



An evaluation of the effectiveness of 'care bundles' as a means of improving hospital care and reducing hospital readmission for patients with chronic obstructive pulmonary disease (COPD)

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1 TITLE

1.1 Full title

An evaluation of the effectiveness of 'care bundles' as a means of improving hospital care and reducing hospital readmission for patients with chronic obstructive pulmonary disease (COPD)

1.2 Short title

Admission and discharge care bundles for COPD

2 SUMMARIES OF RESEARCH

2.1 Lay summary

Avoiding unnecessary use of emergency hospital services is one of the biggest challenges currently facing the National Health Service (NHS). Many initiatives have already been set up to try to tackle the problem and yet the number of people admitted to hospital at short notice continues to rise. Chronic obstructive pulmonary disease (COPD) is the name for a collection of long-term conditions that affect the lungs. It is one of the most common respiratory diseases in the United Kingdom and accounts for 10% of hospital admissions each year. Nearly a third of these patients are re-admitted to hospital within 28 days of discharge.

We think that use of COPD care bundles could play a key role in resolving the issue of unplanned admissions. Care bundles are a way of ensuring that staff are able to provide a co-ordinated package of care to patients with COPD at the point that they arrive at or are sent home from hospital. Although several small studies have suggested that care bundles lead to better care for patients with COPD, a larger national study is needed if we are to show that these findings are reliable. This application outlines a way in which we could measure the effect of introducing COPD bundles as part of routine hospital care at both patient and organisational levels.

Most of the information needed for this study is easy to obtain because it is routinely collected by hospitals in the course of their own management activity. Some of the data needed will relate to individual patients or specific members of staff but these can be collected and recorded in a way which does not contain any personal details and maintains confidentiality.

The proposed study will include up to 20 hospital trusts in England and Wales who have agreed to deliver the COPD care bundles and another group of up to 20 hospital trusts who will not be delivering them. By comparing how many patients are admitted to, discharged from and readmitted to each type of hospital over time, and what happens to patients during and after their stay, we will be able to assess how successful COPD care bundles are. More specifically, we will look at:

- numbers of patients admitted with COPD
- number of COPD patients seen and discharged from hospital
- number of deaths of COPD patients while in hospital
- number of days spent in hospital by patients with COPD
- proportion of patients with COPD who are readmitted
- levels of satisfaction in patients with COPD
- how patients with COPD are managed in hospital
- how much it costs to care for a patient with COPD in hospital

Our multi-disciplinary team is well placed to carry out this study as it includes individuals with a wide range of academic, clinical and management expertise who have a proven reputation in delivering high quality research. We are committed to carrying out work which responds to the needs of clinicians, managers, patients and carers and which can, in turn, offer a chance for real service improvement within the NHS. Since the care bundles are being rolled out across the NHS, this presents a timely opportunity to evaluate their success. The results of this study could reduce the need for patients with COPD to re-attend hospital, offer healthcare professionals clearer guidance on COPD management and reduce costs by reducing avoidable hospital admissions.

2.2 Expert summary

This research seeks to evaluate the effectiveness of care bundles (i.e. a co-ordinated package of care) as a means of improving hospital care and reducing readmissions for patients with chronic obstructive pulmonary disease (COPD). It is designed as a controlled before-and-after study with nested case studies. The chosen study population will be people admitted to hospital with a primary cause of acute exacerbation of COPD or AECOPD. The intervention under consideration is the delivery of care bundles at the point of admission and discharge. Acute trusts chosen as comparator sites will deliver usual care for patients admitted with AECOPD.

The study will compare trust level aggregated statistics between ≤ 20 hospital trusts who will deliver the care bundle intervention and a broadly comparable group of ≤ 20 hospital trusts who will not be delivering the care bundle intervention during the study period (**Level 1**). From this initial group, a sample of 8 implementation sites will be identified, paired with 8 comparator sites, for more detailed quantitative study using routine data from hospital discharge datasets and also for follow-up of mortality (**Level 2**). Data will be collected on COPD admissions over the course of a 12-month period prior to, and following, the implementation of the care bundle intervention, ensuring that data are collected during the same 'before' and 'after' period for paired implementation and comparator sites. In addition, a purposeful sample of up to 4 implementation sites and at least 2 comparator sites will be selected as case studies for in-depth investigation, using a mixture of qualitative methods (**Level 3**). Implementation sites will be purposively over-sampled in order to reflect the variation of care bundle implementation across sites.

A range of outcomes will be measured including:

primary outcome

- COPD readmission rates at 28 days

secondary outcomes

hospital utilisation

- total number of COPD admissions
- length of stay for patients with COPD
- total bed days for COPD admissions
- COPD readmission rates at 90 days
- overall readmission rates at 28 days

patient outcomes

- in-hospital mortality
- mortality at 90 days
- patient and carer experience

care bundle delivery and resource use

- total number of patients for whom COPD care bundle used
- compliance with delivery of COPD care bundles
- time taken to deliver COPD care bundles
- costs and cost-effectiveness of in-patient care

In Level 3 sites, the implementation case studies will examine in detail the context and process of delivery of the COPD care bundles, along with patient, carer and staff experiences of receiving and delivering the care bundles. The qualitative methods used will be: observations of admissions and discharge; interviews with patients, carers and staff in hospital and community settings; and analysis of relevant documents (e.g. clinical protocols, local guidelines and policies). The same methods will be used in the comparator sites, including: observations of admission and discharge care for patients with COPD; interviews with patients, carers and staff; and analysis of documents. Patients from both implementation and comparator case study sites will be followed-up for a 30-90 day period post-

discharge using face-to-face and telephone interviews to examine patient and carer experiences of post-discharge care and use of services. Community/social care staff involved with these patients will also be interviewed (face-to-face or by telephone) during this period, to examine perspectives on the role and value of care bundles, the impact on post discharge care and experiences of providing care for patients with COPD in the community.

Analysis of the quantitative data will estimate the difference in change in outcome between implementation and comparator sites before and after introduction of the COPD care bundle intervention. Within the case studies, qualitative data from multiple sources will be analysed using a range of approaches, to provide detailed description of the context and processes of care, and elucidate and explain the decision-making processes, and interactions between staff, patients and carers, that impact the delivery of care at admission and during and after discharge. Economic analysis will estimate the incremental NHS secondary care costs per patient in the care bundles trusts/periods compared to the comparator trusts/periods. Cost-effectiveness (cost per additional survivor at 90 days) of the care bundles and their probabilistic uncertainty will be described using cost-effectiveness acceptability curves, based on bootstrapped re-sampling of the observed cost and outcomes data. Sensitivity analyses will be performed where appropriate.

This research will provide independent evidence of the impact of COPD care bundles on care during and after hospital admission and future readmissions. It will also indicate how a co-ordinated care package might improve quality of care, equity of access, patient and carer experience and service delivery for COPD patients within the acute setting, taking into account cost implications and implementation challenges.

3 INTRODUCTION

3.1 Background

This research aims to evaluate the impact of admission and discharge care bundles for patients admitted to hospital with chronic obstructive pulmonary disease (COPD). COPD is the name for a collection of long-term conditions that affect the lungs, including chronic bronchitis, emphysema and chronic obstructive airways disease. People with COPD have trouble breathing in and out, due to long-term damage to the lungs, usually because of smoking. COPD usually affects people over the age of 35, although most diagnoses occur in people in their fifties.

COPD is one of the most common respiratory diseases in the United Kingdom (UK). It is estimated that the prevalence of COPD in the UK is over 3 million, of which only about 900,000 have been diagnosed. It accounts for 10% of hospital medical admissions (over 90,000 annually) in the UK (*Health and Social Care Information Centre; 2012*). The majority of people with COPD also have other medical problems, most commonly ischaemic heart disease which occurs in 25% of patients (*RCP; London, 2008*). Many people discharged from hospital after an acute exacerbation of chronic obstructive pulmonary disease (AECOPD) have depression (64%) and anxiety (40%) with over 80% having at least one other condition such as coronary heart disease. This multi-morbidity means that managing their healthcare needs is challenging (*Barnett; Lancet 2012, Gruffyd-Jones, Primary Care Respy Journal 2007*). What is more, in many patients, co-morbidities such as heart failure go unrecognised (*Rutten; Eur Heart Journal 2005*). Nearly a third of these patients are re-admitted to hospital within 28 days of discharge and this proportion is rising following a 2% increase (to 33%) in the readmission rate from 2003 to 2008 (*Price; Thorax 2006, RCP; London 2008*). Mortality rates in hospital have changed little over the same time period (7.5% in 2003 and 7.7% in 2008).

There is considerable pressure on managers and clinicians in the NHS to reduce emergency hospital admissions. Emergency admissions to hospital for long-term conditions, including COPD, are included in the NHS Outcomes Framework and are the subject of initiatives to reduce emergency admissions such as the NHS Ambulatory Emergency Care Directory for Adults (*NHSI, Coventry 2010*). This document suggests that COPD admissions could be reduced by 10-30% if evidence based care is implemented. COPD is the second most common cause of emergency admission to hospital and the fifth largest cause of readmission, costing the NHS an estimated £491 million per year. The number of admissions has increased by 50% in the last decade and accounts for one million bed days per annum. It is probable therefore that this issue will remain a challenge for the NHS for the foreseeable future.

A Royal College of Physicians Audit conducted in 2003 found that on average patients spend 8.7 days in hospital during an admission for COPD. There was wide variation observed in all outcomes between hospitals. In particular the inter-quartile range for mortality was 9-21%. (*Chronic Obstructive Pulmonary Disease; National Clinical Guideline Centre 2010*). A significant element of this variability is explained by access to expert care, as length of stay and mortality was reduced in units with more respiratory specialists (*Price; Thorax 2006*). There are evidence-based interventions which have been demonstrated to improve outcomes for patients admitted with COPD but provision of these interventions varies considerably across acute NHS units (*RCP; London 2008*). There is, therefore, an opportunity to improve outcomes for patients by ensuring care is consistently provided to a high standard.

3.2 Development of care bundles for COPD

Admission and discharge care bundles for COPD have been developed by the British Thoracic Society (BTS) in association with NHS Improvement (NHSI). Care bundles are being implemented in health care as a way of focusing improvement efforts on a defined set of factors and actions which contribute to achievement of a clearly specified aim. Care bundles are a simple way of focusing improvement efforts on a set of actions which contribute to achievement of a clearly specified aim. Improvement theory suggests that care bundles allow clinical teams to focus their efforts on a small number of measurable strategies aimed at improving specified outcomes (*BTS/NHSI; 2012*). Protocol-based care also enables staff to quickly see what action should be taken, when and by whom. They allow practice to be standardised and reduce variation in the treatment of patients. They are also an important tool in improving the quality of care, as variance from the agreed care pathway can be measured easily - allowing systemic factors that inhibit provision of best care to be identified. Previous NHSI Lung studies have included care bundles for asthma and a community acquired pneumonia care bundle is also being implemented. However, apart from some evidence from the United States and from a couple of pilot studies in the UK, the impact of care bundles on processes and outcomes of care is unknown.

