthesis report.^{23,24} It is also
48 211 unknown how many ReSPECT forms have been completed during the pandemic, who were
49 212 receiving them and what recommendations were being documented. This is particularly

1
2
3 213 important as there have been concerns in both the media and various healthcare
4 214 organisations that ACP and DNACPR documents have been “applied in a blanket manner to
5 215 whole groups” such as care home residents.^{25,26}
6
7 216 It should also be considered that irrespective of the pandemic, all published studies on the
8 217 ReSPECT form have included small samples and the majority have been secondary care
9 218 orientated. This study is the first to explore the implementation, use and outcomes of all
10 219 documented ReSPECT forms (from primary and secondary care) for a large patient
11 220 population, specifically the approximately one million patients served by the BNSSG CCG.
12 221

13
14 222 There are two unknowns that contribute to the rationale for this study. Firstly, the
15 223 implementation of the ReSPECT process in the BNSSG area was started four months before
16 224 the pandemic began. In this period it is reasonable to assume that clinicians were still
17 225 adopting to the new process. As the pandemic began it is also likely that clinicians’ usage of
18 226 the ReSPECT form changed due to both gained experience and necessity. We will explore
19 227 which patients were receiving a ReSPECT form during the first year of implementation and
20 228 any changing patterns over the year. We will also explore the equity of which patients had a
21 229 documented ReSPECT form such as the proportion of those with a cancer diagnosis or those
22 230 in a care home or similar communal residence. Additionally, the impact of the ReSPECT
23 231 process on patient outcomes in emergency and ‘End of Life’ situations during the pandemic
24 232 has not yet been investigated. Therefore, through investigation of the ReSPECT form
25 233 implementation and its outcomes we hope to inform future ReSPECT form usage in the
26 234 BNSSG area, future implementation processes across the UK, and contribute to the evidence
27 235 base for any subsequent effects on the patient outcomes.
28
29
30
31
32
33

34 238 **Aim**

35 239 To describe the characteristics of patients in the BNSSG CCG area who had a ReSPECT form
36 240 recorded in their primary care medical records before, during, and after the first wave of the
37 241 COVID-19 pandemic and to analyse any differences in outcomes for those patients who died
38 242 with a community-completed ReSPECT form, a hospital-completed ReSPECT form, or
39 243 without a ReSPECT form.
40 244

43 245 **Objectives**

- 45 246 1. To quantify how many ReSPECT forms were completed before, during and after the first
46 247 peak of COVID-19 and the clinical and demographic characteristics of patients with a
47 248 documented form.
- 48 249 2. To describe any changes in clinical and demographic characteristics of patients with a
49 250 ReSPECT form added to their notes during these periods
- 51 251 3. To identify any changes in patterns of priorities, recommendations and DNACPR decisions
52 252 documented on ReSPECT forms during these periods
- 53 253 4. To measure any differences in routinely collected outcomes for those patients who died
54 254 with a ReSPECT form that was completed either in the community or in hospital or who
55 255 died without a ReSPECT form. These outcomes are: emergency department attendances,
56 256 emergency hospital admissions, district nurse home visits, hospice referrals, prescription
57 257 of anticipatory medication, and if the patient died in their preferred place of death (if
58 258 documented).

259 **Methods**

261 **Study overview and setting**

262 This is a quantitative study, conducted in two phases, which will take place within the
263 Bristol, North Somerset and South Gloucestershire (BNSSG) CCG area:

- 264
265 1. Implementation Phase – An observational cross-sectional study of all patients for
266 whom a ReSPECT form was completed between 1st October 2019 and 30th
267 September 2020. We will evaluate the number of ReSPECT forms completed across
268 all general practices and secondary care settings in the BNSSG CCG area before,
269 during and after the first COVID-19 wave. Across these time periods we will describe
270 any changes in clinical and demographic patterns of patients with ReSPECT forms,
271 along with any shifting patterns in the priorities, recommendations and DNACPR
272 decisions documented.
- 273
274 2. Outcomes Phase – A retrospective cohort study of all patients who died between 1st
275 October 2019 and 30th September 2020. We will compare any differences between
276 routinely collected outcomes for those patients who died with a ReSPECT form
277 completed in the community, a ReSPECT form completed in hospital, or who died
278 without a ReSPECT form. These outcomes will be: emergency department (ED)
279 attendances, emergency hospital admissions, community nurse visits, hospice
280 referrals, prescription of anticipatory medication (and how long before death), place
281 of death, and whether the patient died in their preferred place of death (if
282 documented). Only deceased patients are included in this phase as their patient
283 journey is ‘complete’ and any difference in outcomes is likely to give a fully
284 representative picture.

