British Thoracic Society

The British Thoracic Society Pilot Care Bundle Project:

A Care Bundles-Based Approach to Improving Standards of Care in Chronic Obstructive Pulmonary Disease and Community Acquired Pneumonia

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Authors:
Dr James Calvert, North Bristol NHS Trust
Dr Wei Shen Lim, Nottingham University Hospitals NHS Trust
Dr Chamira Rodrigo, Nottingham University Hospitals NHS Trust
Dr Alice Turner, Queen Elizabeth Hospital Research Laboratories, Birmingham
Miss Sally Welham, British Thoracic Society

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Foreword

The British Thoracic Society aims to improve standards of care for people with respiratory disease and to support those who provide that care. To that end, the Society has long been involved in the production of clinical guidelines which provide recommendations for best practice in the diagnosis, investigation and management of respiratory conditions. Over the past few years, the Society has expanded its programme of quality improvement work to include a comprehensive national clinical audit programme and, more recently, the development of quality standards. To complement these initiatives, and to further promote improvements in respiratory care for the benefit of patients, the Society has now undertaken a pilot project to explore the development and introduction of care bundles for COPD and for Community Acquired Pneumonia.

Variation in measures of COPD care occurs across the country, and we know that rates of hospital admission and mortality for community acquired pneumonia also differ considerably. Care bundles are designed to ensure that every patient receives the best care every time, by emphasising the key interventions in any management pathway. They do not necessarily aim to innovate, but work by bringing together clinical teams to ensure that everyone is focussed on delivering the elements of care that are of the greatest proven benefit.

We are delighted that this pilot project has provided evidence for the effectiveness of care bundles in these important areas. This report provides a summary of the project findings, and highlights lessons learned by the participating hospitals together with examples of good practice. We hope that this report will provide useful information for those who wish to introduce care bundles in their own institution.

The Society is extremely grateful to Dr James Calvert for providing the clinical leadership for this project, and to Dr Wei Shen Lim for his expert advice and guidance in relation to the pneumonia elements of the project. However, as both would acknowledge, the main emphasis in care bundles is on teamwork and we are therefore equally grateful to everyone involved in each of the project hospitals for their sterling work throughout the course of the project. We hope that you will enjoy reading this report, but above all we hope that it will help you to improve the care of your patients.

Dr Bernard Higgins
Chairman, British Thoracic Society Executive Committee

December 2014

Executive Summary

This report describes the results of a Pilot Study of the implementation of care bundles for Chronic Obstructive Pulmonary Disease (COPD) and Community Acquired Pneumonia (CAP) undertaken by the British Thoracic Society (BTS) with the support of NHS Improvement (NHSI).

Over a 13 month period between November 2012 and December 2013, clinicians from 21 NHS Trusts and Health Boards in England and Wales participated in a project examining the feasibility and benefits of a care bundles-based approach to quality improvement in the care of patients admitted to hospital with an acute exacerbation of COPD (AECOPD) and Community Acquired Pneumonia (CAP).

During the study period, high level data was collected on the outcomes of care for 11,748 patients admitted with AECOPD, and 14,451 patients admitted with CAP. Patient level data on processes and outcomes of care were collected on 3,266 COPD admissions and 2,563 CAP admissions.

In total, 1,438 bundles were delivered. Review of monthly data showed a sequential increase in the proportion of patients admitted who received bundle-based care. However, the overall total number of patients who received a bundle was small compared with the total number of patients admitted. This was expected due to the short duration of the pilot study. As a result there was no association between receipt of bundle-based care for patients with AECOPD or CAP and mortality measured using Trust level data derived from Hospital Episode Statistics (HES).

Encouragingly, review of patient level data showed that use of a care bundle was associated with a reduction in 30 day in-patient mortality from CAP from 13.6% to 8.8%. In addition, analysis of the association of the elements of the COPD admission bundle with outcomes of care demonstrated a statistically significant reduction in mortality from AECOPD in patients in whom oxygen was prescribed at admission (OR 0.22 95%CI 0.05-0.88), and in patients in whom care was delivered within 4 hours of admission (OR 0.60 95% CI 0.42-0.87). This is the first time that use of a COPD bundle has been noted to be associated with a reduction in in-hospital mortality.

The presence of an oxygen prescription was also associated with a reduction in length of stay for those with COPD (OR for length of stay <5 days 1.84 95%CI 1.38-2.46). This and the reduction in COPD mortality confirms once again the importance of oxygen prescribing as highlighted in the BTS Guideline on the Emergency Use of Oxygen in Adult Patients (1).

Overall, the results from this pilot are encouraging, and suggest that wide implementation of the BTS CAP and COPD care bundles is practically feasible, and has the potential to impact not only on processes of care, but also on important measurable clinical outcomes.

Dr James Calvert FRCP PhD MPH
Chair, BTS Professional and Organisational Standards Committee
Consultant Respiratory Physician - North Bristol Lung Centre

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Introduction

The Berwick Report (2) on safety of patients in the National Health Service (NHS) highlighted the need to place the quality of patient care, especially patient safety, above all other aims. It suggested that the way to achieve this was by fostering the growth and development of NHS staff - including their ability to improve the processes in which they work. To achieve this, the NHS requires to put in place a system of support driven by an agenda of capability building to deliver continuous improvement.

The British Thoracic Society Strategic Plan (2014) reiterates that the main goal of the BTS is to promote improvements in respiratory care for the benefit of patients. To achieve this aim, the Society has developed a number of programmes to support respiratory practitioners in delivering best care. These include evidence-based guidelines, quality standards and a well-established clinical audit programme.

The BTS clinical audit programme has been running for more than 10 years and offers clinicians the opportunity to collect data through a web-based interface and to compare outcomes of care achieved in their own organisation with the outcomes of care achieved by other contributors to the audit. At present, national clinical audits are available in eight areas . The programme of BTS national respiratory audits is included in the list of national clinical audits recommended by the National Advisory Group on Clinical Audit and Enquiries (NAGCAE) for inclusion in Quality Accounts for Trusts in England. Two important areas reviewed in national audits include adult community acquired pneumonia and COPD. The 2013-2016 national COPD audit programme is part of the National Clinical Audit and Patient Outcomes Programme (NCAPOP).

The number of institutions participating in BTS national respiratory audits is high and has increased each time a given audit has been run. The last Adult Community Acquired Pneumonia Audit (CAP) in 2012/13 involved more than 50% of acute hospital trusts in the UK and collected data on 5,430 patient episodes. Despite the commitment shown by clinicians involved in the audit, analysis of the data highlighted comparatively little change in standards of pneumonia care nationally over the three years from 2010/11 to 2012/13. The 2009/10 CAP audit report (3) highlighted the hurdles facing respiratory practitioners in influencing practice in emergency and acute medicine departments whilst managing heavy clinical workloads. Following discussion of the report by BTS it was decided to initiate a programme of work aimed at developing the resources already offered by BTS to include a project to examine ways in which the Society could support clinicians wishing to engage in active service improvement.

In 2012, a strategic partnership was formed between the British Thoracic Society (BTS) and NHS Improvement (NHSI) (under the auspices of the Department of Health Respiratory Programme) to design a pilot project encompassing education in service improvement methodology, and the use of care bundles as a vehicle to deliver better care. NHSI remained involved in the project from the project's inception in 2012 until NHSI ceased to function at the end of March 2013.

Two areas of respiratory medicine were identified for inclusion in the project. Community-acquired pneumonia was chosen as a body of evidence already exists in the United States supporting measurable improvements in care following implementation of pneumonia bundles and there was a desire to see if these improvements could be replicated in the UK.

COPD was chosen as the second area, as it is one of the commonest causes of hospital admission in the UK and a large-scale evaluation of the use of care bundles in COPD has not been published. However, results of national surveys demonstrate (www.rightcare.nhs.uk & www.erpho.org.uk/inhale.aspx) significant variability in outcomes of care for patients with the condition across the UK. The hope is that by standardising care this variability can be reduced and quality of care for patients improved.

This report summarises the lessons learned from the BTS pilot study of care bundle implementation in the NHS.

3 Background

3.1 COPD & Pneumonia

COPD accounts for 10% of hospital medical admissions (over 90,000 annually) in the United Kingdom. The number of admissions has increased by 50% in the last decade and accounts for one million bed days per annum. Inpatient mortality was 7.7% and 90-day mortality was 14.0% in the 2008 national COPD audit run by the Royal College of Physicians(4). Thirty-five percent of patients were re-admitted to hospital within 90 days. On average, patients spend 5 days in hospital. There was wide variation observed in all outcomes between hospitals. In particular the inter-quartile range for mortality was 8.5-18.3%(4, 5). A significant element of this variability is explained by access to expert care as outcomes were better in units with more respiratory specialists (5). There is therefore an opportunity for improving outcomes for patients by ensuring care is consistently provided to a high standard.

Community acquired pneumonia (CAP) has an annual incidence of between five and eleven per thousand in the adult population. Between 1997 and 2005 the age standardised incidence of hospitalisation with a primary diagnosis of pneumonia increased by 34%. The proportion of adults with pneumonia who require admission to hospital is reported as being between 22% and 42%. In-hospital mortality in the UK is thought to vary between 6% and 20%. Despite the availability of pneumonia severity scoring indices, a significant variation in physicians' decisions to admit to hospital and treatment protocols still exists(3).

Data from the national BTS CAP audits over the last 4 years, comprising a total of over 13,831 patients, indicate that there is significant variation in the management of CAP across institutions, that adherence to local and national guidelines is poor and that mortality from CAP is high. Adherence to CAP antibiotic recommendations, including the use of combination (beta-lactam + macrolide) antibiotics in patients with moderate and high severity CAP has been shown in the BTS audit dataset and in other cohort studies to be associated with improved outcomes. Currently, around 45 – 50% of patients with moderate and high severity CAP are empirically treated with single agent beta-lactams alone and only 51.7% receive antibiotics in-line with local guidelines. Finally administration of the first dose of antibiotics took >4 hours in 41.3% of patients despite guideline recommendations and evidence that earlier administration of antibiotics is associated with improved outcomes. (6).

Since the BTS Care Bundle Project was planned the results of a quality improvement project in the north west of England (Advancing Quality Alliance (AQuA) Project)(7) have been published. This demonstrated that reliable implementation of a pneumonia bundle is associated with an absolute reduction in mortality of 1.9 % for patients receiving bundle led care (95% confidence interval [CI], 0.9 to 3.0; P = <0.001).

Results of a single hospital study of a bundle covering the care of COPD patients at hospital discharge has demonstrated that a care bundle approach is associated with a reduction in the 30 day readmission rate and improved compliance with key processes of care such as screening patients for and offering smoking cessation(8).

The background to the development and implementation of the BTS Pilot Care Bundle Project is described below is described in the following sections.

3.2 Care Bundles

High quality healthcare is defined as care which is safe, timely, effective, efficient, equitable and patient centred (9). Improvements in standards of care reduce variability in outcomes and promote optimal use of resources, avoiding waste.

Variation in care, for which there is already established evidence-based best practice, can result in error, harm and poorer outcomes for patients. Ensuring reliability in delivery of healthcare mitigates against waste and reduces error. One method of improving quality of care is through the use of care bundles.

A bundle is a structured way of improving the process of care and thereby improving patient outcomes. It is a small, straightforward set of evidence-based clinical interventions or actions – generally 3-5, which when performed reliably improve patient outcomes. The bundle resembles a list, but the way in which a bundle is created is unique. The care processes described in the bundle are all necessary and sufficient. If any of them are missed out it means that the success of the care being monitored and driven by the bundle will be less good. It is therefore a cohesive unit of actions that must all be completed to achieve the best outcomes.