There is some evidence from single pilot sites in the UK that the implementation of in-patient care pathways or bundles can improve clinical outcomes such as mortality, hospital readmission rates and hospital length of stay (*Robb E; BMJ 2010*). Hopkinson and colleagues have shown a downward trend in 30-day readmissions in patients with COPD in whom a bundle approach to discharge was applied (*Hopkinson; Thorax 2011*). A more recent study of a comprehensive care management program in a different patient group (out-patients with COPD) conducted in the Veteran's Administration system in the USA was stopped when an excess of deaths was observed in the intervention group. (*Fan V; Annals of Int Med 2012*) The cause of the excess mortality could not be determined. Considerable caution was exercised when deciding on the key elements of the COPD discharge bundle in view of this finding. However, a subsequent systematic review and meta-analysis including the Fan et al study did not identify any increased mortality for self-management interventions in COPD. (*Jolly K, University of Birmingham, personal communication July 2014*)

The content of the COPD care bundles is based on interpretation of published evidence of interventions that improve patient outcomes (see Box 1 and 2, page 12). It was felt that a single care bundle could not encompass the range of measures required. Therefore, two sets of care bundles were derived: one to be completed at the point of hospital admission (admissions care bundle), aimed at reducing in-hospital mortality for COPD and reducing length of stay, and a bundle to be completed before discharge from hospital (discharge care bundle) aimed at reducing re-admissions. Together, these comprise 10 evidence based actions, which when completed in full, aim to lead to an improvement in the overall care of patients admitted to hospital with an acute exacerbation of chronic obstructive pulmonary disorder (AECOPD). The study also includes a programme of education and training in quality improvement and implementation to facilitate the roll-out of the bundles in each trust. A team from each participating trusts will be supported to implement the care bundles and to gather data to support evaluation of the bundles. Senior management support for the programme has been secured at each trust.

Following completion of this study, the following benefits for participating trusts are anticipated:

- shorter length of stay and reduced mortality / readmission rates for patients with COPD
- improved care experience for patients admitted with COPD and their carers
- creation of a multi-disciplinary team confident in quality improvement methodologies

COPD admission care bundle (see Box 1, page 13)

It is vital that the care provided to people admitted with an acute respiratory illness is co-ordinated and delivered in a timely way. The COPD admission care bundle is designed to facilitate this. The first step is to ensure that a correct diagnosis of AECOPD is established as soon as possible at the point of hospital admission. 1) The diagnostic process, which begins with a history and physical examination, should be supported by early availability of an ECG and chest x-ray. 2) Current guidelines suggest that patients should be placed on optimum medical therapy (controlled oxygen and nebulised therapy) for one hour and should then be assessed for whether non-invasive ventilation (NIV) is required. 3) The patients with highest mortality from COPD following hospital admission are those who are admitted in ventilatory failure, thus early recognition and an appropriate response to hypoxia and respiratory acidosis are critical (*O'Driscoll; Thorax 2008*). 4) Correct prescription of medications (including nebulisers, steroids and antibiotics) is also necessary. 5) Finally, since results of the 2003 national COPD audit suggest that review by a respiratory specialist reduces in-hospital mortality (*Price; Thorax 2006*), and given that the majority of deaths occur within 72 hours of admission, all patients admitted with an acute exacerbation of COPD will be seen by a member of the respiratory team within 24 hours of admission. This could be a specialist nurse or physiotherapist, specialist registrar or consultant.

COPD discharge care bundle (see Box 2, page 13)

It is also vitally important the care provided to patients at discharge from hospital is well organised and delivered efficiently. Structured discharge planning is one intervention that has been shown to reduce further hospital admissions (*Purdy; King's Fund 2010*). The BTS COPD discharge bundle aims to ensure that patients have been assessed appropriately prior to discharge, are confident in the use of their medications and have ready access to advice and assistance should they deteriorate following discharge from hospital. The discharge bundle includes: 1) Assessment of respiratory medications and inhaler technique prior to discharge. 2) A written plan for how to manage a further acute exacerbation of their COPD and a discharge pack of "emergency" drugs prior to discharge. 3) Assessment of smoking status is undertaken by assessing willingness to quit and for those patients indicating a wish for further assistance, referral to a stop smoking programme will be undertaken. 4) All patients will be assessed for suitability for pulmonary rehabilitation prior to discharge. 5) Both stopping smoking and early pulmonary rehabilitation have been shown to reduce future hospital admissions (*NICE; London 2010*). Finally, community follow-up will be organised within two weeks of discharge from hospital.

This research provides the opportunity to evaluate in-patient care bundles for one common condition in acute hospital trusts across England and Wales. The primary outcome to be measured will be COPD readmission rates at 28 days post-discharge with secondary outcomes to include mortality, length of stay, patient and carer experience, process and costs of care. The outputs will include detailed data on the outcomes, process and delivery of the care bundles which will inform the further implementation of the care bundles for COPD as well as the development and implementation of care bundles for other conditions. Collaboration with the BTS and NHSI means the study has its roots embedded in the NHS and the intervention is pragmatic and generalisable to sites beyond academic or tertiary care centres. The findings will feed directly into service delivery organisations and this will, in turn, ensure dissemination amongst clinicians and managers 'on the ground'. The research team's existing links with the British Lung Foundation will facilitate the sharing of information with patient and carer groups across the UK.

3.3 Evidence explaining why this research is needed now

There is a move within the NHS to ensure that people with long-term conditions receive more co-ordinated care in the management of their health. However, there is little research evidence from the UK to support this approach to COPD care. In the USA and Spain, studies have examined integrated or coordinated care packages for COPD and these have been shown to reduce readmission rates (*Casas; ERJ 2006, Rice; AJRCCM 2010*). The care bundles proposed are a method of co-ordinating care both within the hospital and, on discharge, across the in-patient-community interface. Individual components of the care bundles are supported by NICE guidance, with more recent evidence suggesting, but not proving, that self-management improves the overall management of exacerbations and clinical outcomes (*Taylor; BJGP 2012, Bischoff; BMJ 2012*).

The value of care bundles as a way of co-ordinating and improving care has recently been shown across a number of long-term disease care pathways in a UK setting by Robb and colleagues (*Robb; BMJ 2010*) who observed a fall of 18.5 in the hospital standardised mortality rate for their institution following bundles implementation for patient care in 13 diagnoses. This study will add to the existing

evidence base on the introduction of clinical care bundles. There are a number of areas in which care bundles have been developed and evaluated including ventilator and central line care, sepsis prevention and management, induction of labour and anterior cruciate ligament repair. There is an increasing body of literature from organisations such as the Institute for Healthcare Improvement (IHI) and NHS Improvement work in this area as well as original literature describing implementation of these initiatives (*Resear; IHI 2012, NHS Improvement; Leicester 2011*).

Research into the implementation of care bundles in other clinical areas has identified the impact of 'secular trend' (rising improvements that would have happened anyway) and 'decline effects' (difficulty replicating promising results from other studies) (*Dixon-Woods; Implementation Science 2013*). Many interventions that attempt to improve practice fail to exceed the overall 'rising tide', and so have problems showing that they have added value. Both the national and local contexts can also impact implementation and this needs to be adequately captured in evaluations. Dixon-Woods et al. describe three types of characteristic response to the programme they studied - transformed, boosted and low impact. They also highlight that what happens in non-intervention settings often remains 'obscure'.

The introduction of a COPD discharge care bundle, very similar to the one proposed in this study, to one hospital, resulted in improvements in both the rate and process of delivery of the component interventions in addition to a non-significant reduction in 30-day readmissions. (*Hopkinson; Thorax 2011*). Delivery of a similar care bundle at another hospital resulted in a 26% reduction in readmission rates at one year follow-up (*Mann B; NICE Shared Learning Awards 2012*). Therefore, the evaluation of care bundles for COPD across a wider sample of hospital trusts within the NHS is very timely. The COPD care bundles were developed under the auspices of the British Thoracic Society and NHS Improvement in response to these early initiatives, with specialist input from individuals from nursing, physiotherapy, medical and quality improvement backgrounds. The package available to participating implementation trusts provides prompts on the main actions for clinicians but the instructions on how care is provided can be edited to allow adaption to local circumstances.

This research will provide independent evidence of the impact of COPD care bundles on hospital admissions and readmissions. It will also indicate how a co-ordinated care package might improve quality of care, equity of access, patient and carer experience and service delivery for COPD patients within the acute setting, taking into account cost implications and implementation challenges. The research will also explore potential enablers / inhibitors to the delivery of the COPD care bundles. Potentially, the research could also inform the development and delivery of care bundles for other health conditions.

4 JUSTIFICATION FOR STUDY DESIGN

The COPD care bundles group components of care into clinical pathways, one aimed at newly-admitted patients and one at patients about to be discharged. Adherence to the admission or discharge care bundle therefore means that a patient's care at point of admission or discharge has been delivered according to a protocol and the use of the care-bundles provides a mechanism for co-ordinating efforts by enabling staff to identify completed and required actions.

The study is being conducted in partnership with the British Thoracic Society. The study will include a group of acute hospital trusts who have agreed to deliver the COPD care bundle intervention as well as a group of broadly comparable trusts who will not be delivering the intervention during the study period. The commitment by implementation trusts to delivering care bundles and the roll-out of the training programme has precluded delivery of a randomised controlled trial, therefore we have selected a controlled before-and-after study as the most robust study design to measure any association between care bundles and better costs and outcomes of AECOPD care. The study involves three different levels of data collection and analysis to build a comprehensive dataset which will evaluate the effectiveness, efficiency and acceptability of the care bundle package.

5 STUDY AIMS AND OBJECTIVES

5.1 Study aim and research question

Aim: This research seeks to evaluate the effectiveness of care bundles (i.e. a co-ordinated package of care) compared to usual care as a means of improving hospital care and reducing readmissions for patients with exacerbated chronic obstructive pulmonary disease (COPD).

Research question: How do the COPD admission and discharge care bundles developed by the British Thoracic Society impact on outcomes for patients admitted with an acute exacerbation of COPD?