287 **Implementation Phase**

289 *Design*

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

294 *Data collection*

295 This data will be collected from the Public Health Management (PHM) data resource (also
296 known as the System Wide Dataset), retrospectively from 1st October 2019 to 30th
297 September 2020.²⁷ The PHM data resource is used for various purposes by the CCG, one of
298 those being population health management. The PHM data resource routinely collects
299 administrative health and social care data from primary care, secondary care, community
300 services, mental health and adult social care for the local population in the Bristol, North
301 Somerset and South Gloucestershire area. For a defined set of purposes focusing on
302 population health management, BNSSG CCG may choose to commission named providers to
303 analyse, for a limited time, effectively anonymised minimised extracts of these data. This
304 particular study is being undertaken for the purposes of reviewing, evaluating and
305 transforming current health and care service provision across and within the population.

1
2
3 306 Our study team (as a named provider) works as a data processor under a project specific
4 307 data sharing agreement (DSA), which is designed in reference to the overarching data
5 308 protection and impact assessment.
6 309

7 310 The PHM dataset consists of two tables – attributes and activity. The first table contains
8 311 information regarding patient characteristics, such as demographic information (age and
9 312 sex), clinical information (long term conditions), socio-economic information (deprivation
10 313 index) as well as other data like smoking status and social status. The second table contains
11 314 information regarding patient contacts such as point of delivery (e.g. secondary care,
12 315 inpatient, elective), specialty (e.g. dermatology), provider, dates, times and cost. More
13 316 details of its contents can be found in the Github online repository.²⁸
14 317

15 318 The BNSSG area represents a diverse population, from both urban and rural areas.²⁹ In 2017
16 319 the BNSSG population was approximately 951,000, with a median age of 36, just below the
17 320 national median age of 40.4.³⁰ 9.8% of the BNSSG population have black and Asian
18 321 ethnicity. This is slightly below the national average of 14.6% but represents a large amount
19 322 of local variation, with Bristol above the national average at 16%.³³ BNSSG is a relatively
20 323 affluent area with only 16% of its population living in the most deprived national quintile
21 324 (the national average being 20%).^{31,32}
22 325

23 326
24 327 Inclusion criteria:

- 25 328
- 26 329 • All patients aged 18 and over with a completed ReSPECT form in their primary care
27 330 medical record.

28 331 Exclusion criteria:

- 29 332
- 30 333 • Patients under 18 years old.
 - 31 334 • Patients without a completed ReSPECT form in their primary care medical record.

32 335
33 336 All data collected will be pseudonymised. In addition to the number of ReSPECT forms
34 337 completed we will also collect data on specific variables. These variables were determined
35 338 in consultation with the study advisory group (composed of stakeholders from local
36 339 commissioning, clinical and academic organisations). Sociodemographic variables were
37 340 specifically chosen to describe our population within our dataset limitations. One such
38 341 limitation is 'Ethnicity' which is poorly documented within local electronic patient records.
39 342 The 'Medical Conditions' variables were chosen due to their perceived relevance to
40 343 clinicians in identifying patients that would benefit from the ReSPECT process. The 'ReSPECT
41 344 and End of Life' variables were chosen, again within the limitations of our data, to
42 345 specifically fulfil our aims of exploring patterns of priorities, recommendations, and
43 346 outcomes of the ReSPECT form. These will be collected from electronic patient records using
44 347 general sociodemographic codes, medical condition codes and ReSPECT form specific codes
45 348 as detailed in Table 1.
46 349

47 350

48 351

49 352

Sociodemographic	Medical Conditions	ReSPECT and End of Life
Practice code	Dementia	Date of ReSPECT form completion
Gender	Learning Disability	Setting in which the form was completed (Primary vs Secondary)
Age	Cancer diagnosis	Clinical Priorities (detail below)
Lives in a Nursing or Residential Home?	Electronic Frailty Index ³³	Clinical Recommendations (detail below)
Housebound	Charlson Score ³⁴	Preferred place of death
Lower Super Output area (LSOA) ³⁵		Preferred place of death discussed with family
		Patient capacity and involvement in the process
		Who was involved in the process if the patient didn't have capacity?
		DNACPR code in primary care record

Table 1. Sociodemographic, Medical and ReSPECT form data to be collected

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.