The elements of the bundle should be based on the best available evidence. A bundle should focus on how care is delivered as well as what care is delivered. Bundles are easy to monitor, as each step in the bundle is either completed or not completed. This clarity can allow variance from agreed practice to be easily measured and defects repaired.

Care bundles are believed to improve patient care by focusing improvement efforts on a set of factors and actions which contribute to achievement of a clearly specified aim. Care bundles allow clinical teams to focus their efforts on a small number of measurable strategies aimed at improving specified outcomes. Protocol-based care also enables staff to quickly see what action should be taken, when and by whom. Care bundles 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. This fosters high quality care by ensuring that clinician judgement is supported by best available evidence at the point of care and that barriers to implementation of evidence-based management plans are removed where possible. The value of care bundles across a number of care pathways has been demonstrated in a UK setting by Robb and colleagues(10) who observed a fall of 18.5 points in the hospital standardised mortality for their institution following bundle implementation for patient care for 13 diagnoses.

3.3 Bundle Implementation

Care bundle development is relatively straightforward. The challenge is implementation. One method of operationalising care bundles in the healthcare setting is through the use of "plan, do, study, act" (PDSA) cycles. This model of improvement empowers local teams to develop and undertake small changes to their practice in a controlled manner. This permits testing of change in a real work setting with rapid small scale testing. It also indicates whether proposed changes will work in the environment in question(11).

To facilitate implementation of care bundles through the use of PDSA cycles, practitioners require a number of resources to be available - including:

i) High level endorsement from senior staff members within the organisation to allow variation from previously endorsed practices with minimal bureaucracy.

ii) Data to establish a clearly measureable baseline to ensure that any changes tested lead to a measureable improvement.

iii) A small amount of financial resource to free up time for busy clinicians to carry out the work.

iv) Peer support and collaborative working.

v) Assistance with collection and display of data e.g. online data templates and production of run time charts. (Run time charts or statistical process control charts were developed in industry to display observed data in a time sequence. Typically they are used to represent aspects of output or performance. They have the advantage of only requiring small amounts of data for each data point, as conclusions drawn from them are derived from analysis of trends over time)(12).

4 Care Bundle Development

The BTS Care Bundle Project initiation meeting took place in October 2011 and was run jointly by BTS and NHS Improvement (NHSI). Subject matter experts in the area of COPD and Pneumonia were identified from a number of medical and allied professional groups (see page 50). An introduction to change methodology was provided by NHSI and experience from a number of groups already using care bundles was provided. Meeting participants were asked to define the key measureable outcomes that could be used to assess whether the implementation of care bundles had led to an improvement in standards of care. They were then asked to discuss and agree 4 to 5 components of care regarded as critical to achieving these outcomes. The measures to be collected for the high level outcomes defined are given below in 4.1.1.

4.1 Measurement

Data were collected in 2 domains:

1 Hospital acquired statistics were collated monthly to allow measurement of the outcome of bundle implementation.

2 Process measures were collected at a patient level, and were uploaded throughout the project to the BTS audit website which had a specific data collection area for the BTS care bundle project. Centres were asked to upload at least 25 sets of patient data on a monthly basis for each of COPD and pneumonia admissions. These data were then tabulated to provide real time reports via the BTS audit system that could be downloaded and reviewed by centres entering data to allow them to assess their progress in changing care pathways to embed bundle implementation. Reports also allowed centres to view, on an anonymised basis, the aggregate data of all other centres entering data.

The high level data points and their definitions are given below.

4.1.1 High Level Outcome Data

The following high level measures were collected to measure the overall benefit of introducing care bundles. Data in these domains were collected monthly by Trust data analysts and were entered via the data collection tools on the BTS audit system website over the course of the project.

4.1.1.1 COPD

COPD was defined as all patients receiving an ICD-10 diagnostic code of J41-44 as the primary diagnosis. Data collected (per month) included:

1. Total number of COPD admissions from trust data.
2. Total number of COPD patients seen and discharged from A&E or Emergency Medicine.
3. Total number of patients in whom bundle used.
4. In-hospital mortality.
5. Length of stay for patients with COPD.
6. Total bed days for patients with COPD per 1000 patients on QOF register over the age of 16.
7. COPD readmission rate at 28 days.

4.1.1.2 Pneumonia

Pneumonia was defined as all patients receiving an ICD-10 diagnostic code of J12-18 (all sub-categories excluding 18.0) as the primary diagnosis. Data collected (per month) included:

1. Total number of CAP admissions from trust data.
2. Total number of patients in whom bundle used.
3. In-hospital mortality.
4. Total bed days.
5. Length of stay.
6. Pneumonia readmission rate at 28 days.

Process measures were collected at an individual patient level to provide data on the steps necessary to ensuring reliable implementation of each of the bundle elements.

The following documents can be found for reference on the British Thoracic Society Website (https://www.brit-thoracic.org.uk/audit-and-quality-improvement/bts-care-bundles-for-cap-and-copd/):

- Data collection templates developed by BTS
- Examples of alternative data collection templates designed by participating centres (Centres were encouraged to retain bundle elements unchanged but to design alternative templates to meet their organisations operational needs)
- Templates for collecting process measures at an individual patient level to understand pathways being implemented.

5 Care Bundle Components

Following the care bundle initiation meeting in 2011 the bundle elements described below were selected by the participating subject matter experts to be the actions most likely to produce an improvement in the outcomes being measured.

5.1 COPD Care Bundles

5.1.1 Admission Care Bundle (Acronym: DARTS)

DARTS=**D**iagnosis + **A**ssessment (for oxygen) + **R**ecognition (of acidosis) + **T**imely medications + **S**pecialist review

Five actions were selected with the aim of improving care of patients with acute exacerbations of COPD at the point of their admission to hospital (**Figure 1**).

Bundle Statement 1: A correct diagnosis of AECOPD should be confirmed.
The first step is to ensure that a correct diagnosis of AECOPD is established as soon as possible at the point of hospital admission. The diagnostic process, which begins with a history and physical examination, is supported by early availability of an ECG and chest x-ray. These 2 diagnostic tests are therefore key to supporting successful completion of admission bundle item 1.

Bundle Statement 2: An oxygen assessment should be undertaken and the correct target range prescribed within 30 minutes.
Early recognition and response to hypoxia is critical. However patients with severe COPD may have a reduced hypoxic respiratory drive. Therefore for patients with COPD a target saturation range of 88–92% is suggested pending the availability of blood gas results(1). It was agreed that a correct oxygen prescription should be made within 30 minutes of admission.

Bundle Statement 3: Recognise and respond to respiratory acidosis within 1 hour of admission.
Patients with highest mortality from COPD following hospital admission are those who are admitted in respiratory failure - early recognition and an appropriate response to respiratory acidosis is key to improving early mortality. This requires an arterial blood gas for all patients admitted to hospital with oxygen saturations of 94% or less (on air or controlled oxygen)(8, 13). Following interpretation of the results of this investigation, early assessment for suitability for non-invasive ventilation (NIV) is required. Current guideline recommendations 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 NIV is required.

Bundle Statement 4: Medication (steroids and nebulisers) to be administered within 4 hours of admission.
Patients admitted to hospital with an infective exacerbation of COPD have a mean in-patient mortality of 7.7%. Their treatment and assessment should be timely as for any other seriously ill patient. Correct prescription of medications (including nebulisers, steroids and antibiotics) within 4 hours was felt to reflect the severity of some COPD patients' condition.

Bundle Statement 5: Review by respiratory team to take place within 24 hours of admission.
Results of the 2003 national COPD audit suggest that review by a respiratory specialist should reduce in hospital mortality(5). Given that the majority of deaths occur within 72 hours of admission it was felt that the aim should be for all patients admitted with an acute exacerbation of COPD to be seen by a member of the respiratory team within 24 hours of admission. This could be a specialist nurse, specialty trainee (SpR) or consultant.

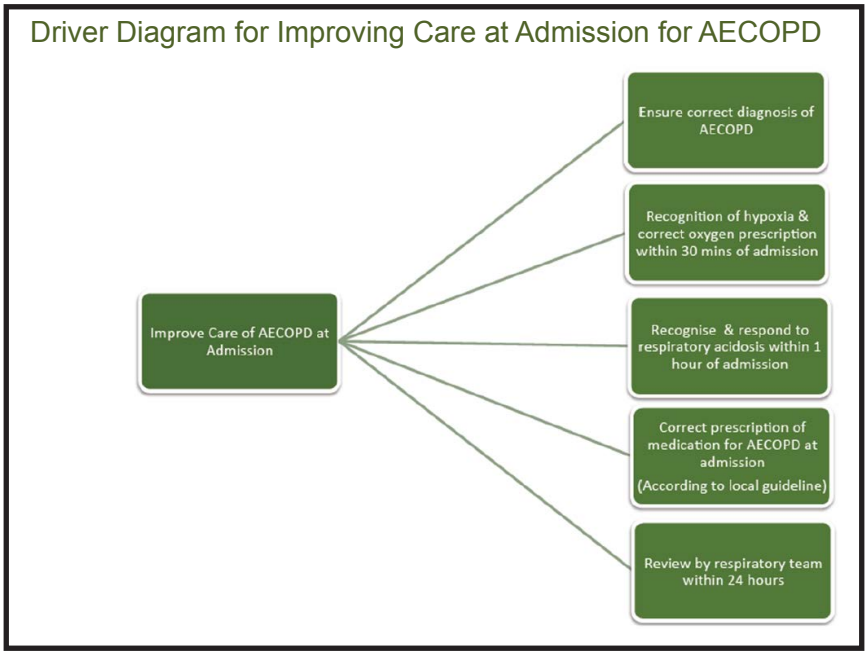

Figure 1: Admissions Bundle Driver Diagram

5.1.2 Discharge Care Bundle (Acronym: TAPSS)

TAPSS= **T**echnique (inhalers) + **A**ction plan + **P**ulmonary rehabilitation + **S**moking (smoking cessation) + **S**pecialist follow-up

At 25-30%, the 90 day readmission rate for patients discharged following an admission with COPD is high, but as yet there is little evidence for individual interventions that consistently reduce this figure. However, studies have been conducted of integrated care packages and these have been shown to reduce readmissions rates(14, 15). Hopkinson and colleagues have also shown a downward trend in 30 day readmissions in patients with COPD in whom a bundle approach to discharge was applied(8).

A consensus was reached on the key elements of a COPD discharge bundle. It was agreed that the elements should be aimed at ensuring that patients have been assessed appropriately prior to discharge, and are confident in the use of their medications. It was also felt to be important that patients have ready access to advice and assistance should they deteriorate following discharge from hospital. The discharge bundle incorporates five elements (**Figure 2**):

Bundle Statement 1: All patients should have their respiratory medications and inhaler technique assessed prior to discharge.
On direct questioning 98% of respiratory patients report using their inhaler correctly. On testing however 8% show a correct technique(16). This problem can be exacerbated in the elderly where issues such as visual acuity, manual dexterity and cognitive impairment can act as an additional barrier to correct inhaler use (17, 18). However, correct use of inhalers is associated with improved outcomes for patients including a reduction in risk of exacerbations and hospital admission(19). Repeated instruction is required to ensure that inhaler technique is optimised(20). Every opportunity must be taken to promote good inhaler technique.

Bundle Statement 2: All patients should receive a written plan for how to manage a further acute exacerbation of their COPD and should receive a discharge pack of "emergency" drugs prior to discharge.
Self-management plans in COPD teach patients how to carry out disease specific elements of self-care. They appear to be associated with improved well-being and reduced risk of hospitalisation(21). Early treatment of COPD exacerbations is associated with a more rapid recovery from the acute episode, reduced risk of hospitalization and better health-related quality of life(22). Self-management strategies are a complex intervention and the optimum form and method of delivery of self-care education is not yet clear. The provision of self-management education and a discharge drug pack, as part of the bundle intervention, is intended to assist the patient in optimising self-management of subsequent exacerbations with the aim of reducing the risk of readmission. However it is recognised that this is an element of the care bundle with a less secure evidence base as well conducted trials of self management have highlighted that not all patients become successful self-managers. Therefore not all individuals will experience

improved outcomes(23, 24). Continued inclusion of this element of the bundle will need to be reviewed in light of data to be collected as part of a planned systematic assessment of the BTS COPD Bundle (see page 43).