5.2 Study objectives

The objectives of the research are:

- a) to determine the impact of implementing COPD care bundles on the proportion of patients re-admitted to hospital within 28 days of discharge (primary outcome)
- b) to assess the impact of COPD care bundles on in-hospital mortality, length of stay and total bed days
- c) to monitor readmission and mortality rates in the 90 days following discharge
- d) to compare resource utilisation, NHS secondary care costs and cost-effectiveness of care at implementation and comparator sites
- e) to assess the impact of COPD care bundles on patient and carer experience using qualitative data from case study sites
- f) to describe in detail the local context and process of COPD care bundle implementation across a range of case study sites, including information on the setting (location, relationship with other services), current practice/policies, workforce impact (training, workload, number and range of staff involved, skill-mix and expertise), clinician-patient decision-making at admission and discharge, post-discharge care and patient and carer experience
- g) to compare the process of care for patients receiving COPD care bundles with usual care for COPD, identifying enablers and inhibitors to the provision of best quality care, using quantitative and qualitative methods

6 RESEARCH PLANS / METHODS

6.1 Design

The research will use a controlled before-and-after design to compare the costs and outcomes of introducing care bundles with usual care for patients admitted to hospital with an acute exacerbation of COPD. The research will also include nested case studies. It will compare trust-level aggregated data between ≤ 20 acute trusts who deliver the COPD care bundles intervention (implementation sites) and a broadly comparable group of ≤ 20 acute trusts who do not deliver the COPD care bundles intervention (comparator sites).

From this initial group, a sample of 8 implementation sites will be identified, along with 8 paired comparators, for more detailed quantitative study, including gathering of process data from routine hospital discharge data and follow-up of mortality. These pairings will be determined on the basis of a number of criteria including current COPD admission, 28-day re-admission and COPD mortality rates. From these 8 implementation and 8 comparator sites, a purposeful sample of up to 4 implementation sites and at least 2 comparator sites will be selected as case studies for in-depth investigation, using a variety of qualitative methods. Implementation sites will be purposively oversampled in order to capture

a richness of data on care bundle implementation. One implementation site will also be recruited from among the Level 1 sites to pilot data collection at Levels 2 and 3.

As a general principle, data will be collected at each implementation site over a 24-month period - 12-months immediately preceding the implementation of the COPD care bundles and 12-months after the start of the intervention. Data will be collected during the same 'before' and 'after' periods at the comparator sites broadly comparable to each of the implementation sites at Level 1, and to the paired sites at Level 2.

The study involves three different levels of data collection and analysis as follows:

Level 1:

This will use routinely collected trust-level aggregated quantitative data to compare the primary outcome, COPD 28-day readmission rates plus secondary outcomes including length of stay, total bed days for COPD admissions, COPD 90-day readmission rates and in-hospital mortality at up to twenty broadly comparable pairs of trusts. In implementation sites, the total number of patients in whom the bundles are used will also be collected if this information is readily available. All of the required data is anonymous and is routinely reported by NHS Trusts and will be uploaded by trust data analysts to the study database on a monthly basis using data that would be routinely uploaded to the Secondary Uses Service (SUS) as part of NHS reporting arrangements.

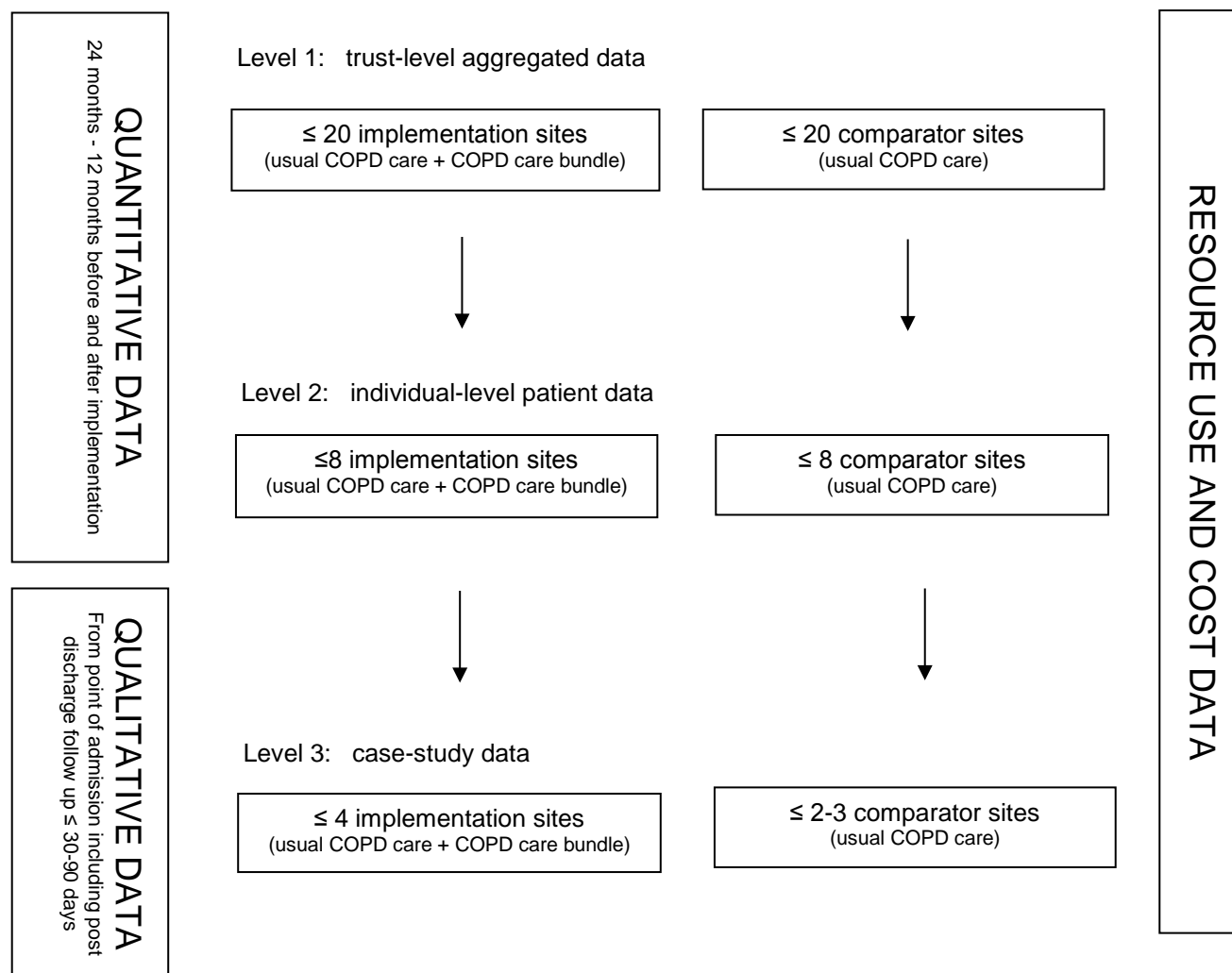
Level 2:

A sample of eight implementation sites will be identified, along with their eight paired comparators, for a more in-depth quantitative study. The eight pairs of sites will be recruited from among the Level 1 sites in collaboration with the BTS. Routinely collected data will be reported from each site at pseudo-anonymised individual patient level. These data are routinely reported to SUS and will be linked to 90-day mortality data. In addition, process measures on delivery of components of COPD care will be collected at both implementation and comparator sites for a subset of 140 patients per site.

Level 3:

Up to eight sites drawn from the sites providing Level 2 data will be selected as qualitative case-studies. We will aim to include sites with different features such as extent of implementation of the care bundles, specialist staffing levels, service provision and socio-demographic profiles. These case studies will examine in detail the context and process of care and impact of the care bundles on staff, patient and carers. A schematic of the study design is presented in Figure 1.

Implementation sites will be purposively oversampled in order to capture a richness of data on care bundle implementation. One implementation site will also be recruited from among the Level 1 sites to pilot data collection at Levels 2 and 3.

Figure 1: Flowchart diagram describing research design

6.2 Setting

The setting for the research is acute hospital trusts in England and Wales. Twenty-five acute trusts from across England and Wales signed up to participate in the British Thoracic Society care bundle initiative in 2012. We anticipate that up to up to 20 of these sites will be co-opted as our Level 1 participants, allowing for a degree of non-participation attrition, and a similar number of comparator sites will also be recruited.

6.3 Study population

The target study population will be people admitted to hospital with an acute exacerbation of COPD as their primary cause of admission (AECOPD). This may be a first admission or a second or subsequent admission for that patient during the study period. The research will also include qualitative input from clinical and management staff who provide care for these patients within the NHS setting and, where appropriate, their families and carers.

Inclusion criteria:

- people over 18 years of age admitted to an acute hospital with COPD
- primary cause of admission is COPD (ICD-10 diagnostic codes J41-44)

Exclusion criteria:

- people admitted to hospital with COPD where this is not the primary cause of admission
- elective admissions for COPD

6.4 Sample size

The primary outcome used in the sample size calculation is the proportion of people readmitted to hospital within 28 days of discharge for an AECOPD. The acute hospital trusts that are potential implementation sites for the study each have, on average, 600-800 admissions per hospital trust per year.

We have based our sample size calculation on Level 2 sites where we will have pseudo-anonymised individual patient data. If we have 8 pairs of implementation and comparator sites in Level 2 providing individual patient data, this will provide a sample of around 10,000 admissions per year. Assuming an intra-cluster correlation co-efficient (ICC) of 0.01 and cluster size of 625, giving a design effect of 7.25, there will be 90% power at the 5% significance level to detect a 10% absolute difference in the COPD readmission rate at 28 days, assuming 30% of patients are re-admitted in comparator sites. A random sample of one in five patients will be selected from Level 2 implementation and comparator sites for data on adherence to the care bundles and on delivery of the components of the care bundles. The total sample will be in the region of 2240 (16 x 140). This provides greater than 90% power to detect a 0.22 SD difference in means on a continuous measure such as readmission rates at 28 days at 5% significance level. In this case, the sample size has a design effect of 2.4, corresponding to an ICC of 0.01 and cluster size of 140.

A minimum sample of at least four implementation sites and two comparator sites will be selected from the Level 2 data, to serve as qualitative case studies. These will be purposefully selected to ensure variation across stages of implementation of care bundles in the implementation sites and for both case and comparator sites we will aim to include sites with different features such as specialist staffing levels, service provision and socio-demographic profiles. Flexible sampling will allow addition of further sites should advantages of including more case studies become apparent from early analysis of case study data. Implementation sites will be purposively oversampled in order to capture a richness of data on care bundle implementation. We will also do some additional sampling for 'light touch' data collection in some implementation sites in response to issues that emerge during the study. Although not 'full' case studies, these interviews with key staff will enhance the dataset.