Clinical Priorities	Prioritise sustaining life, even at the expense of comfort
	Prioritise sustaining life moderately over comfort
	Prioritise sustaining life slightly over comfort
	Balance between sustaining life and comfort is equal
	Prioritise comfort slightly over life sustaining treatment
	Prioritise comfort moderately over life sustaining treatment
	Prioritise comfort, even at the expense of sustaining life
Clinical Recommendations	Wishes to be kept comfortable at home prioritising symptom control - does not want any active treatments (End of Life care)
	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).
	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, severe pneumonia) even if these

	treatments cause discomfort. Would not want ventilation or admission to ITU
	Wishes to be admitted to hospital for full investigation and treatment of any new serious health problems, including ventilation and ICU where this is medically recommended.
	Please enter plan in free text box

Table 2. Options on electronic patient record template for 'Clinical Priorities' and 'Clinical Recommendations'

Outcomes

Primary

- The rate of ReSPECT form completion across three time periods (ReSPECT forms / four-month period):
 - Before the first wave - 1st October 2019 (the introduction of the ReSPECT form in the BNSSG area) to 31st January 2020.¹⁵
 - During the first wave - 1st February (the first cases of COVID-19 in the UK along with rising awareness) to 31st May 2020.^{16,36,37}
 - After the first wave - 1st June (a significant easing of restrictions following the first national lockdown and a decrease in the COVID alert level) to 30th September 2020.³⁸

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 programs '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 X^2 tests. For continuous variables we will use mean averages and standard deviations for summarisation and analysis of variance (ANOVA) tests (or Kruskal-Wallis tests for non-normal data) for differences between time periods

407 **Outcomes Phase**

408

409 *Design*

410 A retrospective cohort study will be undertaken that will allow us to identify any differences
411 in numbers between routinely recorded outcomes for those patients who died after
412 completing a ReSPECT form with a clinician in the community, in hospital, and those who
413 died without a ReSPECT form.

414

415

416 *Data Collection*

417 Data collected for the outcome phase will also be from the PHM data resource.

418

419

420 Inclusion criteria:

- 421 • All patients aged 18 and over, who died between 1st October 2019 to 30th September
422 2020.

423

424 Exclusion criteria:

- 425 • Patients aged under 18 years old at the time of death.

426

427 All data will be pseudonymised with the following data collected for each patient:

428

- 429 • Emergency department attendances
- 430 • Emergency hospital admissions
- 431 • Community nurse home visits
- 432 • Hospice referrals
- 433 • Anticipatory medication packs prescribed, and the how long these were prescribed
434 before death - These are medication packs prescribed to patients to keep at home
435 when clinicians feels that the patient could quickly deteriorate and develop
436 symptoms related to the terminal phase of life.
- 437 • Place of death
- 438 • Whether patient died in preferred place of death

439

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

443

444

445 *Outcomes*

446

447 Primary

- 448 1. The difference in secondary care usage (Emergency department attendance and
449 emergency admission) between the patient groups (Community ReSPECT form,
450 Hospital ReSPECT form and No ReSPECT form).

451

452 Secondary

- 453 1. The difference in community care usage (community nurse visits, hospice referrals)
454 between the patient groups.

2. The difference in the patient groups in regard to frequency of anticipatory medication packs prescribed and how long (days) these were prescribed before death.
3. 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 programs 'R' and 'STATA'. Logistic regression models (adjusting for age, gender and the Charlson co-morbidity index) will be used to compare the patient care outcomes above between those who received a ReSPECT form in the community, in 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 Patient and Public involvement 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 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: 28/07/2020).

BNSSG CCG are the controllers of the pseudonymised data with patient opt-outs applied.³⁹ The ethical and governance arrangements for the collection, curation, onward sharing and subsequent processing of these data are formally agreed within data sharing agreements and data protection impact assessments between the primary and secondary care data controllers and the BNSSG CCG.⁴⁰ 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 is 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 Appendix 1.

1
2
3 500

4 501

5 502 **Data management**

7 503 Before patient data is released to the research team it will be pseudonymised by the BNSSG
8 504 CCG, with each patient record assigned a study ID number. This data will be stored securely
9 505 on the institutional network file store which will only be accessible with a password.