Bundle Statement 3: Smoking status should be assessed together with a willingness to quit and for those patients indicating a wish for further assistance, a referral should be made to a stop smoking programme.
Smoking remains the biggest preventable cause of death and disease in the UK and accounts for approximately 50% of health inequalities between socioeconomic groups(25). In a study of factors predicting short and medium term mortality in hospitalised patients over the age of 65, current smoking was the factor associated most strongly with risk of death during the follow up period(26). Exposure to cigarette smoke has also been associated with an increased risk of hospital readmission within one year after discharge following an admission with an infective exacerbation of COPD(27). Finally, two-thirds of smokers expressed a wish to stop smoking when asked if they wished to quit (www.smokinginengland.info). It is clinically effective and congruent with the bundles aim of reducing risk of death and hospital readmission to include a clear focus on smoking cessation. More importantly it is in keeping with the majority of patients wishes. Clinicians should use every patient contact to explore patients wishes with regard to stopping smoking.

Bundle Statement 4: All patients should be assessed for their suitability for pulmonary rehabilitation prior to discharge.
Systematic review of the evidence base for the benefits of pulmonary rehabilitation concludes that rehabilitation relieves dyspnea and fatigue, improves emotional function and enhances patients' sense of control over their condition. Pulmonary rehabilitation therefore forms an important part of the long term management of stable COPD(28). However, the provision of pulmonary rehabilitation in the period immediately following hospital discharge for an exacerbation has also been shown to improve patient well being in addition to reducing risk of hospital readmission(29-31). Finally, review of the enablers and barriers to physical activity in COPD patients identified hospital admission as an opportunity to work with patients to overcome practical and psychological factors preventing patients from increasing activity levels(32). Clinicians should aim to actively recognise and address barriers to physical activity.

Bundle Statement 5: Community follow up within two weeks of discharge from hospital should be organised. 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.
The 2004 NICE COPD Guideline stresses the importance of follow up for patients following an exacerbation of COPD(13). This provides an opportunity to review patients' medication and offers the opportunity to identify those patients experiencing an early deterioration following discharge. The timing, mechanism and venue for this follow up is not yet clear. However respiratory follow-up of patients within 30 days of discharge is associated with a reduced risk of readmission(33). The same benefits may also be obtained through telephone follow up by the hospital team when this is supported by a comprehensive package of care including the opportunity for early reassessment in the event of a deterioration(34).

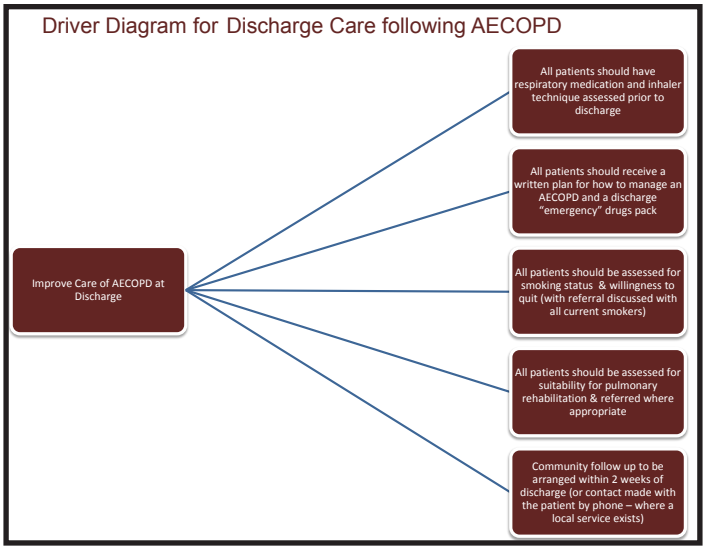

Figure 2: Discharge Bundle

5.2 Pneumonia Care Bundle (Acronym: COST)

The elements selected for the BTS CAP bundle were chosen from the BTS CAP Guidelines(35) and focus on the most important domains in the management of pneumonia within the first 4 hours of admission (**Figure 3**). This is the time period when appropriate management is likely to have the greatest impact on prognosis.

COST= **C**hest x-ray (CXR) + **O**xygen (assessment) + **S**everity (Scoring) + **T**imely & appropriate treatment

Bundle Statement 1: Perform a CXR within 4 hours of admission in all patients with suspected CAP.
Accurate and early diagnosis of CAP is critical to avoid inappropriate treatment (in general, only about half of patients initially suspected to have CAP actually have confirmed CAP). On the basis of assessment of the chest x-ray and risk score, antibiotics should be prescribed using the correct antibiotic (based on local guidelines) and the correct mode of administration (oral versus IV) depending on the severity of the patient's condition.

BTS CAP Guidelines recommendation *"All patients admitted to hospital with suspected CAP should have a CXR performed as soon as possible to confirm or refute the diagnosis. The objective of any service should be for the CXR to be performed in time for antibiotics to be administered within 4 h of presentation to hospital should the diagnosis of CAP be confirmed."*

Bundle Statement 2: Assess oxygen saturation in all patients admitted with CAP and prescribe supplementary oxygen where appropriate according to BTS Guidelines.
Early oxygen assessment has been studied as an indicator of the quality of processes of care in the management of CAP and early oxygen assessment has been associated with improved prognosis. The provision of oxygen, when needed, naturally follows after appropriate assessment.

BTS CAP Guidelines recommendation *"All patients should have the following tests performed on admission: oxygen saturations and, where necessary, arterial blood gases in accordance with the BTS Guidelines for Emergency Oxygen Use in Adult Patients."*

Bundle Statement 3: Record Severity of illness, supported by CURB65 score in all patients.
Severity assessment is widely accepted as critical in deciding site of care, depth of investigations and antibiotic choice. The CURB65 score is an internationally validated severity score for CAP.

BTS CAP Guidelines recommendation*There is no specific recommendation that severity should be assessed as this was taken to be self evident. The Guidelines contain the recommendation that "For all patients, the CURB65 score should be interpreted in conjunction with clinical judgement."*

Bundle Statement 4: Administer timely (at least < 4 hours from presentation) and targeted antibiotics appropriate to severity of illness
The BTS Guidelines offer clear recommendations relating to the timing and type of empirical antibiotics – single/ combination/ IV/ PO stratified according to disease severity.

BTS CAP Guidelines recommendation *"The objective of any service should be to confirm a diagnosis of pneumonia with CXR and initiate antibiotic therapy for the majority of patients with CAP within 4 h of presentation to hospital."*

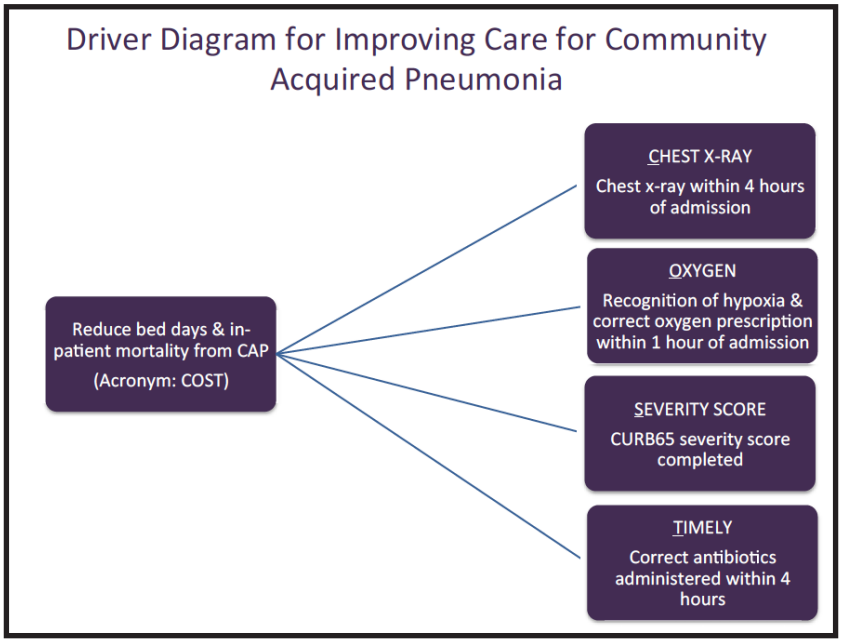

Figure 3: Community Acquired Pneumonia Bundle

6 Setting up a quality improvement project

Components of the service improvement element of the BTS Care Bundle Project were derived from the NHS Improvement Lung Improvement Project Support Pack (2010/2011).

(Resources from the NHS Lung Improvement Programme can be accessed via the legacy websites available on the NHS IQ website: http://www.nhsiq.nhs.uk/8579.aspx)

The relevant components of the NHSI lung project support pack are summarised below:

The project support pack stresses the need to spend time on preparatory work to ensure sustainability of the interventions. At the first BTS project meeting participants were encouraged to:

- Consider who would make up their team (see below);
- Identify an executive sponsor;
- Develop and tabulate a project plan;
- Understand the current service using measures such as process mapping;
- Collect baseline data and agree a data collection plan.

6.1 The Right Team

Some of the biggest risks to any project come from the team. It is important that the team has people with the right skills and abilities to do the job and that they will be able to give continued support and availability to participate in the improvement initiative. Results of the AQuA (7) and North West London Hospitals NHS Trust (10) projects suggest that it can take as long as 3 years to embed a service improvement plans in an organisation.

6.1.1 Core Team Membership

Core team members should be drawn from across the patient pathway and should:

- understand the pathway;
- be able to influence the decision making process;
- be prepared to test and implement changes across the pathway;
- be mandated to take decisions regarding changes/improvements in their respective areas.

Teams were encouraged to ensure that the project had adequate support from information departments and that an analyst was available to support the team.

6.1.2 Executive Sponsor

An Executive Sponsor is required to oversee progress, provide strategic support to the project and to support the team in accessing HR, Finance and IT teams when required and to escalate key issues as appropriate.

6.1.3 Project Plan

A project plan is fundamental to the establishment of the project. It sets the timeline for improvement and establishes the project priorities and resources needed.

The plan should include:

- Data and measures;
- Envisaged sustainability and a plan for spread of the project;
- A clear timeline and list of responsibilities;

6.1.4 Understanding the current service

A quantified baseline is required to understand the service that is being redesigned to provide a benchmark against which improvements can be measured. In order to establish this baseline the following actions are necessary:

- Establish data and information sources
- Establish what clinical and/or medical audit data are available?
- Analyse known bottlenecks or problem areas
- Plan for on-going manual data collection (where, when and how); Manual data collection informs process performance and is essential to ensure changes being made to processes achieve the intended outcomes.
- Undertake a process mapping exercise.

6.2 Resource and Project Timeline

Participants in the pilot project were given access to the NHS Lung Improvement website which provided access to resources to assist in process mapping and measurement e.g. production of SPC charts. The website has been archived but can still be viewed at http://tinyurl.com/pm2q8dq

The necessary support and education for the project were provided through a series of face-to-face and WebEx meetings commencing in November 2012 and finishing with a final meeting in March 2014. The context and themes of the meetings are given below:

6.2.1 Training day 1 (November 2012):

Full day

Learning objectives:

- Aims of project
- Introduction to service improvement (why, how, case studies)
- Introduction to Care Bundles (with examples)
- Introduction to Process Mapping
- Introduction to data requirements and data analysis

6.2.2 WebEx 1 (January 2013)

4 weeks following first meeting – 60 minutes (30 mins for data analysts, 30 minutes for clinical team members) – to answer queries arising from first training day and to set the scene for the next face to face meeting.