6.5 Study intervention

The intervention under consideration is the delivery of care bundles developed by British Thoracic Society at:

- i) the point of admission to hospital
- ii) the point of discharge from hospital

Acute trusts chosen as comparator sites will deliver usual care for patients admitted with COPD.

Training for implementation sites

The COPD care bundle packages will be delivered at implementation sites by NHS staff as part of initiatives to improve care pathways for respiratory patients. The joint BTS/NHS Lung Improvement study teams are supporting the initial spread of the BTS COPD care bundles. Each participating site has committed a senior member of the respiratory medical team, a specialist nurse and a data analyst or trust audit manager to participate in a series of change management workshops and data collection training. It is this early commitment to the roll-out of the care bundles programme have which precluded randomisation of sites to the intervention and, therefore, the conduct of a randomised controlled trial.

The COPD care bundles take the components supported by evidence in the NICE guideline and group these components into clinical pathways, one aimed at newly admitted patients and one at patients about to be discharged. Each care bundle is summarised with a checklist and prompts for actions. These clinical 'tools' can be placed in the written patient medical record or added to an electronic record to prompt the clinical teams to deliver care and complete sections of the toolkit as the care is delivered. Adherence to the COPD admission or discharge bundle, therefore, means the patient's care at admission or discharge has been delivered according to an evidence-based protocol and the use of the tool provides a mechanism for co-ordinating care by enabling staff to identify completed and required actions. Local sites can edit or adapt the tools to add instructions for use in their own particular setting. Further information about the tools is available on the BTS website:

<http://www.brit-thoracic.org.uk/Delivery-of-Respiratory-Care/BTS-NHSI-Care-Bundle-Study-Documents.aspx>.

Roll-out of the BTS care bundles initiative is supported by a series of workshops and WebEx based meetings. Venues and facilitators are provided by the BTS and the educational content of the workshops was developed and delivered by NHS Improvement and BTS. Where it is possible to cluster hospitals from local areas, teams are encouraged to share learning and work together. Mentors, drawn from the BTS membership, who have experience of quality improvement methodology or implementation of bundles, provide support to the training workshops. The evaluation will pay particular attention to the issues of on-going education and staff involvement in the case study sites for example by observing any ongoing educational initiatives and interviewing staff about their training in the care bundles, experience of delivery and feelings of engagement.

The main components of the care bundles are set out in Box 1 and 2.

In the comparator sites, usual care for COPD will continue to be delivered. Comparator sites will be asked to agree not to introduce COPD care bundles during the study period. The components of the current standard care pathway for patients admitted with AECOPD should encompass the current NICE guidance (*NICE; Chronic obstructive pulmonary disease 2010*). This agreement will be underpinned by the following:

- all sites will be asked to sign a written agreement to stay in their chosen arm for the duration of the project.
- payment of research costs to sites providing Level 2 data will be subject to this agreement being honoured.
- the commitment to stay in the chosen arm will continue for the 12-month study period. Comparator sites will then be at liberty to introduce the care bundles.
- feedback data will be provided to implementation and comparator sites on completion of the evaluation in comparison with anonymised data from the other sites. This information may be of interest to those late adopters who choose to be in the comparator group until they see evidence that bundles are worth the extra expenditure.
- if a site does breach the non-adoption protocol, we will either use the information collected on that pair of sites up to that point or consider re-pairing any sites that lose their partner.

Box 1
COPD admission care bundle

- 1) ensure correct diagnosis of AECOPD with both:
 - a. chest x-ray - result of chest X-ray documented in the notes within 4 hours and
 - b. ECG - result of ECG documented in the notes within 4 hours
- 2) recognise and respond to respiratory acidosis within 3 hours of admission
 - a. arterial blood gas within 1 hour – if oxygen sats less than 94% on air or controlled oxygen
 - b. when pH less than 7.35 – assess suitability for NIV and implement within 3 hours of admission
- 3) recognition of hypoxia and correct oxygen prescription within 30 minutes of admission - with target range of 88%-92%
- 4) correct prescription of medication for AECOPD at admission
 - a. steroids - prescribed and administered within 4 hours of admission when necessary
 - b. antibiotics - prescribed and administered within 4 hours of admission where necessary
 - c. nebulisers - prescribed and administered within 1 hour if appropriate
- 5) review by a respiratory specialist within 24 hours – may be conducted by a respiratory specialist nurse, doctor or physiotherapist

Box 2
COPD discharge care bundle

- 1) assess respiratory medications and inhaler technique prior to discharge.
- 2) all patients should receive:
 - a. written plan for how to manage a further acute exacerbation of their COPD; and
 - b. discharge pack of “emergency” drugs prior to discharge
3. assess smoking status by assessing willingness to quit and for those patients indicating a wish for further assistance, refer to a stop smoking programme
- 4) assess for suitability for pulmonary rehabilitation prior to discharge
- 5) organise community follow up within two weeks of discharge from hospital. Where it is not possible to achieve this, consideration should be given to establishment of a system whereby patients are contacted by phone following their discharge from hospital and are offered the opportunity for support.

6.6 Outcome Measures

The following high-level measures will be used to evaluate the overall benefit of introducing care bundles. The majority of these data are routinely collected within the NHS. Data in these domains will be collected monthly by trust data analysts.

Level 1: Sites will report a range of aggregated data including:

- 1) COPD readmission rate at 28 days (primary outcome measure)
- 2) total number of COPD admissions from trust data (denominator)
- 3) in-hospital mortality for COPD admissions
- 4) length of stay for COPD admissions
- 5) total bed days for COPD admission
- 6) COPD readmission rate at 90 days
- 7) overall readmission rates at 28 days
- 8) total number of COPD patients seen and discharged from A&E
- 9) total number of patients in whom bundle used (implementation sites only, where routinely recorded)

Level 2: Sites will report the same outcomes as Level 1 but at pseudo-anonymised individual level for all COPD patients during the study period. In addition, outcome measures will include:

- 1) mortality data – sites will undertake data linkage to death registry data to determine 90-day mortality
- 2) process measures - for implementation sites, data on compliance with the components of the COPD bundles will be recorded on the clinical tools. At each comparator site, a sample of medical records will be reviewed to monitor compliance with the care processes recommended in the BTS care bundles. In addition, medical records for a small number of implementation patients will also be reviewed, as source data verification to ensure that the case bundle clinical tool is a true reflection of the tests and procedures undergone and as recorded in the medical records. This will also ensure that any differences between implementation and comparator aren't due to different methods of measurement in the two arms.

Level 3: The 'outcomes' of the qualitative Level 3 case studies will be detailed qualitative data from observations and interviews regarding the context, process and patients/carer/staff experiences of delivering and receiving care bundles.

Qualitative data from case studies will enable comparison of the context, process and experience of care for patients receiving care bundles and usual care. They will also help to explain variations in practices, processes and decision making that may impact the delivery and receipt of care at admission or discharge. During the qualitative case studies, we will carefully document the content and delivery of the care bundles, to describe what the care bundles comprise, and similarities and differences in organisation and delivery of the bundles across case study sites. Follow-up with patients, carers and staff will include exploration of how care bundles impact post-discharge care and patient experience of community based services and self-care. This will be elicited through interviews with primary, community and social care staff in the 30-90 day post-discharge period (e.g. GP practices, district nursing staff, social care staff, and staff from community respiratory services such as specialist nurses, pulmonary rehabilitation and smoking cessation). During this period, interviews with patients and carers will assess confidence in the use of medications, access to advice and assistance should they deteriorate following discharge from hospital, and take up of smoking cessation and early pulmonary rehabilitation.

Following prior theoretical work on the implementation of care bundles in other contexts, the qualitative case studies will examine the extent of professional ownership of the bundles and the extent to which there is enthusiasm for or suspicion about the drivers for the care bundles, as this may impact implementation. We will also monitor 'decline effects' as previous studies of COPD care bundles have highlighted the importance of ongoing training for maintaining delivery of the bundles. Purposeful sampling of sites at different stages of implementation of the care bundles will allow some examination of 'trends' in adoption of the bundles across the case study sites and, therefore, help us to understand what the care bundles constitute in different sites, and how differences in implementation might contribute to differences in patient experience and outcome. This will further inform the literature around potential variations in implementation of care bundles. We will also do some additional sampling for 'light touch' data collection in some implementation sites in response to issues that emerge during the study. Although not 'full' case studies, these interviews with key staff will enhance the dataset.

Measures of resource use and cost

We will estimate the total NHS in-patient costs of care for all COPD patients at sites that provide Level 1 data, based on aggregate data on in-patient admissions, length of stay and total bed days. For sites providing Level 2 routine data, we will build up a more complete picture of NHS secondary care costs at an individual patient level based on routine data provided on all patients (e.g. length of stay, HRG code, procedures) and from process measures recorded in the medical record audit to be conducted by trust staff (costs to be met by research grant). This will be on 140 patient records per site and will include details of medications and procedures (e.g. chest X-ray, ECG) during in-patient stay at both implementation and comparator sites. From observations (time and motion study) in Level 3 sites, we will estimate the nursing and clinical staff time taken and the consumables required (e.g. medications) to deliver care bundles at admission and discharge.

6.7 Data collection

It is anticipated that the implementation sites will implement the COPD care bundles at varying times during the evaluation period. At Level 1, data collection within broadly comparable sites will be conducted across the same time-period. For Level 2, data collection will be conducted across the same time-period for paired implementation and comparator sites. In addition, one Level 1 implementation site will be used to pilot data collection for Level 2 and 3.

Level 1: Sites will report a range of aggregated routine data retrospectively for the 12 months prior to the start of the intervention roll-out. Data will then be recorded prospectively during the 12-month intervention period and a 90-day period thereafter to monitor any readmissions. All of the required data is anonymous and the majority is routinely reported by NHS Trusts. Data will include:

- 1) COPD readmission rate at 28 days (primary outcome measure)
- 2) total number of COPD admissions from trust data (denominator)
- 3) in-hospital mortality for COPD admissions
- 4) length of stay for COPD admissions
- 5) total bed days for COPD admission
- 6) COPD readmission rate at 90 days
- 7) overall readmission rates at 28 days
- 8) total number of COPD patients seen and discharged from A&E
- 9) total number of patients in whom bundle used (implementation sites only)

Outcomes 1-8 will be reported by implementation and comparator sites using data that would be routinely uploaded to the Secondary Uses Service (SUS) as part of NHS reporting arrangements. Data will be forwarded by sites and input by a researcher to a spreadsheet.