11 506 Dissemination of quantitative patient data findings will be on an aggregate level with no
12 507 individual patient data being published. Data will be stored for 10 years after completion of
13 508 the study as per University of Bristol recommendations.

14 509

15 510

16 511 **Dissemination of findings**

18 512 Upon completion of this study a manuscript will be prepared. It will also be submitted to a
19 513 peer reviewed journal for publication. The results will also be presented at scientific
20 514 meetings and disseminated through university and social media networks. This manuscript
21 515 will also help inform future commissioning decisions in the BNSSG area.

22 516

23 517

24 518

25 519

26 520 **Author's Contributions**

28 521 The study concept and design were conceived by AMD, LP, LS and CC. Analysis was planned,
29 522 and will be performed, by CAW and AMD. AMD prepared the manuscript with editorial
30 523 contributions from LP, CAW, LS and CC.

31 524

32 525

33 526

34 527 **Funding statement**

36 528 This study will be completed by AM, whose role is funded the by Health Education England
37 529 as part of an Academic Clinical Fellowship in General Practice, with LP as primary supervisor.
38 530 LP is funded by a National Institute of Health Research (NIHR) Doctoral Fellowship. CAW's
39 531 role was supported in part by the Medical Research Council (MCR) and Wellcome Trust
40 532 Institutional Strategic Support Fund (WT ISSF), awarded to CAW on a Daphne Jackson Trust
41 533 Development Fellow in collaboration with the Elizabeth Blackwell Institute at the University
42 534 of Bristol. The WT ISSF3 grant number 204813/Z/16/Z. LS is funded by a NIHR Career
43 535 Development Fellowship. Grant numbers have been stated where applicable.