6.2.3 Training Day 2 (February 2013)

Full day

3 months after training day 1.

- Review of process maps and plans for participating centres.

6.2.4 WebEx 2 (March 2013)

6 weeks after second training day: Trouble shooting (1 hour).

6.2.5 WebEx 3 (June 2013)

3 months after training day: Trouble shooting (1 hour).

Additional WebEx meetings were held in September and November 2013.

6.2.6 Project Close

Full Day (March 2014)

12 months after first meeting.

- Presentations and review of results for centres. Discussion of lessons learned.

7 Project Methods

In July 2012, a call for expressions of interest from hospitals across the UK to participate in a pilot study of care bundles was offered to BTS members via the BTS e-newsletter. Interested institutions were requested to provide written confirmation that their Trust would support participation in the project.

A total of 22 Trusts (24 hospitals) were formally invited to participate in the BTS Pilot Care Bundle Project which was planned to extend over a period of 13 months. Project participants were invited to an initial project meeting held in central London in November 2012, and provided with background materials. Participants were also provided with online access to the care bundle project data collection system hosted on the BTS audit system website.

7.1 Study population

Nineteen hospitals collected data for the COPD admission bundles, 17 for the COPD discharge Bundle and 18 hospitals (16 Trusts) for the CAP Bundle. Details of participating centres are provided in the Acknowledgments section of this document (pages 46-49).

Centres implementing the COPD Admission bundle were requested to work towards including all subjects admitted with a suspected acute COPD exacerbation (AECOPD) irrespective of their route into the hospital. The 5 individual elements of the Admission Bundle include:

1. Establishing a correct diagnosis of AECOPD (this required a record of a CXR and ECG having been performed within 4 hours of admission);
2. Assessing a patients oxygenation and prescribing a target range for the patients oxygenation within 1 hour of admission;
3. Recognising and responding to respiratory acidosis – this required an arterial blood gas to be performed on all patients with oxygen saturations ≤ 94% after 1 hour of optimal treatment and controlled oxygen;
4. Initiating correct treatment. This required a record of administration of steroids, antibiotics and nebulised therapy within 4 hours of admission;
5. Review by a member of the respiratory specialist team within 24 hours of admission.

Centres implementing the COPD discharge bundle were asked to work towards administering the bundle to all patients admitted with an AECOPD as the main reason for admission prior to discharge from hospital. The bundle has 5 elements:

1. Documentation before discharge that the patients inhaler technique had been checked and medications reviewed by a member of the respiratory team;
2. Documentation that the patient had a written self management plan and was being discharged with an emergency drug pack;
3. Documentation that the patient had been assessed for their smoking status and offered assistance to quit where appropriate;
4. Documentation that the patients suitability for pulmonary rehabilitation had been made and that rehabilitation had been offered where appropriate;
5. Arrangement of community follow up (by phone or in person) within 24 hours of discharge.

Centres implementing the CAP Bundle were requested to include immunocompetent adults (≥16 years) hospitalised with CAP. Inclusion criteria were age over 16 years with symptoms suggestive of lower respiratory tract infection, radiologically confirmed CAP, and treatment for CAP by the admitting clinical team. Adults previously discharged from hospital within 10 days of admission were excluded from the project. The four individual elements of the CAP care bundle consisted of:

1. A chest X-ray within 4 hours of hospital admission in all adults with suspected CAP;
2. Assessment of oxygen saturation in all patients and prescription of supplemental oxygen in keeping with BTS oxygen guidance.
3. Severity assessment, supported by the CURB65 score; and
4. Administration of antibiotics according to CAP severity within 4 hours of hospital admission.

In all cases bundle implementation was at the discretion of the admitting clinical team.

In addition to collection of individual patient level data, to inform an understanding of the process performance of the patient pathway, high level outcome data were collected on a monthly basis to provide information on the outcomes of care. The high level data set comprised information on:

- Total number of COPD and CAP admissions to the trust,
- Total number of patients in whom the bundle was implemented,
- In-hospital mortality,
- Total bed days,
- Length of stay
- Re-admission rate at 28 days.

COPD patients were defined as all patients receiving an ICD-10 diagnostic code of J41-44 as the primary diagnosis. Pneumonia patients were classified as those with an ICD diagnostic code of J12-18 (all subcategories excluding J18.0) as the primary diagnosis by trust analysts monthly, and the data submitted to the BTS audit website.

All data were recorded using a secure web-based system (via the BTS audit website). Paper data collection sheets and template care bundle documentation was made available via the BTS website (https://www.brit-thoracic.org.uk/audit-and-quality-improvement/bts-care-bundles-for-cap-and-copd/).

Implementation and conduct of the care bundle project was approved and supervised by the BTS Professional and Organisational Standards Committee.

7.2 Statistical analyses

All data submitted for the COPD admission and discharge bundles were analysed in SPSS version v21.0. Initial comparisons between patients receiving and not receiving a bundle were conducted using Chi square for frequency variables and Mann-Whitney for scale variables, since all scale variables were non-parametric in their distribution. Adjustment for centre and other covariates was carried out using generalised estimating equations in order to adjust for clustering due to centres. This technique was primarily used for assessment of the impact of bundle elements on outcome in the admission bundle data. For the two high level outcomes assessed (inpatient mortality and length of hospital stay (LOS)) a logistic regression model was used; the LOS data was too skewed to construct a robust linear regression, hence a logistic model utilising the outcome of LOS<median (5 days) was used instead.

Data is shown as n(%) for all frequency variables, and as median (IQR) for all scale variables. Significance was taken as $p<0.05$.

Statistical analysis of the pneumonia data was performed using SPSS v22.0. Comparisons were made between adults who were managed following implementation of the CAP care bundle and adults who were managed without care bundle implementation. Pearson's χ^2 test was used to compare categorical variables and the Mann-Whitney U test to compare continuous variables that were not normally distributed.

The primary outcome measures were:

- Time to first chest X-ray ≤ 4 hours from admission;
- Time to first antibiotic dose ≤ 4hours from admission;
- National CAP guideline adherent antibiotic choice (low severity CAP: monotherapy with a narrow spectrum beta-lactam (amoxicillin), tetracycline or macrolide; moderate severity CAP: combination narrow spectrum beta-lactam (amoxicillin) plus macrolide, or tetracycline monotherapy or quinolone monotherapy; high severity CAP: combination beta-lactamase stable beta-lactam plus macrolide or narrow spectrum beta-lactam plus quinolone therapy);
- Guideline adherent antibiotic route of administration – which was defined as:
    - Low and moderate severity CAP: oral therapy
    - High severity CAP: intravenous therapy
- Assessment of oxygenation status.

Secondary outcome measures were 30-day in-patient (30-d IP) mortality and length of stay (LOS). All primary outcome measures were adjusted for disease severity (based on the CURB65 score) using a logistical regression model, except for antibiotic choice and antibiotic route, as these two outcomes were already stratified according to disease severity. Thirty day in-patient mortality was adjusted for disease severity using a similar model.

Graphical reports were produced from the BTS care bundle data set by BTS IT colleagues using SAP Crystal Reports software .

8 Results

8.1 COPD Admission bundle results

Patient level data from 3,272 patients were submitted from 19 hospitals. Of these 515 were stated to have had an admission bundle completed, whilst 2,576 did not, and for 181 patients bundle status was not documented by the submitting centre.

High level data describe outcomes for the total number of patients admitted to each centre and are derived from HES data (submitted by participating centres on a monthly basis). During the pilot study period 10,487 patients with COPD were admitted to participating centres. The average length of stay was 7.1 days for those surviving. The readmission rate at 28 days was 16.5%, and 5.7% of patients died during the admission (*Table 1*).

	Mean (N=10,487)	**Variance**
In Hospital Mortality	5.7%	SD: 1.3%
Length of Stay	7.1 days	IQ Range 6.1-7.9 days
Readmission Rate (28-d)	16.5%	IQ Range: 14.1-21.7 %

Table 1: Summary of high level statistics for COPD admissions during the pilot study period derived from hospital episode statistics.

There was considerable variability in the proportion of patients receiving COPD bundles between centres. In aggregate bundle completion rates rose gradually from 1.8% of all patients at the start of the project in November 2012 to 15.6% in October 2013 (**Figure 4**).

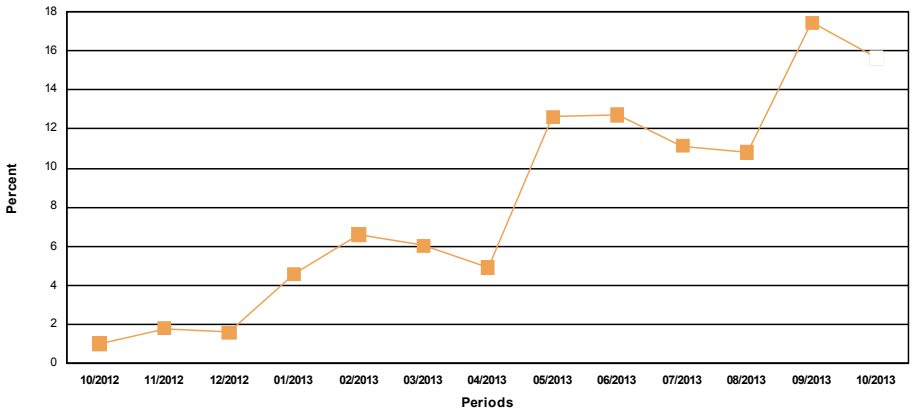

Figure 4: Admission bundle completion rates: Proportion of the total number of COPD patients admitted who received an admission care bundle across the 12 months of the project.

Many patients were in receipt of bundle elements, even without formal use of an admission bundle, as shown in **Figure 5**. However, patients in whom a bundle was applied were more likely to receive a greater number of bundle elements (p=0.005), such that 26.8% of patients with a bundle had four or more bundle elements completed, compared to 18.2% of those without formal application of a bundle.

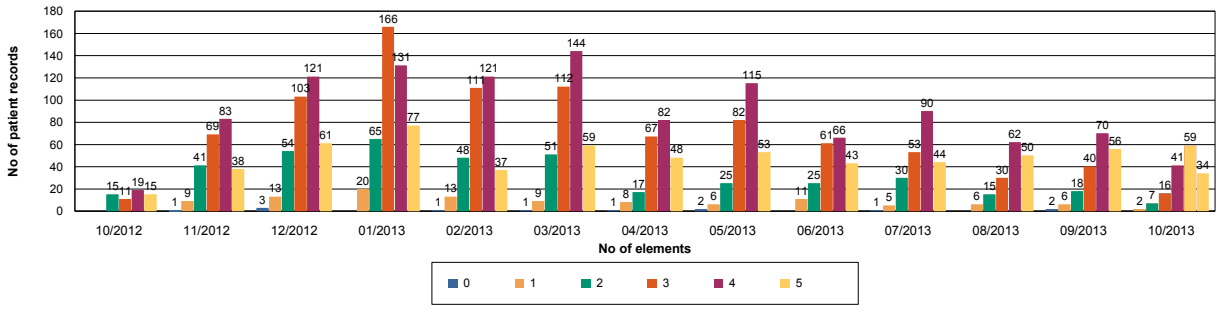

Figure 5: Admission bundle elements received.