COPD readmissions within 28 days are the primary outcome. In addition, data on overall readmission rates at 28 days will be collected to determine local trends for readmission rates for all conditions. We anticipate a high proportion of 28-day readmissions for this patient group will be for COPD, but we plan to capture data on all readmissions. In order to check for coding changes or inconsistent definitions, we will look for changes in the rate of COPD readmission and readmissions overall over the study period. We will explore ways in which changes in coding could impact on the study results, in particular on the primary outcome of COPD readmission and consider how this could be addressed. For example, should COPD readmissions fall but readmission rates remains stable in a particular site, an independent review of the readmissions could be conducted to assess the codes used. Furthermore, the total number of COPD patients seen and discharged from A&E will be recorded to compare rates of AECOPD presentations to A&E and patients with AECOPD treated as ambulatory care cases.

Level 2: Sites will report pseudo-anonymised individual level data on all COPD patients during the study period. Again, data will be reported retrospectively for the 12 months prior to the start of the intervention roll-out. Data will then be recorded prospectively during the 12-month intervention period and a 90-day period thereafter to monitor any readmissions. All of the required data is routinely reported by NHS Trusts and will be forwarded by the trust and entered onto a spreadsheet by a researcher on a monthly basis using data that would be routinely uploaded to the Secondary Uses Service (SUS) as part of NHS reporting arrangements. The individual patient data and additional process data will include:

- 1) non-identifiable patient demographic information. This will include a number of data items reported at the anonymised individual patient level to inform the evaluation, including:
 - a) age in years (5-year age bands will be used where there are small numbers of patients in a particular range e.g. <35 years or >95 years)
 - b) sex
 - c) lower super output area of residence
 - d) ethnicity (highly infrequent ethnicities will be grouped as 'other')
- 2) non-identifiable patient clinical information:
 - a) admission month and year
 - b) source of admission (e.g. GP, A&E)
 - c) ICD-10 diagnosis codes
 - d) OPCS procedure codes
 - e) length of stay; total and by ward (ICU/HDU/general ward)
 - f) discharge destination
 - g) HRG codes
 - h) pseudo-anonymised consultant and GP practice codes
 - i) readmission at 28 days (COPD/all cause admissions) and 90 days (COPD)
 - j) outpatients appointments
 - k) A&E appointments
 - l) in-hospital mortality
 - m) 90-day mortality including number of days after discharge that death occurred (sites will undertake data linkage to death registry data to determine 90-day mortality – see note below)
 - n) total number of patients in whom the bundle was used (implementation sites only)

Data linkage by the Health and Social Care Information Centre (HSCIC) will enable 90-day mortality to be monitored at Level 2 sites. The HSCIC links hospital discharge data to Office of National Statistics (ONS) mortality data to identify deaths of patients both in and outside of hospital within 30, 60 or 90 days of admission (<http://publicdata.eu/dataset/summary-of-deaths-inside-and-outside-hospital-based-on-primary-diagnosis-at-admission>). We will work with NHS data analysts in Level 2 sites to obtain this data in linked but anonymised format.

- 3) process measures - for implementation sites, data on compliance with the components of the COPD bundles will be recorded on the clinical tools. Data on delivery of individual components of the COPD care bundles will be collected from a random sample of 140 medical records at each Level 2 comparator site. Adherence to the COPD care bundle will also be monitored in a random sample of 140 patients at each Level 2 implementation site, as source data verification to ensure that the case bundle clinical tool is a true reflection of the tests and procedures undergone and as recorded in the medical records. This will also ensure that any differences between the implementation and comparator sites are not attributable to different methods of measurement in the two arms. These data will be collected by audit or clinical staff in the sites using data collection proformas which will be retained by the Trust in site files and the information will be transferred, in pseudo-anonymised form to the research team. Allocated research funding is available to pay for this data extraction.

Level 3: Sites selected as case study sites will be evaluated using a range of qualitative methods, notably non-participant observation and interviews conducted by qualitative researchers. Observations within implementation and comparator sites will generate detailed descriptive data on the local contexts and settings where the care bundles are being implemented and how the care bundles are actually implemented, alongside detailed comparative information on usual care. The case studies will look at both advantages and challenges of bundles compared with usual care in hospital and also in the community post-discharge. Interviews within the case study sites will elicit staff, patient and carer perspectives regarding the admission and discharge care bundles and usual care.

Within each case study, we will sample events, times and people. Events to be sampled will include admission, discharge, and COPD related appointments and care occurring around 30 and 90 days after discharge. Of particular interest will be patient experiences and staff-patient interactions during these events. Times to be sampled during the case studies will include different times of the day and week, allowing for weekend as well as weekday admissions and discharge. People to be sampled will include a range of staff, patients and carers involved in admission, discharge and post-discharge care. Staff to be interviewed will include, but not be limited to, those delivering care for COPD patients at admission, discharge and post discharge including medical, nursing, physiotherapy, pharmacy and radiology staff, managers and in the community GPs, GP practice staff including nurses, district nursing staff, social care staff and community respiratory services such as specialist nurses, pulmonary rehabilitation and smoking cessation. In addition, a purposeful sub-sample of patients and carers will be followed for 30-90 days after discharge and interviewed in the community to gather information about the post-discharge experience. We anticipate that follow up will take place at around 2 and 4 weeks after discharge, with either telephone or face-to-face contact with patients and carers. A final contact will be made at around 90 days after discharge. These contacts will be conducted flexibly depending on the preferences of the patient or carer. Post discharge interviews with patients and carers will assess confidence in the use of medications, use of self-care strategies, access to advice and assistance should they deteriorate following discharge from hospital, take-up of community-based services such as smoking cessation and early pulmonary rehabilitation, and any experiences of re-admission to hospital. We anticipate that up to 10 patients, carers (if the patient has a family or friend as a carer), and hospital and community/social care staff involved in their care, will be observed and interviewed in each case study site. In line with usual practice within qualitative research, sampling will be flexible and the precise number of events, time-points and people included will depend upon the saturation of relevant themes within the context of the study objectives.

At the implementation case study sites, initial semi-structured interviews with managers and clinicians involved in implementing the care bundles will gather background information about the stage of implementation, staff perspectives and engagement, and perceived impact on delivery of care. In comparator sites the same techniques will be used to explore current processes of care and any perceived limitations in current care.

In implementation case studies, additional attention will be given to: whether and how care bundles are implemented; when, where and by whom; stage of implementation; barriers and facilitators to implementation; staff-patient interactions regarding the care bundles, staff, patient and carer experiences of implementing / receiving the care bundles, and perceived impact on patient care and subsequent health at discharge and up to 30-90 days post-discharge. Non-participant observation of admission and discharge will gather detailed information on the processes of implementing the care bundles, including staff-patient interactions and decision-making. Interviews with staff, patients and carers shortly after admission or discharge will elicit experiences of delivering or receiving care bundles, and barriers and facilitators to successful implementation. An analysis of relevant documents (e.g. clinical protocols, local guidelines and policies) will also be undertaken. We will give attention both to the national context in which the care bundles are being introduced (e.g. documenting the national policy picture alongside our study) and the local contexts in which the care bundles are being introduced (e.g. documenting the history of the introduction of the care bundles and the extent to which they are perceived as a 'top down' imposed initiative at the chosen case study sites). We will also do some additional sampling for 'light touch' data collection in some implementation sites in response to issues that emerge during the study. Although not 'full' case studies, these interviews with key staff will enhance the dataset.

In comparator sites, attention will be given to: usual practices, policies and decision making regarding admission and discharge; staffing levels, skill-mix and expertise; staff-patient interactions regarding admission and discharge; and staff, patient and carer experiences of these processes. We will examine qualitatively what is happening out with the care bundles and should be able to provide insight into whether improvements from uptake of the care bundles outpace the 'secular trend' of improvements that may have happened anyway.

Level 3: Quantitative data collection:

The quantitative data collection at Level 2 hospitals comprises observations on clinical staff time spent caring for patients on the day of admission and discharge and community, informal care and other resource use collected in patient questionnaires. These data will be collected in a small sample of consenting patients in Level 3 implementation and comparator sites.

Time and motion observations will be conducted by the qualitative researchers from the research team at all Level 3 sites to estimate nursing and clinical staff time taken to deliver care bundles within 24 hours of admission and planned discharge. We anticipate that the researchers would spend approximately 5 consecutive days in each of the Level 3 sites observing the care provided to patients admitted with AECOPD in the Emergency department, medical admissions unit and on to general wards. This would provide a small sample (approximately 15 patients in total at implementation sites and 15 in total at comparator sites) for comparison of clinician time spent on administering immediate post-admission and pre-discharge care. These observations will be conducted discreetly for those patients who have consented to participation. A software package (such as TimerPro) installed on a smartphone will be used to aid recording of these data.

In addition, a questionnaire will be administered by the study team, by telephone or face-to-face to consented patients at 2 and 4 weeks after discharge. Information will include data on community and informal care:

- a) visits, telephone calls or appointments with respiratory community services e.g. respiratory nurse, pulmonary rehabilitation, smoking cessation
- b) contact with other community services e.g. community matron
- c) informal care received from family or friends
- d) provision or purchase of other equipment or devices

6.8 Data Analysis

The three Levels of the study address different objectives as outlined below.

Research objectives addressed by Level 1:

1. to determine the impact of implementing COPD care bundles on the proportion of patients readmitted to hospital within 28 days of discharge
2. to assess the impact of COPD care bundles on in-hospital mortality, length of stay and total bed days
3. to monitor readmission rates in the 90 days following discharge

Research questions addressed by Level 2:

4. to monitor mortality rates in the 90 days following discharge

Research questions addressed by Level 2 and 3:

5. to assess the impact of COPD care bundles on patient and carer experience, using qualitative data from case study sites
6. to compare resource utilisation and costs and cost-effectiveness of care at implementation and comparator sites
7. to describe in detail the local context and process of COPD care bundle implementation across a range of case study sites, including information on the setting (location, relationship with other services), current practice/policies, workforce impact (training, workload, number and range of staff involved, skill-mix and expertise), clinician-patient decision-making at admission and discharge, post-discharge care and patient and carer experience
8. to compare the process of care for patients receiving COPD care bundles with usual care for COPD, identifying enablers and inhibitors to the provision of best quality care, using quantitative and qualitative methods

Quantitative analysis (Levels 1 & 2)

For Levels 1 and 2, we will use appropriate descriptive statistics to summarise the characteristics of participating sites and all outcomes of interest during the 'before' and 'after' periods for both implementation and comparator groups.

At Level 1, for the primary outcome measure and each secondary outcome in turn, we will calculate the mean change following the introduction of care bundles for each site, and then compare these site level summaries between implementation and comparator arms using a paired t-test to accommodate the paired design.