44 536

45 537

46 538

47 539

48 540

49 541

50 542

51 543

52 544

53 545

54 546

55 547

56 548

57 549

58 550

59 551

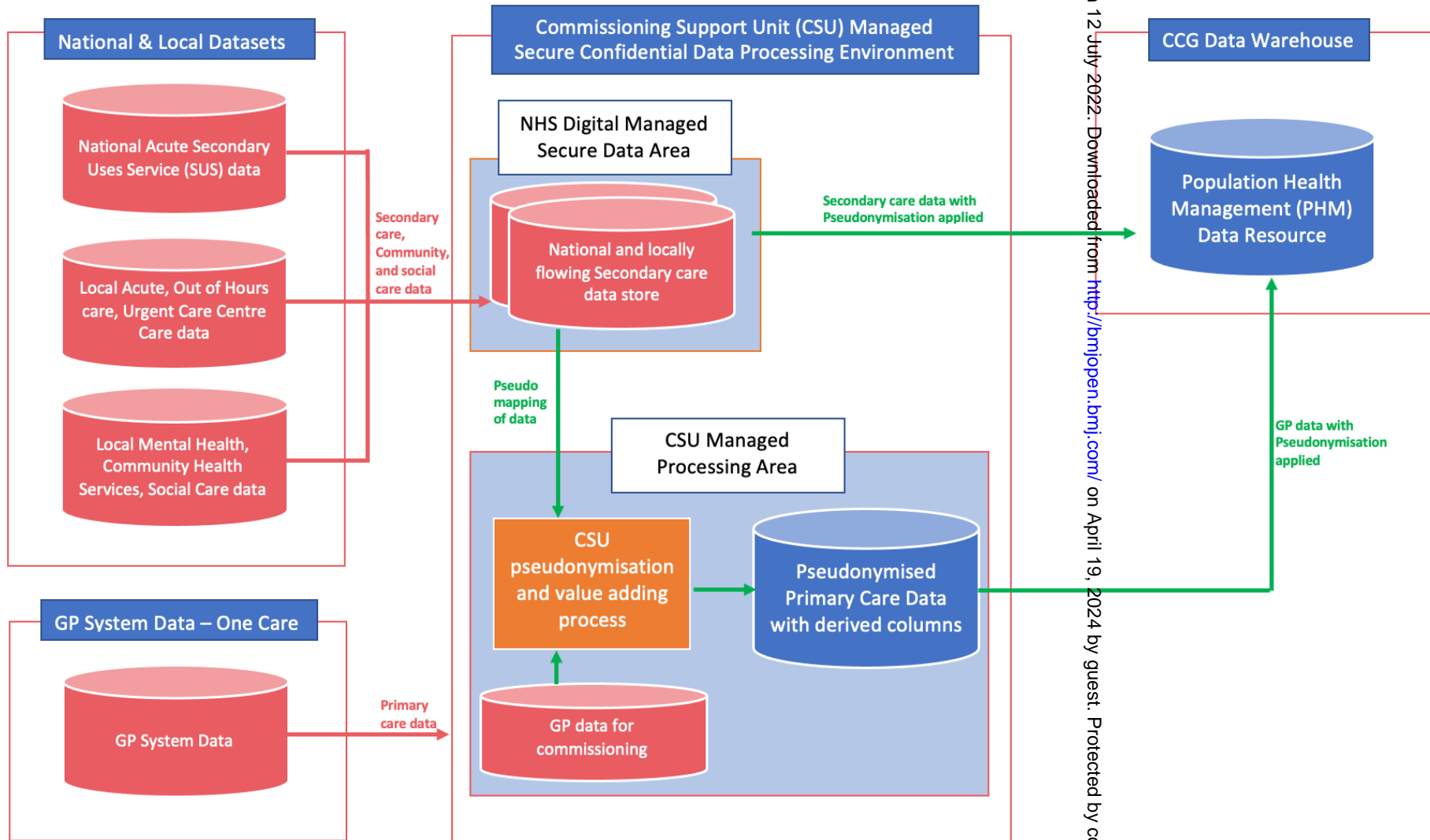
60

541 **References**

1. Hawkes C, Fritz Z, Deas G, Ahmedzai S, Richardson A, Pitcher D et al. Development of the Recommended Summary Plan for Emergency Care and Treatment (ReSPECT). *Resuscitation*. 2020;148:98-107. doi: 10.1016/j.resuscitation.2020.01.003.
2. Fritz Z, Slowther A, Perkins G. Resuscitation policy should focus on the patient, not the decision. *BMJ*. 2017;;j813. doi: 10.1136/bmj.j813.
3. NIHR Funding and Awards Search Website [Internet]. Fundingawards.nihr.ac.uk. 2020 [cited 28 August 2020]. Available from: <https://www.fundingawards.nihr.ac.uk/award/15/15/09>
4. Davies M, Couper K, Jeyes L, Slater P, Speakman J, Arolker M et al. Successful implementation of the ReSPECT (Recommended Summary Plan for Emergency Care and Treatment) process in a large UK based NHS Trust. *Resuscitation*. 2017;118:e95-e96. doi :<https://doi.org/10.1016/j.resuscitation.2017.11.013>
5. Trethewey S, Morlet J, McDonald D, Dowling D, Davies M, Perkins G. Evaluation of ReSPECT forms in critical care: A clinical audit. *Resuscitation*. 2017;118:e93. doi: <https://doi.org/10.1016/j.resuscitation.2017.11.007>
6. Eli K, Hawkes CA, Fritz Z, Griffin J, Huxley CJ, Perkins GD, et al. Assessing the quality of respect documentation using an accountability for reasonableness framework. *Resuscitation Plus*. 2021;7:100145. doi: 10.1016/j.resplu.2021.100145.
7. Clinical Outcomes Group Forth Valley. A Quantitative and Qualitative Evaluation of the ReSPECT (Recommended Summary Plan for Emergency Care and Treatment) Process in Forth Valley Scotland's first ReSPECT pilot: A Case for Change [Internet]. 2019. Available from: <https://ihub.scot/media/6171/respect-report-final.pdf>
8. Jeyes L, Hall M, Slater P, Broderick K, Couper K, Perkins G. The impact of implementation of ReSPECT (recommended summary plan for emergency care and treatment) on the making of treatment escalations in patients with do not attempt cardiopulmonary resuscitation decisions. *Resuscitation*. 2019;142:e62-e63. doi: <https://doi.org/10.1016/j.resuscitation.2019.06.151>
9. Eli K, Ochieng C, Hawkes C, Perkins G, Couper K, Griffiths F et al. Secondary care consultant clinicians' experiences of conducting emergency care and treatment planning conversations in England: an interview-based analysis. 2020. doi: 10.1136/bmjopen-2019-031633.
10. Resuscitation Council UK Statement on the role of the ReSPECT Process during COVID-19 [Internet]. Resus.org.uk. 2020 [cited 28 August 2020]. Available from: https://www.resus.org.uk/sites/default/files/2020-06/COVID%20ReSPECT%20Guidance%2023042020_0.pdf
11. Eli K, Hawkes C, Ochieng C, Huxley C, Baldock C, Fortune P et al. Why, when and how do secondary-care clinicians have emergency care and treatment planning conversations? Qualitative findings from the ReSPECT Evaluation study. *Resuscitation*. 2021;162:343-350. doi: 10.1016/j.resuscitation.2021.01.013
12. Nicholas R, Nicholas E, Hannides M, Gautam V, Friede T, Koffman J. Influence of individual, illness and environmental factors on place of death among people with neurodegenerative diseases: a retrospective, observational, comparative cohort study. *BMJ Supportive & Palliative Care*. 2021;6:bmjsspcare-2021-003105. doi: 10.1136/bmjsspcare-2021-003105.