The odds ratio for receiving each element of the admissions bundle in those receiving and not receiving a bundle is summarised in *Table 2.*

	Odds ratio	**95%CI**
Specialty Review < 24hrs	2.2	1.7 - 2.8
Assessed for NIV pH<7.35	1.80	1.5 - 2.1
Target O2 prescribed	1.45	1.2 - 1.7

Table 2: Odds ratio (95% CI) for receipt of key elements of care in those receiving a bundle vs. those not receiving a bundle

The characteristics of the patients are shown in *Table 3*. Patients in receipt of a bundle were more likely to be female, have spirometrically confirmed COPD, receive treatment for their exacerbation quickly, and to be seen quickly by the respiratory team.

	Whole group	**No bundle**	**Bundle**	**p**
Male	1608 (49.1%)	1346 (52.3%)	231 (44.9%)	0.002
Age	72.2 (64.5-79.6)	72.3 (64.7-79.4)	71.2 (64.0-80.0)	0.12
Sats.	93 (90-96)	92 (88-95)	92 (89-95)	0.21
Blood gases pH pO2 pCO2	 7.41 (7.35-7.46) 8.2 (7.1-9.9) 6.0 (5.0-7.6)	 7.41 (7.35-7.44) 8.17 (7.00-9.84) 6.00 (5.04-7.74)	 7.41 (7.36-7.45) 8.30 (7.30-10.05) 6.09 (4.94-7.43)	 0.07 0.15 0.46
Spirometric COPD	1771 (56.5%)	1366 (53.0%)	322 (62.5%	0.001
CXR done	3069 (94.5%)	2422 (94.0%)	477 (92.6%)	0.17
ECG done within 4 hrs.	2647 (82.6%)	2102 (81.6%)	406 (78.8%)	0.23
Time to nebs (mins)	92 (35-193)	98 (35-206)	80 (29-151)	0.033
Time to steroids (mins)	133 (57-344)	147 (61-394)	99 (38-194)	0.085
Time to antibiotics (mins)	148 (68-280)	157 (80-285)	95 (22-210)	0.012
Time to resp. review (hrs.)	17.0 (7.0-36.0)	17.7 (7.3-39.3)	15.4 (7.2-47.1)	0.030
Diagnostic assessment	1365 (41.7%)	1071 (41.6%)	233 (45.2%)	0.13
Oxygen management	3024 (94.4%)	2384 (92.5%)	470 (91.3%)	0.32
Acidosis management	1117 (34.1%)	872 (33.9%)	184 (35.7%)	0.41
Treatment within 4 hrs.	1555 (47.5%	1241 (48.2%)	231 (44.9%)	0.17
Respiratory review <24 hrs.	1295 (37.6%)	973 (37.8%)	243 (47.2%)	<0.001
LOS (days)	5 (2-9)	5 (2-9)	5 (2-8)	0.36
Outcome Discharged Early discharge scheme Died	 2391 (77.7%) 543 (17.7%) 142 (4.6%)	 1917 (74.4%) 424 (16.5%) 114 (4.4%)	 355 (68.9%) 73 (14.2%) 24 (4.7%)	 0.72
Discharged from ED/AMU	317 (9.7%)	245 (9.5%)	54 (10.5%)	0.50

Table 3: COPD admission bundle: Characteristics of the patients. Data is shown as n (%) or median (IQR). Significant differences between bundle and no bundle groups are highlighted by a p value in bold type.

8.1.1 The impact of an admission bundle on outcome

Simple univariate analysis, adjusting for centre, did not reveal any impact of receipt of a bundle on mortality (p=0.17) or length of stay (LOS; p=0.35). Similarly, the number of bundle elements, adjusted for centre, did not relate to mortality (p=0.16). Number of bundle elements completed correlated with LOS in that patients with a shorter stay generally had fewer bundle elements completed (p<0.01). It is important to recognise that statistical association is not indicative of causality. Whilst most hospitals aim to reduce LOS, to improve service efficiency, omission of one or more bundle elements is unlikely to reduce LOS, since each bundle element indicates an aspect of quality care. Furthermore, short LOS tended to relate to higher readmission rates (**Figure 6**), although this was not statistically significant (p=0.26).

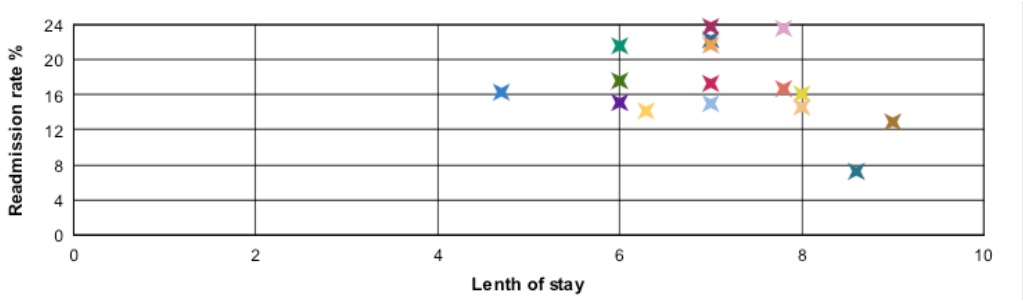

Figure 6: Relationship of LOS to readmission rate. The graph shows the LOS and readmission rate of each centre that submitted data, where each data point represents a centre.

In a multivariate analysis, adjusted for centre and gender (since this differed between patients who did or did not receive the bundle), several components of the admission bundle related to outcome (*Table 4*). Age influenced both mortality and LOS, as might be expected, whilst the oxygen element, acidosis element and treatment time affected one or more of these outcomes.

	Death		LOS<5 days	
	OR (95% CI)	P	OR (95% CI)	p
Age up by 1 year	1.06 (1.04-1.07)	<0.001	0.99 (0.98-0.99)	<0.0001
Diagnosis element done	-	0.97	NA	0.510
Oxygen element done	0.22 (0.05-0.88)	0.03	1.84 (1.38-2.46)	<0.0001
Acidosis element done	-	0.23	1.41 (1.20-1.67)	<0.0001
Treatment given in 4 hrs.	0.60 (0.42-0.87)	0.006	NA	0.961
Resp. review within 24 hrs.	-	0.97	NA	0.592

Table 4: Multivariate analysis seeking associations with outcome of admission. The table shows the odds ratio (OR) for death or a LOS less than the median of 5 days, and their 95% confidence interval, from the multiple regression model. Where an input variable was not statistically significant the OR is not shown as this would not be meaningful.

8.1.2 The impact of respiratory review

Patients reviewed by the respiratory team, whether within 24 hours or not, were more likely to receive a bundle (17.3% v 9.1%, p<0.0001) and to have the diagnosis, oxygen and acidosis elements of the bundle completed (all p<0.0001). Patients seen by the respiratory team were also more likely to have received all appropriate treatment within 4 hours (48.8 v 44.3%; p=0.04), however since respiratory reviews generally occurred considerably later than the 4 hour window this does not reflect actions taken by the respiratory team. Rather, it may reflect that patients considered to be more unwell or requiring NIV, and who were seen more quickly in the Emergency Department (ED)/Acute Medical Unit (AMU) were more likely to be referred to the respiratory team. This is consistent with the fact that patients seen by the respiratory team tended to have higher pCO2 (6.10 v 5.61; p<0.0001) and to receive NIV (61.2 v 44.8%; p=0.003).

Patients reviewed by the respiratory team were also more likely to be discharged via an early supported discharge scheme (EDS; 22.2% v 2.1%) and had a slightly lower death rate (4.4% v 6.3%). The difference in overall outcome (EDS, death or discharge) was statistically significant even after adjustment for centre, which was the main determinant of access to EDS (p<0.0001). The time to respiratory review also tended to influence outcome, mainly because patients seen quickly by the respiratory team were more likely to get access to an EDS; this lost statistical significance when adjusted for centre (p=0.07) consistent with the fact that the centre was the main determinant of access to an EDS.

8.1.3 The impact of age on management

Six hundred and sixty four patients were over the age of 80. Receipt of the admission bundle did not differ in patients above and below 80 (p=0.19), however patients over 80 were less likely to get 4 or more bundle elements completed (p=0.035). This was driven by lack of a robust diagnosis in that the diagnosis element was completed less often (21.8 v 25.1%) p=0.029 and a reduced likelihood of respiratory review (19.9 v 26.2%) p<0.001. NIV was given to fewer patients over 80 (17.5% v 25.3%) p=0.016, even though the acidosis element completion rate was no different (p=0.96) although this may have been because presenting CO2 was generally lower (5.75 v 6.09).

In patients aged over 80, the only factor in the multivariate analysis to impact inpatient mortality was the oxygen element (p<0.001), whilst LOS was impacted by completion of the acidosis element, the effect being more marked than in younger patients (p=0.021, OR 1.76 for LOS<5 days v 1.41 in younger pts.).

8.2 COPD Discharge bundle results

Details from 2,263 patients were submitted from 17 hospitals. Of these 659 were stated to have a discharge bundle completed, whilst 1,547 did not, and for 57 patients their bundle status was not documented by the submitting centre.

Bundle completion rates rose gradually from 4.1% of all patients at the start of the project in November 2012 to 16.7% in September 2013 (**Figure 7**). There was considerable variability between centres.

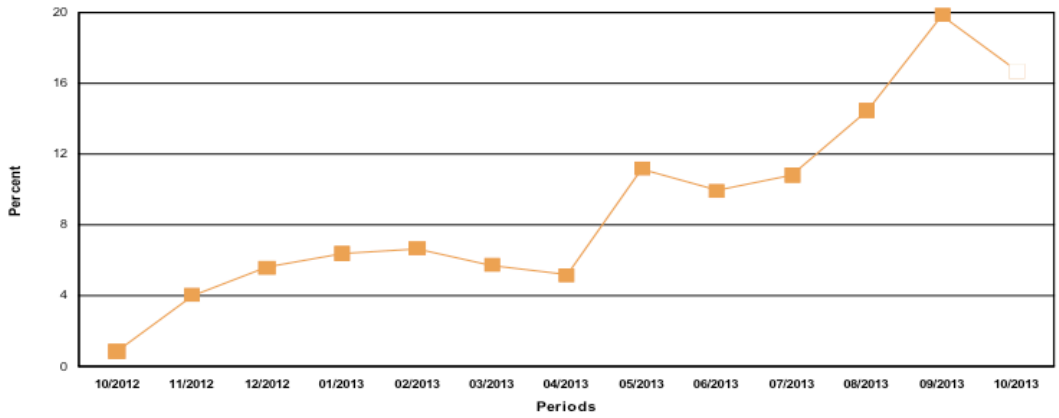

Figure 7: COPD Discharge bundle completion rates: The chart shows the % of the total number of patients discharged each month receiving a discharge bundle during the project.

Many patients were in receipt of bundle elements, even without formal use of a discharge bundle, as shown in **Figure 8**. However, patients in whom a bundle was applied were more likely to receive a greater number of bundle elements (p=0.005), such that 26.8% of patients with a bundle had four or more bundle elements completed, compared to 18.2% of those without.

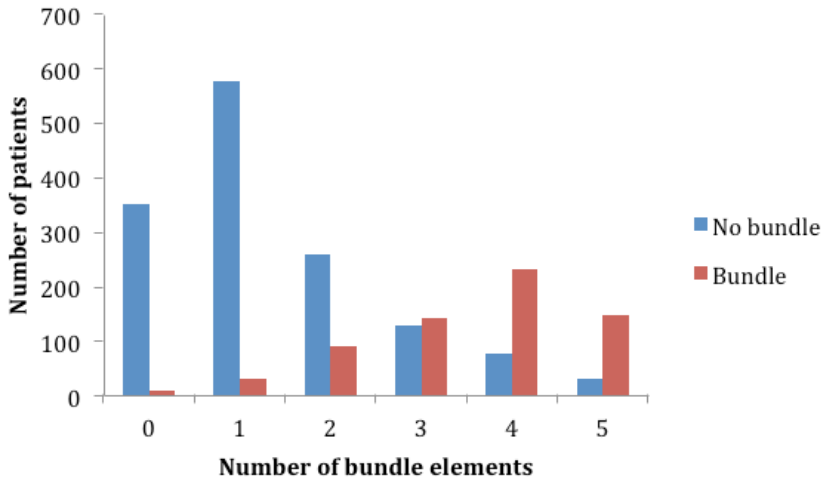

Figure 8: Discharge bundle elements received. The bar chart shows the number of patients both on and off the discharge bundle who received parts of the bundle.