Four research objectives will be addressed using data from Levels 2 and 3. Here the data will be interpreted in a mixed methods framework, which will utilise the qualitative data to better understand the processes of care described by the individual level quantitative data and experienced by patients. For quantitative data at Level 2, where individual patient data is available, we will use appropriate regression models depending on the outcome type to compare the difference in change between implementation and comparator groups. These models will include an interaction term between groups and time period to estimate the difference in change in outcome between implementation and comparator sites before and after introduction of the intervention. This approach is required since the samples in the 'before' and 'after' periods will be of (mostly) different individuals. All models will take appropriate account of the paired design by including indicator variables as covariates to distinguish each pair of sites. This approach will accommodate any between-site variation (clustering) in outcome rates (*Research objectives 1, 2, 3, 4 and 5*). Where a patient is admitted for several distinct episodes during the study period, this will be recorded so that appropriate accommodation of the likely correlation in outcome of these episodes can be made in the statistical model.

Qualitative analysis (Level 3)

For Level 3, analysis of the qualitative case study data will provide a rich description of the range of issues which have been encountered in implementing the care bundles including patient and carer perceptions, range of staff employed, time taken to administer the care bundles and perceived barriers and facilitators to success (*Research objectives 5, 7 and 8*). Analysis will take place alongside data collection, in order to allow the incorporation of insights into the ongoing data collection process. Field notes taken during observation will be coded alongside documentary analysis and interview transcripts, and emerging themes and theoretical ideas will be discussed and refined at team meetings throughout the research. Using data from multiple sources will allow us to build up 'thick descriptions' (*Miles and Huberman; 1994*) of each case study site, developing accounts that attempt to elucidate and explain the internal processes, and the interaction between staff and patients, that impact the delivery of COPD care at admission or discharge. Analysis across the implementation case studies will allow us to identify factors which seem to be consistently related to the successful or unsuccessful delivery of the components of the care bundles, focusing on where, how and why the implementation of the intervention has worked (or not). The use of one or more theoretical frameworks will be explored, possibly based on theories of quality improvement (*NHSI; Coventry 2008*)

Health economics analysis

Table 1 describes the source of resource use data for analysis at Level 2 and 3 hospitals.

Table 1: Inpatient resource use and cost data to be collected at Level 2 and 3

<i>Data to be collected</i>	<i>Level 2 routine data (all level 2 patients)</i>	<i>Level 2 medical record audit (n=140 per Level 2 site)</i>	<i>Level 3 observations and questionnaires (n≈5 per Level 3 site)</i>
Length of stay	x		
Level of ward e.g. ITU, HDU	x		x
Chest X-ray Y/N	x (OPCS code)	x	
ECG Y/N	x (OPCS code)	x	
Arterial blood gases Y/N		x	
NIV(Non-invasive ventilation) Y/N		x	
Oxygen prescribed Y/N		x	
Nebulisers prescribed Y/N)		x	
Steroids prescribed Y/N		x	
Antibiotics prescribed Y/N		x	
Review by respiratory specialist Y/N		x	
Review of inhaler technique Y/N		x	
Self-management plan provided Y/N		x	
Emergency drug pack Y/N		x	
Oxygen alert card Y/N		x	
Assessed for and referred for pulmonary rehabilitation Y/N		x	
Assessed for smoking status and discussion of cessation Y/N		x	
Follow up phone call arranged Y/N		x	
Clinician time administering care at admission and discharge			x (time motion)
Post-discharge primary care use			x (questionnaire)
Community, informal care etc.			x (questionnaire)

We will evaluate the economic impact of care bundles at Level 1 sites by using trust-level data on total number of COPD admissions and the total bed days to describe the total cost of COPD care and the total cost of COPD care per admission at the implementation sites (before and after implementation) and the comparison sites. As we will not have individual patient level data for level 1 sites, we will use relatively crude unit costing methodology (e.g. weighted average of non-elective COPD-related healthcare resource group (HRG) codes) to estimate the incremental impact of care bundles on the total NHS secondary care cost of COPD care.

A more detailed full economic evaluation will be undertaken in Level 2 sites. Individual patient data on COPD admissions and linked information on 90-day mortality (including number of days between discharge and death) will allow us to estimate to cost effectiveness of COPD care bundles from the perspective of NHS secondary care providers. We will estimate per patient secondary care NHS costs during a 90 day period from the index admission using a more detailed HRG unit costing methodology, reflecting variation in length of stay, use of high dependency and intensive care and major procedures performed during hospitalisation (ref: <http://www.ncbi.nlm.nih.gov/pubmed/21905152>). Patient-specific resource use (investigations, treatments, medication, admission, onward referral, and re-consultations) will be valued using routine data sources, for example NHS reference costs, the British National Formulary (BNF) and Unit Costs of Health and Social Care.

The per-patient estimate will include the cost of any readmissions during the 90-day period. Our analysis will also include an estimate of the cost of implementing COPD care bundles (e.g. nursing staff time, medications etc.) based on medical record reviews at Level 2 sites and observations at Level 3 sites. Cost-effectiveness of the care bundles will be evaluated in Level 2 trusts comparing the NHS inpatient costs and outcomes (90 day mortality) of care pre- and post-intervention, both within intervention sites and between intervention and control sites. Cost-effectiveness and the uncertainty surrounding findings will be described using cost-effectiveness acceptability curves (CEACs), based on bootstrapped re-sampling of observed cost and outcome data.

We anticipate there will be areas of methodological uncertainty in resource use measurement and / or valuation. This uncertainty will be addressed by conducting deterministic sensitivity analyses where appropriate. We anticipate that any important economic benefit of care bundles will be primarily manifest through the secondary care costs and mortality outcomes measured in our primary analysis.

6.9 Data Handling

The custodian of the data from the study will be the Chief Investigator, Prof Sarah Purdy. The database will be designed so as to protect patient information, in line with the Data Protection Act 1998. Research staff will ensure that the participants' anonymity is maintained through protective and secure handling and storage of patient information at the study trusts and sites. The participants will be identified only by a patient ID number on the data collection proforma. All documents will be stored securely and made accessible only to study staff and authorised personnel.

6.10 Data Management

Level 1:

A common template will be provided to participating trusts with a request that data is provided in a format as close as possible to that template.

Level 2:

Administrators based at each trust will link the different sources of data (electronic files, questionnaires) and provide to the study team in anonymised format. Each participant will be identified by a unique ID number, with keys held by the trust, to allow source data verification. Paper copies of questionnaires and data collection forms will be held securely by University of Bristol, identified only by unique ID.

Level 3:

All data, including audio recordings, typed field notes and interview transcripts will be stored at the University of Bristol, on a secure drive that it is password protected, backed up and only accessed by members of the research team. The qualitative data from interviews and observations will be anonymised, with unique pseudonyms or identifiers assigned to each participant and any identifiable information removed from interview/observation transcripts. Interviews will be recorded using an encrypted voice recorder approved by the University of Bristol and transcription will be conducted by a University of Bristol-approved transcription service that has signed a confidentiality agreement. The Level 3 researchers will use approved encrypted password-protected laptops to store certain study information while at fieldwork sites e.g. typed field notes. Only the Level 3 researchers will be able to access information on this laptop.

7 DISSEMINATION AND PUBLICATION

A COPD care-bundles publication policy will be developed in line with University of Bristol guidance within the first 12 months of the study, and study publications will be subjected to an independent quality assurance procedure according to this guidance.

As a multi-disciplinary team of co-applicants and collaborators, we have an excellent track record of publishing high-quality research in peer-reviewed journals, in disseminating research findings to the wider NHS for implementation and for use by the academic community in further research studies. Given the importance of the chosen subject area and national reach of the study, we propose a pro-active dissemination and knowledge mobilisation strategy, as follows:

- research reports and associated summaries for funders, stakeholders, service user groups, policy makers, NHS audiences and research bodies such as the King's Fund, Nuffield Trust and NHS Improving Quality
- analytical papers in peer-reviewed journals across a range of disciplines which would appeal to clinical, organisational, sociological, general health and social policy audiences
- publications for wider readership including practitioner journals and general press and broadcast media
- oral and poster presentations at respiratory, general medical, elderly care, primary care, public health, acute / emergency medicine, nursing and social care conferences and fora
- presentations to clinicians, managers, patients and carers in local, national and international health economies.

In addition, we plan to disseminate the study findings via:

- clinical commissioning groups and provider trusts including community and social care providers
- NHS newsletters e.g. NHS networks <http://www.networks.nhs.uk/ces.co.uk>
- a summary of the overall study results will be made available to those participants who have confirmed that they wish to receive them, including clinical staff recruited to the study.
- websites including the British Thoracic Society <http://www.brit-thoracic.org.uk> , NHS Bristol CCG and Avon Primary Care Research Collaborative <http://www.apcrc.nhs.uk> and the University of Bristol <http://www.bris.ac.uk/primaryhealthcare>

We will also explore and develop the use of podcasts and other media to disseminate findings to service users including collaboration with the British Lung Foundation <http://www.blf.org.uk/Home>

This research will provide 'hard' quantitative feedback on the impact of admission and discharge care bundles for patients admitted to hospital with COPD, in terms of their effect on readmission rates, mortality, length of stay, process and costs of care, in comparison with usual care received by patients admitted to hospital for the same condition. Additionally, by observing the process through which these care bundles are delivered, at admission and discharge points, the research will provide 'softer' feedback on the benefits and challenges associated with the implementation of co-ordinated care packages, for both patients and staff.

8 AUDITING AND INSPECTION

8.1. Good Clinical Practice

Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting studies that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety, and well-being of study subjects are protected, consistent with the principles that originated in the Declaration of Helsinki and that the clinical study data are credible. This research study will be run in accordance with GCP.

8.2. Quality Assurance

8.2.1 Accuracy of data collection proforma

The study data collection proforma will be the primary data collection instrument for the medical record audit in Level 2 of the study. All data requested on the proforma will be recorded and a sample will be checked. Data collected on each subject will be recorded by the Chief Investigator (CI), or his/her designee (as noted on the Site Responsibilities Sheet). The CI will be responsible for the timing, completeness, legibility and accuracy of the proforma and he/she will retain a copy of each completed form. All data submitted on the data collection proforma must be verifiable in the source documentation or the discrepancies explained.

8.2.2 Data collection proforma checking

A random sample of 5% of data collected will be checked by a second member of the trust audit or clinical team against the medical records and relevant source data for quality purposes. This percentage will be increased if a significant error rate (more than 10% of those checked) is found.

8.2.3 Audit

Key standards for the study will be identified and the study team will prepare a plan for key data audits in line with these standards. Audits will be conducted at regular intervals according to the audit plan. Where necessary corrective actions will be recorded and a re-audit is undertaken.

8.2.4 Study Monitoring

Study monitoring will be undertaken on behalf of the Sponsor by UH Bristol using their monitoring standard operating procedure.