13. Huxley C, Eli K, Hawkes C, Perkins G, George R, Griffiths F et al. General practitioners' experiences of emergency care and treatment planning in England: a focus group study. *BMC Family Practice*. 2021;22(1). doi: 10.1186/s12875-021-01486-w.
14. Resuscitation Council UK Introduces version 3 of ReSPECT form [Internet]. Resuscitation Council UK. 2020 [cited 18 August 2021]. Available from: <https://www.resus.org.uk/about-us/news-and-events/resuscitation-council-uk-introduces-version-3-respect-form>
15. Remedy – ReSPECT. BNSSG CCG [Internet]. 2019 [cited 20 October 2021] Available from: <https://remedy.bnssgccg.nhs.uk/adults/end-of-life-care-and-hospice/respect/>
16. Coronavirus (COVID-19) in the UK [Internet]. Coronavirus.data.gov.uk. 2022 [cited 5th April 2022]. Available from: <https://coronavirus.data.gov.uk/details/deaths?areaType=overview&areaName=United%20Kingdom>
17. Cascella M, Rajnik M, Aleem A, Dulebohn S, Napoli R. Features, Evaluation, and Treatment of Coronavirus (COVID-19) [Internet]. Ncbi.nlm.nih.gov. 2021 [cited 20 October 2021]. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK554776/>
18. NICE. COVID-19 rapid guideline: managing symptoms (including at the end of life) in the community [Internet]. 2020. Available from: <https://www.nice.org.uk/guidance/ng163/resources/COVID19-rapid-guideline-managing-symptoms-including-at-the-end-of-life-in-the-community-pdf-66141899069893>
19. NHS England. Advance care planning guidance and template [Internet]. 2020. Available from: <https://www.england.nhs.uk/coronavirus/publication/advance-care-planning-guidance-and-template/>
20. Bradshaw A, Dunleavy L, Walshe C, Preston N, Cripps R, Hocaoglu M et al. Understanding and addressing challenges for advance care planning in the COVID-19 pandemic: An analysis of the UK CovPall survey data from specialist palliative care services. *Palliative Medicine*. 2021;35(7):1225-1237. doi: 10.1177/02692163211017387.
21. Lapid M, Koopmans R, Sampson E, Van den Block L, Peisah C. Providing quality end-of-life care to older people in the era of COVID-19: perspectives from five countries. *International Psychogeriatrics*. 2020;32(11):1345-1352. doi: 10.1017/S1041610220000836.
22. Cascella M, Rajnik M, Aleem A, Dulebohn S, Napoli R. Features, Evaluation, and Treatment of Coronavirus (COVID-19) [Internet]. Ncbi.nlm.nih.gov. 2021 [cited 20 October 2021]. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK554776/>
23. Anticipatory Care Planning in a COVID landscape [Internet]. Rcgpp.org.uk. 2020 [cited 20 October 2021]. Available from: <https://www.rcgp.org.uk/about-us/rcgp-blog/anticipatory-care-planning-in-a-COVID-landscape.aspx>
24. Selman L, Lapwood S, Jones N, Pocock L, Anderson R, Pilbeam C et al. What enables or hinders people in the community to make or update advance care plans in the context of Covid-19, and how can those working in health and social care best support this process? [Internet]. 2020 [Cited 20 October 2021]. Available from: <https://www.cebm.net/covid-19/advance-care-planning-in-the-community-in-the-context-of-covid-19/>
25. Lacobucci G. COVID-19: Don't apply advance care plans to groups of people, doctors' leaders warn. *BMJ*. 2020;369:m1419.
26. Joint statement on advance care planning [Internet]. Rcgpp.org.uk. 2020 [cited 20 October 2021]. Available from: <https://www.rcgp.org.uk/about-us/news/2020/april/joint-statement-on-advance-care-planning.aspx>
27. Population Health Management [Internet]. BNSSG Healthier Together. 2022 [cited 28 March 2022]. Available from: <https://bnssghealthiertogether.org.uk/population-health-management/>