The characteristics of the patients are shown in *Table 5*. Patients in receipt of a bundle were more likely to receive all bundle elements, and to be seen by the respiratory medicine team.

	Whole group	No bundle	Bundle	p
Male	1088 (48.2%)	750 (48.5%)	311 (47.2%)	**0.60**
Age	72 (64-79)	72 (64-79)	71 (65-78)	**0.22**
LOS (days)	5 (2-9)	5 (2-9)	5 (3-9)	**0.05**
Discharged from ED/AMU	184 (8.6%)	131 (8.5%)	59 (9.0%)	**0.72**
Respiratory review	1767 (78.7%)	1126 (72.8%)	604 (91.7%)	**<0.0001**
Inhaler technique	860 (38.8%)	327 (21.1%)	508 (77.1%)	**<0.0001**
SM* Given NA Already has Community team for plan/ pack	 563 (24.9%) 208 (10.7%) 294 (15.1%) 827 (36.5%)	 183 (11.8%) 137 (8.9%) 160 (10.3%) 349 (22.6%)	 358 (54.3%) 69 (10.5%) 129 (19.6%) 458 (69.9%)	**<0.0001**
Rescue pack Given NA	 331 (15.0%) 386 (17.5%)	 82 (5.3%) 188 (12.2%)	 230 (34.9%) 195 (29.6%)	**<0.0001**
Oxygen alert card Given NA	 145 (6.6%) 752 (34.3%)	 37 (2.4%) 383 (24.8%)	 101 (15.3%) 348 (52.8%)	**<0.0001**
Smoking cessation referral Done NA Declined	 120 (5.5%) 1293 (59.4%) 260 (11.9%)	 57 (3.7%) 851 (55.0%) 126 (8.1%)	 55 (8.3%) 408 (61.9%) 130 (19.7%)	**<0.0001**
Pulm Rehab Assessed Referred NA Declined Done rehab before	 574 (25.4%) 320 (14.1%) 151 (6.8%) 268 (12.1%) 180 (8.1%)	 434 (28.1%) 133 (8.6%) 83 (5.4%) 93 (6.0%) 93 (6.0%)	 336 (51.0%) 178 (27.0%) 65 (9.9%) 192 (29.1%) 85 (12.9%)	**<0.0001**
Treatment bundle element	819 (36.2%)	311 (20.1%)	490 (74.4%)	**<0.0001**
SM* bundle element	643 (28.4%)	198 (12.8%)	425 (64.5%)	**<0.0001**
Smoking bundle element	1673 (73.9%)	1034 (66.8%)	593 (90.0%)	**<0.0001**
PR** bundle element	531 (23.5%)	208 (13.4%)	310 (47.0%)	**<0.0001**
Telephone contact element	1166 (51.9%)	500 (32.3%)	502 (76.2%)	**<0.0001**

*Table 5: COPD Discharge Bundle: characteristics of the patients. Data is shown as n (%) or median (IQR). Significant differences between bundle and no bundle groups are highlighted by the p value in bold type.*SM: Self management education, **PR: Screening for pulmonary rehabilitation*

8.2.1 The impact of a discharge bundle

Table 6 shows the odds ratio for the likelihood of subjects receiving the key elements of care at discharge when those receiving bundles were compared with those who did not. In all 5 domains of the bundle, those receiving a bundle were more likely to receive best care than those who did not.

	Odds ratio	**95%CI**
Specialty Review before D/C	4.4	3.2 - 6.2
Drug Pack	8.6	6.9 - 10.7
O2 Alert Card	5.9	4.8 - 7.3
Pulm Rehab Review	2.3	1.7 - 3.0
Telephone Follow up	10.8	8.4 - 13.9

Table 6: Odds ratio for receipt of the elements of care in those receiving a bundle vs. those not receiving a bundle

In addition, the use of bundles seemed to be associated with improved reliability in the delivery of care. The figures below indicate that as the proportion of the total number of patients receiving a bundle in each centre increased patients were more likely to have had their treatments reviewed prior to discharge (**Figure 9**) and were less likely to have been sent home without being assessed for pulmonary rehabilitation (**Figure 10**), without a management plan (**Figure 11**) or without a follow up appointment being made (**Figure 12**).

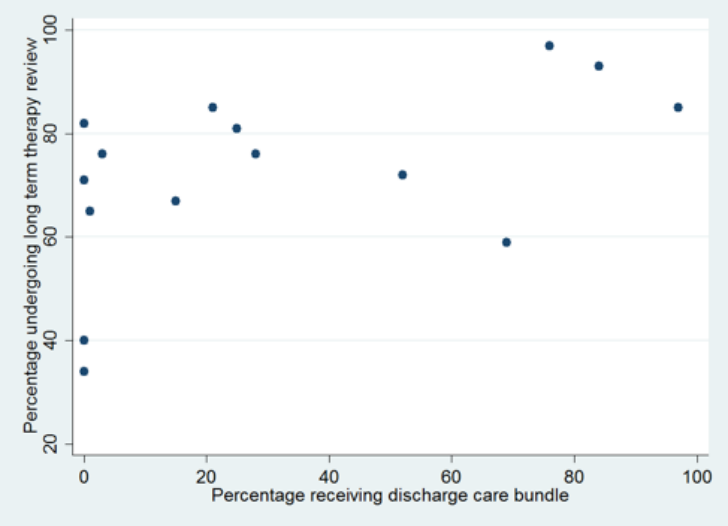

Figure 9: Proportion of patients receiving a therapy review vs. the total number of patients receiving a bundle by centre.

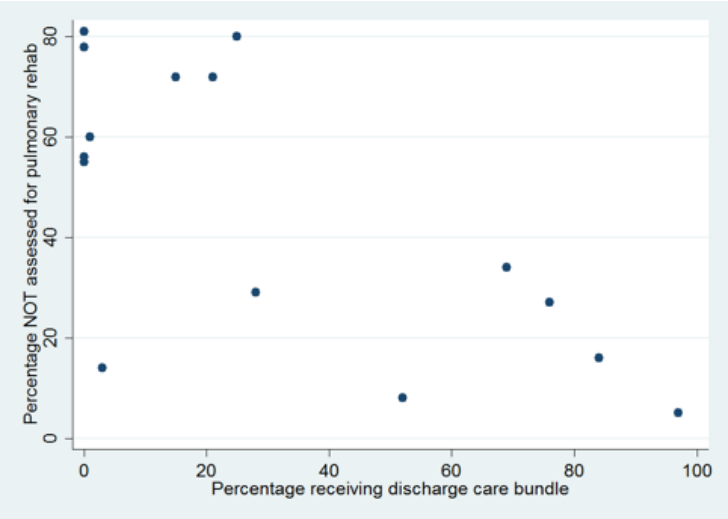

Figure 10: Proportion of patients not assessed for pulmonary rehabilitation vs. the total number of patients receiving a bundle by centre

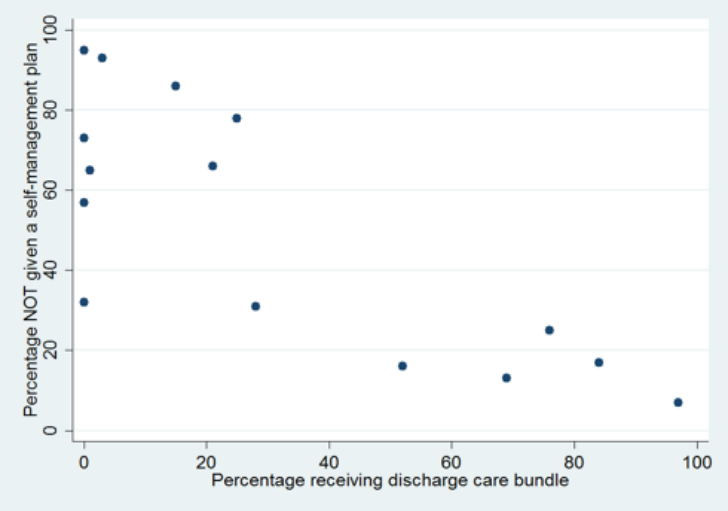

Figure 11: Proportion of patients not provided with a management plan vs. the total number of patients receiving a bundle by centre

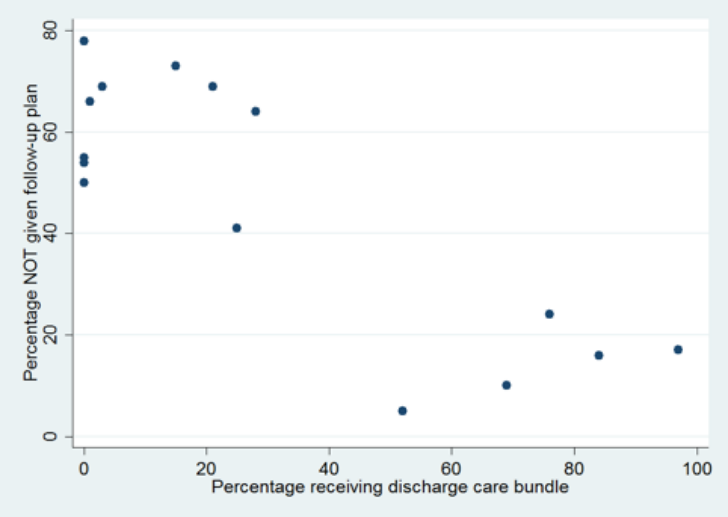

Figure 12: Proportion of patients not given follow up on discharge vs. the total number of patients receiving a bundle by centre

The biggest impact of the discharge bundle is likely to be on readmission rates. However, the data submitted by Trusts regarding readmission rates was patchy and overall insufficient to make a judgment of the effect of the bundle, or its elements. Patient satisfaction might also increase if they had better understanding of their illness and its management. An attempt was made to collect information on patient experience and satisfaction through the use of a generic long term conditions tool (LTC-6). This tool is designed to measure changes in patients knowledge, perceptions and beliefs with regard to care of their long term condition. Use of the tool is suggested as part of the Department of Health's strategy for long term condition management(36) but its validity has not been subject to peer review. In total 156 patient satisfaction questionnaires were submitted. Data both pre- and post- bundle implementation was submitted by 2 Trusts; in both cases patients' self-reported ability to understand and self-manage their COPD improved post-implementation, although low numbers of respondents limit the conclusions that can be drawn.

8.2.2 The impact of respiratory review

Patients reviewed by the respiratory team were more likely to receive a bundle (34.9% v 10.8%, p<0.0001) and to have a greater number of bundle elements completed, such that 28.7% of patients had 4 or more bundle elements completed, compared to 4.2% of patients not seen by respiratory (p<0.0001). The significance of this remained the same after adjustment for centre.