8.3. Ethics and Regulatory Approvals and Reporting

The study will be conducted in compliance with the principles of the Declaration of Helsinki (1996), the principles of GCP and in accordance with all applicable regulatory requirements including but not limited to the Research Governance Framework.

This protocol and related documents will be submitted for review to the NHS Research Ethics Committees (REC) within the NHS. Any subsequent protocol amendments will be submitted to the REC, on the agreement of the Sponsor.

Annual progress reports will be submitted to the NHS REC. The first report will be submitted 12 months after the date on which the favourable opinion was given, and thereafter until the end of the trial. Progress reports will also be submitted to the funder in line with NIHR reporting requirements. Copies of these reports will be sent to the Sponsor prior to submission. Copies of all relevant reports will be made available to the Study Steering Committee (SSC) as appropriate.

An end of study declaration will be submitted to the NHS REC within 90 days of the end of the study. A final report at conclusion of the study will be submitted to the NIHR, the Sponsor, and the NHS REC within one year of the end of the study.

8.4 Insurance / Indemnity

The University of Bristol holds Professional Negligence insurance to cover the legal liability of the University, for harm to participants arising from the design of the research, where the research protocol was designed by the University.

The University of Bristol has arranged Public Liability insurance to cover the legal liability of the University as Research Sponsor in the eventuality of harm to a research participant arising from overall management of the research by the University of Bristol.

The other University engaged in this project (UWE) have their own Public Liability insurance in place for their individual responsibilities. The University of Bristol's insurance policies do not provide an indemnity to any of our collaborators. As Research Sponsor, the University of Bristol will ensure as far as reasonably practicable at the outset of the study that the other collaborators involved hold appropriate legal liability insurance.

These insurance policies do not indemnify any clinical negligence.

8.5 Safety Assessment and Adverse Events

The study will monitor the occurrence of any serious adverse event which arises at Level 3 sites whilst the participant is taking part in the study. In Level 3 case study sites it is possible that an adverse event may be observed by or reported to the qualitative or health economics researcher. There will be no contact with clinicians and no patient identifiable information reported at Level 1 or 2 sites therefore there will be no reporting of adverse events to the study team in Level 1 or 2 Trusts.

8.5.1 Definitions

An adverse event is any unexpected effect of an untoward clinical event affecting the participant. This is classed according to severity i.e.

- a) non-serious adverse event (AE) – which includes discomfort or a slight worsening of symptoms
- b) serious adverse events (SAE) – which may be particular harmful, dangerous or require hospitalisations.

An SAE is defined as one of the following:

- 1. results in death;
- 2. is life threatening;
- 3. requires hospitalisation or prolongation of existing hospitalisation;
- 4. results in persistent or significant disability or incapacity;
- 5. consists of a congenital anomaly or birth defect;
- 6. is otherwise considered medically significant by the investigator.

Given that patients with COPD may be heavy users of secondary care services and hospital admissions are expected they will not be considered as SAEs unless it appears that they may have been related to the research process.

8.5.2 Detecting and recording AEs and SAEs

Adverse events may be reported by several methods:

- 1. directly by the participant (i.e. in person, by email, phone call or voice mail message to the researcher or study team)
- 2. indirectly from family members, carers, guardians or representatives
- 3. from the clinician or trust staff

Participants and trust staff will be asked to notify any adverse event which they believe may have occurred as a result of the study research process. On notification of such an adverse event which may be related to the research process, a researcher should complete an adverse event reporting form within 5 working days, paying specific attention to information regarding the timescale of events i.e. when the event started, were there any specific changes to medication or behaviour preceding the event. Further information should be requested from the participant or clinician or trust staff as necessary. A completed form should be securely sent to the Study Manager who will pass it onto the study clinician to review.

8.5.3 Assessment of relatedness and expectedness

The study clinician will make the following decisions:

1. whether the adverse event is an AE or SAE
2. how related is the event to the study intervention, according to the following definitions:
 - unrelated – where an event is not considered to be related to the study intervention
 - possibly – although a relationship to the study intervention cannot be completely ruled out, the nature of the event, the underlying disease, concomitant medication or temporal relationship make other explanations possible
 - probably – the temporal relationship and absence of a more likely explanation suggest the event could be related to the study intervention
 - definitely – known effects of the study intervention, or based on challenge testing, suggest that study intervention is the most likely cause.
3. expectedness of the event. Is the event an anticipated medical event even if the research had not been taking place?
4. is further action required?

8.5.4 Reporting requirements for SAEs

All reporting of SAEs of a related and unexpected nature will follow regulatory reporting requirements as set out in article 17 of the EU directive 2001. These will be reported to the sponsor immediately and will be reported to the REC within 7 days of the Study Manager becoming aware of the event. Any relevant further information will be subsequently communicated within 8 days. In addition all investigators will be notified.

8.5.5 Observation of sub-optimal clinical practice

Any concerns about clinical practice observed during the COPD care bundles study will be processed according to Appendix 1 Protocol for Observation of Sub-Optimal Clinical Practice, recorded in the study records and reported to the Sponsor in accordance with University of Bristol policy and procedures.

8.6. Financial Aspects

This study is funded by the National Institute for Health Research, Health Services and Delivery Research Programme.

9 PLAN OF INVESTIGATION AND TIMETABLE

The study will be undertaken according to the following plan and timetable:

Study start date: 1 May 2014

Study finish date: 31 August 2017

Duration of study: 40 months

The draft key project milestones will be as follows:

DATE	EVENT
1 May 2014	Begin application for ethics and research governance approvals and liaise with potential implementation sites.
1 June 2014	Begin refinement of study protocol, preparation of research instruments / SOPs and specification of data requirements.
1 July 2014	Submission of ethics application / R&D approval, advertisement of research team posts.
1 August 2014	Drafting of PPI strategy / action plan
1 September 2014	Begin application process for site-specific R&D approvals, piloting of quantitative data collection tools and process evaluation
1 October 2014	Submission of ethics application
26 February 2015	Study Steering Committee meeting
1 May 2015	Site visits begin
1 September 2015	Deadline for implementation sites to have started COPD care bundles intervention, selection of Level 1 and 2 sites, pairing process for implementation and comparator sites
1 October 2015	Selection of Level 3 sites
14 November 2015	Study Steering Committee meeting
1 March 2016	Qualitative data collection begins, health economics data collection commences,
19 April 2016	Study Steering Committee meeting
1 September 2016	R&D approvals are finalised
1 October 2016	Piloting of data analysis plan
20 October 2016	Study Steering Committee meeting
1 November 2016	Qualitative data cleaning and coding begins
31 December 2016	Deadline for receipt of Level 1 and 2 quantitative data
1 January 2017	Quantitative data merging and cleaning begins, qualitative data analysis begins
1 February 2017	Quantitative data analysis begins
28 February	Deadline for completion of Level 3 qualitative data collection and receipt of late / problematic Level 1 and 2 quantitative data
March 2017	Study Steering Committee meeting and PPI feedback meeting
1 April 2017	Drafting of final report and other outputs begins
31 August 2017	Study ends
12 September 2017	Final report available

10 STUDY MANAGEMENT

The key personnel in terms of study management are:

Study sponsor: Dr Birgit Whitman, Research & Enterprise Development, University of Bristol
 Chief Investigator: Prof Sarah Purdy, Centre for Academic Primary Care, University of Bristol
 Study Manager: Dr Melanie Chalder, Centre for Academic Primary Care, University of Bristol
 Study Co-ordinator: Dr Katherine Morton, Centre for Academic Primary Care, University of Bristol
 Study Statistician: Dr Chris Metcalfe, School of Social and Community Medicine, University of Bristol

10.1 Co-applicants:

Dr Melanie Chalder
 Research Fellow
 Centre for Academic Primary Care (CAPC)
 University of Bristol

Dr Alison Heawood
 Senior Research Fellow
 Centre for Academic Primary Care (CAPC)
 University of Bristol

Dr Chris Metcalfe
 Reader in Medical Statistics and Co-Director of Bristol Randomised Trials Collaboration (BRTC)
 School of Social and Community Medicine (SSCM)
 University of Bristol

Prof William Hollingworth
 Professor of Health Economics
 School of Social and Community Medicine (SSCM)
 University of Bristol

Prof Jonathan Benger
 Professor of Emergency Medicine and Consultant in Emergency Medicine
 University of the West of England

Dr James Calvert
 Consultant and Deputy Medical Director of Respiratory Medicine
 North Bristol NHS Trust

Ms Sue Jenkins
 Independent Public and Patient Involvement (PPI) expert
 Sue Jenkins Consultancy

10.2 Collaborating organisations:

The British Thoracic Society
 The University of Bristol
 The University of the West of England
 University Hospitals Bristol NHS Trust
 North Bristol NHS Trust
 NHS Bristol Clinical Commissioning Group

The majority of the co-applicants and collaborators (SP, WH, CM, AH, and MC) are based in the School of Social & Community Medicine at the University of Bristol whilst the others are predominantly located either at the University of West of England (JB, DE) or within local NHS organisations (JC, JU, RB, JA, NJ). All researchers appointed will be Bristol-based and their primary role will be to collect, manage and analyse data from the various study sites.

As Chief Investigator and lead applicant, SP will have overall responsibility for the study whilst MC, as a Co-applicant, will oversee the high-level project management with KM co-ordinating the day-to-day conduct of the work. SP, WH, CM and AH – all Co-applicants - will supervise the research staff. Together with the rest of the Study Management Group, they will develop a detailed study protocol and a suite of research instruments and standard operating procedures for data collection. As Co-applicants, WH, CM, and AH will be responsible for ensuring that their particular specialist areas of work (health economics, statistical analysis and qualitative methods) are fully and appropriately addressed. They will also supervise the data analysis for their particular specialism and also the preparation of the relevant section of the final report. Similarly, as Co-applicants with clinical or NHS management expertise, JC, JB, JU, RB, JA and NJ will ensure that the research takes account of prevailing clinical and NHS priorities. As experts in PPI, SJ and DE will ensure that patients, carers and other interested members of the public are encouraged and facilitated to make a contribution to the research at all stages.

10.3 Study Committees:

Study Management Group

A Study Management Group (SMG) comprising SP, MC, WH, CM, AH and the researchers will meet monthly to discuss progress on the various components of the research and ensure it follows the agreed protocol and timetable. The remainder of the co-applicants (JB, JC, RB, JA, NJ, SJ) will be encouraged to attend these meetings at regular intervals. Bristol Randomised Trial Collaboration (BRTC) will provide ongoing support to the research team to ensure a high quality design and implementation. Meetings will be convened face-to-face with teleconference facilities for members who are unable to attend in person. Minutes of the meetings will be taken and routinely circulated amongst the SMG membership as well as being made available to the Study Steering Committee as requested.