- 1
2
3 610
4 611
5 612
6 613
7 614
8 615
9 616
10 617
11 618
12 619
13 620
14 621
15 622
16 623
17 624
18 625
19 626
20 627
21 628
22 629
23 630
24 631
25 632
26 633
27 634
28 635
29 636
30 637
31 638
32 639
33 640
34 641
28. SWD User Guide [Internet]. BNSSG Business Information GitHub Repository. 2022 [cited 28 March 2022]. Available from: <https://github.com/BusinessInformationBNSSG/SWD/blob/main/SWD%20User%20Guide.xls>
29. Norman J, Thompson C. Single System and CCG plan 2019/20 [Internet]. Bristol: Bristol, North Somerset and South Gloucestershire Clinical Commissioning Group; 2019. Available from: https://bnssgccg-media.ams3.cdn.digitaloceanspaces.com/attachments/govbody_7May19_item6.4.pdf
30. Population estimates for the UK, England and Wales, Scotland and Northern Ireland - Office for National Statistics [Internet]. Ons.gov.uk. 2021 [cited 20 October 2021]. Available from: <https://www.ons.gov.uk/peoplepopulationandcommunity/populationandmigration/populationestimates/bulletins/annualmidyearpopulationestimates/mid2020>
31. Diversity in the UK - Diversity UK [Internet]. Diversity UK. 2021 [cited 20 October 2021]. Available from: <https://diversityuk.org/diversity-in-the-uk/>
32. Case for Change - Addressing the Health and Wellbeing Gap [Internet]. Bristol.gov.uk. 2017 [cited 20 October 2021]. Available from: <https://www.bristol.gov.uk/documents/20182/34748/Case+for+Change+-+Addressing+the+Health+and+Wellbeing+Gap+2017+%28BNSSG%29/c4765bc1-0c3d-5db4-bd03-36ce6395b1bd>
33. Clegg A, Bates C, Young J, Ryan R, Nichols L, Ann Teale E et al. Development and validation of an electronic frailty index using routine primary care electronic health record data. Age and ageing. 2016 May 1;45(3):353-60.
34. Charlson ME, Pompei P, Ales KL, MacKenzie CR. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. Journal of chronic diseases. 1987 Jan 1;40(5):373-83.
35. NHS Data Model and Dictionary [Internet]. NHS Digital 2022 [cited 28 March 2022]. Available from: https://www.datadictionary.nhs.uk/nhs_business_definitions/lower_layer_super_output_area.html#:~:text=Lower%20Layer%20Super%20Output%20Areas,statistics%20in%20England%20and%20Wales.
36. Coronavirus [Internet]. Google Trends. 2020 [cited 20 October 2021]. Available from: <https://trends.google.com/trends/explore?geo=GB&q=%2Fm%2F01cpyy>
37. The United Kingdom – Communicating COVID-19 [Internet]. COVID19.philemerge.com. 2020 [cited 28 August 2020]. Available from: <https://COVID19.philemerge.com/the-united-kingdom/>
38. Timeline of UK government coronavirus lockdowns [Internet]. The Institute for Government. 2021 [cited 20 October 2021]. Available from: <https://www.instituteforgovernment.org.uk/charts/uk-government-coronavirus-lockdowns.>
39. Opt out of share your health records [internet]. NHS. 2021 [cited 28 March 2022]. Available from: <https://www.nhs.uk/using-the-nhs/about-the-nhs/opt-out-of-sharing-your-health-records/>
40. How we use your information [Internet]. BNSSG Clinical Commissioning Group. 2022 [cited 28 March 2022]. Available from: <https://bnssgccg.nhs.uk/about-us/how-we-use-your-information>

Appendix 1: Data Inputs and flow for the PHM data resource



6/bmjopen-2021-060253 on 12 July 2022. Downloaded from <http://bmjopen.bmj.com/> on April 19, 2024 by guest. Protected by copyright.