8.2.3 The impact of age on management

Patients aged over 80 tended to receive the discharge bundle less often than patients below this age (26.6% v 31.0%; p=0.057). This was driven by a lack of the treatment part of the bundle (medication review/inhaler technique; 31.8% v 37.5%; p=0.018), reduced consideration of pulmonary rehabilitation (PR element of bundle completed in 16% v 25.7%; p<0.0001) and a reduced likelihood of receiving a post-discharge telephone call (38.5% v 48.3%). Although there was a significant difference in completion rate of the smoking element of the bundle (p<0.0001) this was largely due to a higher number of those who had already stopped smoking (76.8% v 54.1%) in the older age group. Nevertheless only 2% of older smokers were referred to cessation services, compared to 6.6% of younger smokers. Use of self-management strategies did not differ by age (p=0.79). Since receipt of a bundle and each of its component parts related strongly to respiratory review, and patients over 80 were less likely to be seen by the respiratory team (71.1% v 81%; p<0.0001), this might account for some of the differences seen. Amongst patients who were reviewed by the respiratory team, the proportion receiving a bundle did not vary by age (p=0.61), treatment reviews were conducted equally (p=0.61), self-management strategies (p=0.20) and post discharge telephone contact (p=0.17) were used equally. However, differences in access to smoking cessation services and PR remained, and were of similar magnitude to the group as a whole (both p<0.0001).

8.3 Pneumonia Bundle

Implementation of the CAP care bundle in participating trusts (n=16) was progressive over time. A monthly total of over 100 care bundles implemented across participating sites was only achieved in the eighth month of the pilot. (**Figure 13**)

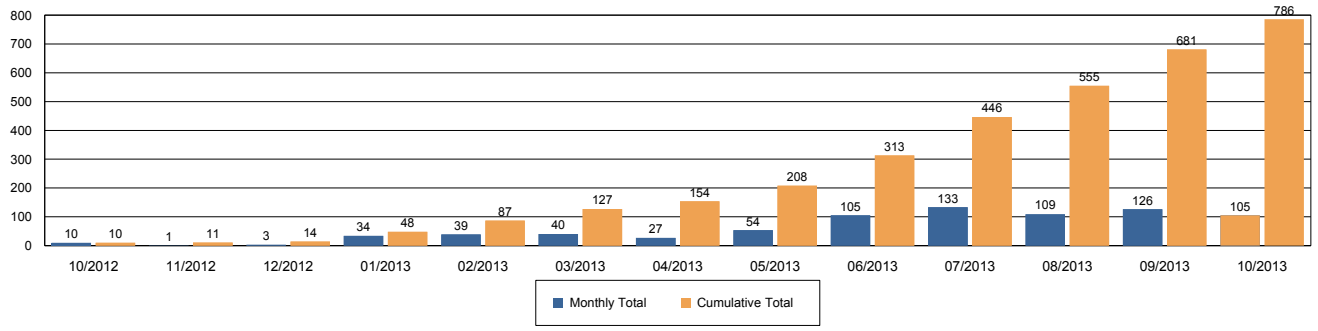

Figure 13: Number of CAP care bundles applied over the period of the pilot (from high level data)

Individual patient level data from a total of 2,563 adults were submitted by 16 participating trusts (18 hospitals) (*Table 7*). The median age of the cohort was 75.3 years (inter-quartile range (IQR) 59.4-85.1) and 1,319 (51.5%) were male. Disease severity stratified according to CURB65 score was low, moderate and high in 1,154 (45.0%), 706 (27.5%) and 703 (27.4%) adults respectively; these proportions were consistent with data from the national BTS CAP audit.

Adults for whom data regarding CAP bundle implementation were unavailable (n=132) and adults without radiological evidence of pneumonia (n=313), were excluded from all subsequent analyses. Of the remaining 2,118 adults, the CAP bundle was implemented in 250 (11.8%). No statistically significant differences were seen between the 'bundle implementation' group versus 'no bundle implementation' group with regard to the area of first assessment, baseline characteristics or disease severity (*Table 8*).

Trust	**No. of patients (%)**
	Total cohort = 2563
ABM University Health Board	54(2.1)
Cent Manchester/Manchester Chlds Univ Hosp NHST	92(3.6)
George Eliot Hospital NHS Trust	159(6.2)
Gloucestershire Hospitals NHS Foundation Trust	236(9.2)
Heart of England NHS Foundation Trust	283(11.0)
James Paget University Hosp NHS Foundation Trust	155(6.0)
North Bristol NHS Trust	176(6.9)
Royal Cornwall Hospitals Trust	108(4.2)
Royal Liverpool and Broadgreen Univ Hospitals NHST	256(10.0)
St George's Healthcare NHS Trust	172(6.7)
Taunton & Somerset NHS Foundation Trust	26(1.0)
University Hospitals of Leicester NHS Trust	154(6.0)
Whittington Hospital NHS Trust	176(6.9)
Worcestershire Acute Hospitals NHS Trust	171(6.7)
Yeovil District Hospital NHS Foundation Trust	126(4.9)
York Teaching Hospitals NHS Foundation Trust	219(8.5)

Demographics	
Age-median years (IQR)	75.3(59.4-85.1)
Male	1319(51.5)
Disease severity	
Low severity (CURB65 0-1)	1154(45.0)
Moderate severity (CURB65=2)	706(27.5)
High severity (CURB65 3-5)	703(27.4)

Table 7: Participating trusts and baseline characteristics of cohort. Data denote number of patients (%) unless stated otherwise (IQR, inter-quartile range)

8.4 Primary outcome measures

Data regarding timing of antibiotic administration, timing of chest X-ray and oxygenation assessment were unavailable for 370 adults, leaving 1,748 adults for these analyses. Time to chest X-ray ≤4 hours and oxygenation assessment were not associated with CAP bundle use (*Table 9*). Time to first antibiotic ≤4 hours was significantly better with CAP bundle use (adjusted odds ratio (OR) 1.52, 95% confidence interval (CI) 1.08-2.14; p=0.016).

Data regarding type and route of antibiotic administered were unavailable for a further 55 adults. Guideline adherence according to antibiotic route and type was not associated with CAP bundle use (Adherence by antibiotic route 63/143 (44.1%) in the CAP bundle group versus 573/1550 (37.0%) in the group without CAP bundle implementation, OR 1.34, 95%CI0.95-1.90, p=0.094; adherence by antibiotic type 42/143 (29.4%) in the CAP bundle group versus 387/1550 (25.0%) in the group without CAP bundle implementation, OR 1.25, 95%CI 0.86-1.82, p=0.247).

8.5 Secondary outcome measures

Of 2,118 adults, mortality data were absent for 6 adults. Thirty-day IP mortality was lower with CAP bundle use following adjustment for disease severity (30-day IP mortality 22/250 (8.8) versus 253/ 1862 (13.6) for CAP bundle versus no CAP bundle groups respectively; OR 0.61, 95%CI 0.39-0.97, p=0.035; adjusted OR 0.59, 95%CI 0.37-0.95; p=0.030). Unadjusted length of stay following exclusion of all deaths was longer for the CAP bundle group (median years (IQR) 6.1(3.1-11.4) versus 5.2(2.4-9.5), p=0.042).

High level data revealed no observable trends attributable to implementation of the CAP care bundle in relation to mortality rate over the 12 month period of the pilot project (*Table 10*).

	CAP bundle (n=250)	No CAP bundle (n=1868)	OR	95%CI	p value
Area first assessed	n (%)	n (%)			
ED	213(85.2)	1571(84.1)	Reference		0.077
MAU	30(12.0)	275(14.7)	1.24	0.83-1.86	
Other	7(2.8)	22(1.2)	2.92	1.15-7.39	
Age-median years(IQR)	72.6(62.5-83.8)	75.5(60.6-84.3)			0.69
Male	134(53.6)	953(51.0)	1.11	0.85-1.44	0.443
Low severity (CURB65 0-1)	104(41.6)	809(43.3)	Reference		0.876
Moderate severity (CURB65=2)	75(30.0)	513(27.5)	1.14	0.83-1.56	
High severity (CURB65 3-5)	71(28.4)	546(29.2)	1.01	0.73-1.39	

Table 8: Clinical characteristics according to bundle implementation: CAP, community-acquired pneumonia; OR, odds ratio; CI, confidence interval; ED, emergency department; IQR, interquartile range

	CAP bundle (n=196)	No CAP bundle (n=1552)	OR	95%CI	p value	aOR*	95%CI	p value
Outcome measure	n (%)	n (%)						
CXR < 4hours from admission	164(83.7)	1314(88.8)	0.93	0.62-1.39	0.717	0.93	0.62-1.39	0.708
Antibiotic <4 hours from admission	146(74.5)	1022(65.9)	1.51	1.08-2.12	0.016	1.52	1.08-2.14	0.016
Oxygen assessment	188(95.9)	1473(94.9)	1.26	0.60-2.65	0.541	1.26	0.60-2.65	0.544

*Table 9: Primary outcome measures: CAP, community-acquired pneumonia; OR, odds ratio; CI, confidence interval; ED, emergency department; IQR, interquartile range; CXR, chest X-ray; *odds ratio adjusted for disease severity*

Month	Admitted (n)	Died (n)	Mortality rate (%)
October 2012	1127	193	17.1
November 2012	1048	191	18.2
December 2012	1429	268	18.8
January 2013	1774	301	17.0
February 2013	1405	265	18.9
March 2013	1641	344	21.0
April 2013	1365	230	16.8
May 2013	1049	200	19.1
June 2013	900	190	21.1
July 2013	916	170	18.6
August 2013	708	130	18.4
September 2013	722	113	15.7
October 2013	878	142	16.2
Total	14962	2737	18.3

Table 10: High level data – patients admitted with CAP in participating institutions (October 2012 to October 2013)

8.6 Project Participant Qualitative Survey

Following completion of the BTS Pilot Care Bundle Project, participants were asked to complete a survey reflecting their qualitative experience of participation.

Twenty out of the total 21 Trusts provided a response. Fourteen trusts reported working on the COPD admission care bundle, nineteen reported working on the COPD discharge Bundle and fifteen reported working on the pneumonia care bundle.

Feedback from participants was also sought at the final project meeting.

8.6.1 Executive Sponsorship

Participating centres were encouraged to seek an executive sponsor for the project prior to commencement. 84% selected the medical director and the remaining centres chose to work with the Director of Nursing. The expectation was that teams would use the authority of the participating director to ensure that the project met organisational objectives for quality improvement prior to commencement. In addition the nominated directors could act as a facilitator to ensure access to sufficient resource for the project team.

43% of the participating teams reported using their directors to help overcome obstacles. The assistance provided took a number of forms. In two centres the director was able to provide a small budget to cover the costs of printing. In 3 organisations the nominated director provided updates on the implementation of the project to the trust board. Finally other teams were able to use authority borrowed from the director to ensure access to resources from the audit department for obtaining case notes and from the IT department when it was necessary to make adjustments to trust information systems to allow collection of process and outcome information necessary for the project .

8.6.2 Project Inception and planning

8.6.2.1 Process Mapping & Pilot studies

Prior to starting the project, teams were encouraged to undertake a process mapping exercise. This was undertaken by 10/20 centres (50% - 2 centres did not answer). Reasons given for not conducting a project mapping exercise included lack of time, lack of faith in project mapping as an improvement technique and lack of engagement from colleagues. Two centres highlighted a lack of staff available with knowledge of the technique.

Service development teams were available in 12 of the participating centres and six offered assistance. Project mapping was undertaken in all of these centres. Other assistance provided by the service development team included project planning and organising meetings.

Only 7 teams used PDSA cycles as the means of piloting roll out of care bundles. Six centres piloted bundles on the respiratory ward and 7 piloted in the medical admissions or emergency medicine departments.

8.6.2.2 Resources

Five centres were provided with a small amount of money to assist with the care bundle implementation. In 3 centres the sum was < £200, in one it was £5000. Six centres received assistance with staff for the project – in one centre this was a full time band 6 nurse. Money was used predominantly for printing and data entry costs.

8.7 Incentives for Bundles Implementation

Project participants cited a range of incentives for project participation. Three centres cited poor audit/performance results (BTS Audit, HSMR mortality data and Dr Foster data). Others described a number of direct and indirect financial incentives.