Study Steering Committee

A Study Steering Committee (SSC) has been appointed to oversee the research on behalf of the funder and to provide independent advice to the Study Management Group in relation to progress made, adherence to protocol, patient safety and consideration of new information. The membership will include an independent chairperson, three independent members (health economics, statistics, qualitative methods, primary care clinician, secondary care clinician) as well as PPI representation. The Chief Investigator, Study Manager and Study Statistician will be available to attend as appropriate. Observers from the NIHR HS&DR and sponsor institution (UoB) will be invited to each meeting. Minutes of the meetings will be taken and routinely circulated amongst the Study Management Group membership as well as being made available to the NIHR HS&DR.

11 PATIENT AND PUBLIC INVOLVEMENT

11.1 PPI and study protocol development

Our choice of research topic was informed initially by discussions between one of our clinical co-applicants and local service users, in relation to managing their COPD. These patients and their carers, who were part of a number of established networks and organisations such as the British Lung Foundation, Asthma UK and the South West Patient & Carer Forum, voiced their concerns that research which aimed to reduce time spent in hospital for COPD or improve how COPD care was delivered, both in hospital and in the community, was of key importance.

In addition to input at the topic identification / prioritisation stage, we have also sought feedback from members of the public on our research ideas and implementation plans, as part of the development of our funding application and study protocol. We were particularly keen to understand if they felt that our proposed research aim and approach might lead to improvements in service delivery or health outcomes that were pertinent to them, as service users or potential service users. We also asked them to consider whether the way in which we were intending to approach PPI seemed relevant and feasible.

11.2 Approach to PPI

We believe that, to show a demonstrable and sustained impact, any PPI efforts should be underpinned by two principles – consultation and collaboration. Previous consultation with local service users about what makes PPI effective suggests that we must also consider five themes - access, communication, consistency, empowerment to self-manage and peer support. In order to facilitate this, we have planned robust yet flexible mechanisms for including PPI at all stages of our work programme, from initial design to eventual dissemination – to be encapsulated in a PPI strategy / action plan. The PPI strategy / action plan will specify the various stages of the research process (e.g. study design, data collection, data analysis, interpretation, dissemination) and the types of task (e.g. reviewing study documentation and research instruments, attending meetings / workshops, interpreting findings, reporting findings, presenting results) in which we would expect to involve patients, carers and members of the public over the duration of the study, drawing on the guidance drafted by the NIHR advisory group INVOLVE - <http://www.invo.org.uk>.

The success of our multi-level, thematic approach to PPI will hinge upon on recruiting a panel of at least three PPI representatives to work as an 'expert panel' alongside the research team throughout the course of the study, to develop key measures / outputs which are meaningful to them as well as identifying ways of interacting with patients and carers which will be effective yet realistic. We will also co-opt one patient or carer to a specially convened PPI development group to assist with the drafting and implementation of a PPI strategy / action plan for the study. Additionally, we will invite a representative from the PPI 'expert panel' to sit alongside other independent members from academia, NHS management and clinical practice on the Study Steering Committee (SSC).

We are currently in the early stages of setting up both the PPI 'expert panel' and development group, using contacts from a range of local relevant organisations and fora in primary, secondary and community care e.g. the South West patient forum, HOT clinics, pulmonary rehabilitation classes, Smoking Cessation and Breathe Easy groups. It is envisaged that we will elicit sufficient interest to be in a position to co-opt individuals to either the PPI 'expert panel' or development group on a short or long-term basis (in line with their own preferences) and to ask members to participate in a way which is appropriate to their experience and expectations.

Whatever their background or level of commitment to the study, all PPI contributors will be encouraged to work with the research team to ensure that their roles and contributions are meaningful, clearly defined and sufficiently sufficient well supported / resourced. A programme of training and support will be offered to all members of the study team, including all PPI representatives, ensuring that learning and development is developed and undertaken in a way which is appropriate, accessible and reflective of best practice. This could include a variety of approaches (training courses, seminars and networking events) dependent upon what researchers and members of the public found most useful. It is hoped that by investing resources into PPI training, we will succeed in embedding patient and carer ideas / concerns into the core research design, implementation and dissemination.

12 STUDY EXPERTISE

The research draws upon the expertise of a wide range of experienced research, evaluation, management and healthcare professionals, including the following:

12.1 Chief Investigator

Professor Sarah Purdy — Professor of Primary Care and Associate Dean of Health Sciences at the University of Bristol, an honorary consultant at NHS Bristol, and a general practitioner (GP). She leads a multi-disciplinary research group on unplanned admissions and is the Lead Director for ITHAcA, an NHS / academic partnership aimed at reducing avoidable admissions. Sarah has a number of ongoing and completed grants in the topic area from NIHR and other funders.

12.2 Co-applicants

Dr James Calvert - Consultant Respiratory Physician and Deputy Medical Director at North Bristol NHS Trust. He is also a Senior Clinical Lecturer at the University of Bristol. He is the clinical lead for the British Thoracic Society Care Bundles study as well as being Respiratory Lead at the South West Strategic Health Authority (SHA).

Prof Jonathan Benger - Professor of Emergency Medicine at the University of West of England and a Consultant in Emergency Medicine at University Hospitals Bristol NHS Trust. He is the National Clinical Director for Urgent Care and chairs the Clinical Effectiveness Committee of the College of Emergency Medicine. His main research interests are service delivery and organisation including workforce development, resuscitation, critical illness and emergency airway management, as well as pre-hospital care and ambulance design.

Dr Chris Metcalfe - Reader in Medial Statistics at the University of Bristol, Co-Director of the Bristol Randomised Trials Collaboration, an NCRI-accredited and UKCRC-registered clinical trials unit. His main areas of research expertise are the design, conduct and analysis of randomised trials and other pragmatic studies of complex interventions implemented in clinical practice.

Prof William Hollingworth - Professor of Health Economics at the University of Bristol. His applied research is focussed on measuring cost-effectiveness of healthcare interventions in randomised controlled trials and observational studies. He has expertise in the use of routine hospital data including Hospital Episode Statistics.

Dr Ali Heawood - Senior Research Fellow at the University of Bristol. She is a social scientist specialising in qualitative health services research, often in the context of mixed methods studies. She is an affiliated member of the MRC ConDuCT-II Trials Methodology Hub based at the University of Bristol.

Dr Melanie Chalder - Research Fellow at the University of Bristol. Her expertise lies in the design, management and delivery of large-scale research studies - most recently the NIHR HTA-funded TREAD randomised controlled trial. She is currently the lead applicant on an NHS-funded feasibility study modelling volume and severity of COPD presentations to unscheduled care.

Ms Sue Jenkins - independent consultant working across the private, public and charity sectors. She has an MBA from INSEAD, specialising in Strategy and Organisation Behaviour and is familiar with current management literature. Her recent experience includes working with Amnesty International, where she was Interim Head of Organisation Development and Save the Children UK. She is a former Non-Executive Director of NHS Richmond (with a focus on Patient and Public Involvement) and has been involved in the care of a family member with COPD.

12.3 Collaborators

BTS / NHSI care bundle study team

Prof David Evans - Professor in Health Services Research (Public Involvement) at the University of the West of England

Mrs Jo Underwood, Associate Director of Commissioning at NHS Bristol, NHS Bristol CCG (or designated deputy)

Dr Nabil Jarad, Consultant Respiratory Physician at University Hospitals Bristol NHS Trust

Ms Rosalyn Badman, Respiratory Nurse Specialist at North Bristol NHS Trust

Ms Jane Ashford, Respiratory Nurse Specialist at University Hospitals Bristol NHS Trust

12.4 Advisors

In addition to the co-applicants and collaborators, our work will incorporate expertise from the wider research context. The following experts have agreed to be advisors to the study:

Prof Sue Dopson - Rhodes Trust Professor of Organisational Behaviour at the Saïd Business School, University of Oxford. Her research centres on transformational change in the public and healthcare sectors. She has written and edited many major works on this topic and her research has informed and influenced government bodies such as the Department of Health and the National Institute for Health and Clinical Excellence (NICE) in relation to the dissemination of clinical evidence into practice, medical leadership and the role of the support worker in the NHS.

Prof Robbie Foy - Professor of Primary Care at the Leeds Institute of Health Sciences, general practitioner and public health specialist. His academic area of expertise is implementation research and he is a currently member of the NICE Implementation Strategy Group and Deputy Editor-in-Chief of the Implementation Science journal.

Mrs Helen England - Director of Service Delivery for BrisDoc, an organisation providing a variety of NHS services at the primary / secondary care interface within Bristol. Mrs England has an MBA and is a former SDO Management Fellow with considerable experience of organisational change in the NHS as both a Director of Commissioning and Head of Modernisation and Public Involvement.

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Appendix 1

Care Bundles for COPD

Protocol for Observation of Sub-Optimal Clinical Practice

(Also refer to local policies and procedures)

Hazardous Situations

If the researcher finds themselves in a situation that they deem as dangerous to themselves or others (e.g. an aggressive or threatening situation):

1. Stop all research activities and raise the alarm locally.
2. Ensure personal safety.
3. Report activity to appropriate authorities, e.g., on-site security, police, etc.
4. Ensure that surrounding persons (e.g., patients, visitors and staff) are alerted to the situation.
5. Once the situation has been resolved complete relevant hospital and research paperwork.

Observation of Acts or Omissions That May Lead to Immediate Patient Harm

If the researcher observes a situation that may lead to immediate patient harm (e.g. the imminent administration of an incorrect drug) they should:

1. Stop the research and alert clinical staff to their observations and concerns.
2. Report the situation to a senior clinician, (e.g. consultant or matron) responsible for the clinical area immediately.
3. Once the situation has been resolved complete relevant hospital and research paperwork.

Observation Of Care That Causes General Concern

If the researcher observes a situation or staff actions where the standard of care gives general cause for concern they should:

1. Make an objective note of what they have observed, and the nature of their concerns.
2. Report their concerns to a senior clinician, (e.g. consultant or matron) responsible for the clinical area at the next opportunity.
3. Complete relevant hospital and research paperwork.

Complaints From Patients, Family, Carers Or Friends

If the researcher receives a clinical complaint from a patient, family carer or friend regarding the clinical care received (and not related to the research study) they should:

1. Explain to the complainant that the researcher is not in a position to directly influence care.
2. Refer the complaint to locally available services (e.g. NHS complaints procedure, PALS, etc.).
3. Alert the nurse in charge of that clinical area to the nature of the concerns expressed and the request to register a complaint.