Direct financial incentives included CQUIN payments (Commissioning for Quality and Innovation). Four centres had a CQUIN in place for implementing COPD discharge bundles, 1 was incentivised to implement the COPD admission bundle, and 1 centre was incentivised to introduce both. CQUIN payments were offered to 4 trusts for implementing the pneumonia bundle. The financial value of the payments varied in size from £33K to £750K (median value £400K). One centre reported that the bundle was

implemented as part of a community commissioned disease pathway aimed at reducing admissions.

Indirect incentives included a need to reduce length of stay (2 centres) and a withdrawal of tariff payments for patients readmitted after an initial episode of care.

Experience of the benefits of the CQUIN payments was mixed. One small hospital with a cohesive group of staff who were highly motivated to deliver the bundles initiative felt the CQUIN was a barrier to implementation as it introduced significant bureaucracy. Three centres indicated that they were already introducing the bundles before the CQUIN was in place and its introduction did not substantially affect the project. Overall however the consensus seemed to be that CQUINS helped to align organisational objectives with clinical objectives and led to clinicians wishing to engage in service improvement receiving readier access to administrative, and project management resource.

8.8 Participant reflection on project participation

Participants were asked to highlight the key positive and negative elements of participating in the pilot study

All participating centres highlighted positive areas arising from project participation. A third of the centres highlighted the benefits of exposure to teaching on change management methods. Others highlighted the benefit of informal learning that could be gained from communicating with colleagues in other centres, and the insight this offered into potential solutions to obstacles encountered. Fifty percent of centres felt that project participation had raised the profile of the needs of respiratory patients or knowledge of optimum care of COPD and pneumonia within their organisations. A number of centres highlighted that BTS endorsement for the project helped with uptake of the project with non-respiratory as well as respiratory colleagues.

There were a number barriers which were described by the majority of participating sites. These centred principally around the lack of time clinicians have to change care pathways on a large scale. This barrier was compounded in 4 centres by a lack of engagement from colleagues outside the respiratory service. A final common theme was the difficulty in introducing change in a care pathway in which junior doctors play a large role due to rapid turnover in this staff group.

8.9 Stage of bundle implementation by conclusion of pilot study

Project participants were asked to offer their opinion on the areas in which they felt that bundles were fully implemented in each of the key clinical areas in their hospital. Responses are summarised in *Table 11*.

	No. of trusts working on each bundle	Respiratory	ED	MAU	Not fully implemented anywhere
COPD Admission	15	5	5	8	7
COPD Discharge	18	13	3	8	5
CAP	16	5	6	6	8

Table 11: Total number of trusts working on each bundle and the number of trusts reporting that the bundles were fully implemented in different areas of their organisation.

9 Case Studies

9.1 Royal Liverpool University Hospital

Dr Justine Hadcroft, Consultant Respiratory Physician

The Royal Liverpool Hospital is a large city centre teaching hospital with a busy Accident and Emergency department and an Acute Medical Admissions Unit staffed almost entirely by acute physicians with in-reach from specialist physicians and nurses. When BTS called for applications to participate in the pilot, the Royal had already been involved in Advancing Quality (Pneumonia) since its inception, but despite this we continued to have a high pneumonia mortality. We have an active COPD Early Supported Discharge scheme (ACTRITE) which has recently been extended to provide admission avoidance in addition to its early hospital discharge function. Our COPD mortality and length of stay were lower than the national average, but our readmission rate was high. We have a team of COPD specialist nurses whose main purpose is to assist the Emergency Floor with the management of patients with COPD exacerbations, including the identification of patients requiring non-invasive ventilation.

The first 6 months of the pilot was spent preparing for the introduction of care bundles: modifying the care bundle proformas for ease of use of the admitting doctors and nurses in our trust (who would be the ones administering the admission bundles), educating all those who would come across the care bundles, and collecting baseline data. We launched the Care Bundles exactly half way through the year, on May 1st 2013 and spent the ensuing 6 months trying to encourage use of the bundles, re-educating and collecting data. Our Accident and Emergency department in particular embraced the care bundles, and found them a useful aid to managing patients with COPD and CAP, and the majority of bundles which were completed were started in A&E.

At the end of the pilot period, we had entered 256 CAP cases, 341 COPD admissions and 237 COPD discharges into the BTS web tool. 70 CAP care bundles, 66 COPD admission care bundles and 69 COPD discharge care bundles were completed.

I encountered various challenges during the project, the hardest of which was trying to encourage care bundle use in the AED and AMU, departments in which I did not work. Where I was able to convince an enthusiastic group of doctors and nurses that they were useful, they were used much more often. Constant education and reminders were necessary. The BTS's requirement that a senior manager (in our case the medical director) agree to the project gave us the authority to work across departments for the benefit of the trust's patients.

My advice to future participants is:

- Involve the teams who will be responsible for seeing these patients on admission: identify an enthusiastic medic and several enthusiastic nurses in each department.
- Allow the departments to develop the bundles to their own requirements.
- Find out how to access people to help (Service Improvement was my secret saviour).
- Education, Education, Education!

9.2 Birmingham Heartlands Hospital

Dr Alice Turner, Senior Lecturer & Honorary Consultant Physician

Heartlands Hospital is a large inner city teaching hospital with a busy Accident and Emergency department and an Acute Medical Admissions Unit staffed by a mixture of acute physicians and specialist physicians. When BTS called for applications to participate in the pilot, Heartlands had just conducted the first audit of COPD inpatient care since the appointment of a new COPD lead (Dr Turner). This had shown low rates of completion of several aspects of good COPD care, such as referral for pulmonary rehabilitation. We also had readmission rates marginally above the national average. In addition we had undergone several external reviews (PWC, Deloitte, West Midlands Quality Review Service) of various aspects of COPD care, and it had been suggested by one that our mortality rate for patients cared for by respiratory was higher than the national average. Whilst this was most likely due to the fact that we are a 3 site Trust and most of those requiring inpatient NIV come to Heartlands, hence our patients were more unwell, it was apparent that we needed a simple way in which to improve care quality. Our pneumonia audit results indicated results largely in line with the national average, but again external reports had raised a question regarding mortality rate. We were aware of the results from the London CLAHRC regarding COPD care bundles, and were considering how to introduce this when the opportunity to work with the BTS came. We have daily respiratory ward rounds for new admissions, direct access to ward based NIV via respiratory physiotherapists and several clinical nurse specialists in COPD, whose role in part is to review in-patients with COPD.

The 3 months from October to December 2012 were spent preparing for the introduction of the care bundles, gaining feedback on proposed local forms through grand rounds and email circulations to medical teams. We launched the Care Bundles on Jan 1st 2013 and spent the ensuing 9 months trying to encourage use of the bundles, re-educating and collecting data. We issued pocket sized cards which staff could attach to their ID badge detailing some of the bundles in order to continually remind staff. The COPD discharge bundle was really taken up by our Clinical Nurse Specialist (CNS); part way through the year one of them left to take up a post in AMU and continues to be our 'respiratory champion' there. Towards the end of the project our local CCG showed interest in using the COPD discharge bundle as a CQUIN; our experience and data gathered during the project has been useful in negotiations.

At the end of the pilot period, we had entered 283 CAP cases, 190 COPD admissions and 209 COPD discharges into the BTS audit web tool. 10 CAP care bundles, 59 COPD admission care bundles and 160 COPD discharge care bundles were completed.

There were various challenges during the project, the hardest of which was trying to encourage care bundle use in the ED, a department in which neither I nor the COPD nurses worked. Constant education and reminders were necessary; pocket cards were particularly useful in this regard, although our Trust was not able to fund them. In the end educational funding was provided by a pharmaceutical company. By the end of the year I had begun to conclude that the 'carrot' of improving patient care was not going to be enough to sustain and continue improvement, hence I agreed with the 'stick' approach of a CQUIN, although this will not be implemented in this financial year. Prior to implementation of the CQUIN we plan to make some systematic changes to nurse education on AMU and respiratory wards, to make sure that the bundle can be delivered independently of CNS on most of the wards with high numbers of COPD patients. We were unable to introduce the CAP bundle paperwork effectively, even though completion of all elements of the bundle improved over the year, so this will need some local refinement if it is to succeed.

I have little to add over the advice from Liverpool, except the link to external agencies as sources of help in implementing bundles – for instance the pressure from the local Clinical Commissioning Group (CCG) is helping us to get more Trust systems in place to sustain bundle delivery, and pharmaceutical industry help has aided our education programme considerably.

10 Discussion

The BTS Pilot Care Bundle Project had two principal aims. First to establish whether care bundle implementation was feasible and practical in an NHS environment. Second to see whether successful implementation of bundles were associated with increased reliability in delivery of care with a consequent improvement in clinical outcomes - principally a reduction in mortality, reduced length of stay and a reduction in the readmission rate following discharge of patients from hospital.

The project has been successful in both respects. At the outset it was anticipated that it would take at least three years to fully implement the system changes necessary to ensure that care bundles were delivered reliably to all patients with an acute exacerbation of COPD and community-acquired pneumonia. This has been confirmed by the results of the study. The case study described by Dr Hadcroft, Consultant Physician at the Royal Liverpool University Hospital, and analysis of the community-acquired pneumonia data set has shown that the initial planning phase necessary prior to implementing care bundles can last as long as 6 to 8 months.

At project inception, fewer than 2% of patients cared for in participating institutions received a care bundle. At the end of the pilot project, 13 months later, 17.4% of patients admitted with an acute exacerbation of COPD received an admission bundle, 19.9% received a discharge bundle and 20.3% of patients admitted with a diagnosis of community-acquired pneumonia received a pneumonia bundle. This suggests that teams were only just beginning to put in place the necessary system changes to ensure reliable delivery of the intervention. It is therefore unsurprising that neither the COPD admission or discharge bundle was associated with a significant change in any of the high-level outcome measures measured using HES data. However, it is encouraging to note that a reduction was seen in 30 day in-patient mortality for patients receiving a pneumonia bundle albeit that the magnitude of the reduction was greater than expected and may have been partially explained by confounding factors.

10.1 Commentary on COPD Admission and Discharge Bundles

There is evidence that receipt of a COPD care bundle was associated with significantly improved outcomes at the individual level after analysis of patient level data. Receipt of the oxygen component of the admission bundle was associated with an 80% reduction in mortality, and receipt of the care bundle within four hours of hospital admission was associated with a 40% reduction in mortality.

Despite the fact that correlation does not equal causation in an observational study such as this, these findings are congruent with trial evidence elsewhere in the literature which suggest that delivery of controlled oxygen in patients with AECOPD is associated with a reduction in mortality(37). Furthermore receipt of the oxygen element of the care bundle and timely non-invasive ventilation was associated with an increased likelihood of a length of stay of less than five days. Again these findings are congruent with the literature showing improved outcomes in association with the appropriate use of NIV(38).

It is possible that some of the statistical associations noted occurred as a result of confounding, as patients receiving a care bundle were almost twice as likely to have been seen by the respiratory team. Patients seen by the respiratory team were more likely to have had the oxygen and acidosis elements of the bundle completed. In addition, they were more likely to have received all appropriate treatments within 48 hours.

Results of the 2003 National COPD Audit seem to suggest that patients with a primary respiratory diagnosis at admission are more likely to achieve better outcomes when reviewed by a specialist team. It is likely that the respiratory team will be aware of the key elements of care and thus be more likely to deliver them in a timely manner. It is also likely that respiratory practitioners assessing individual patients will be integrated into a wider respiratory team delivering the holistic care that is likely to provide the best outcome for respiratory patients. However, it provides the tantalising hope that if non-respiratory specialists could be encouraged to deliver the elements of care contained in care bundles, they would come closer to achieving the improved outcomes achieved by respiratory practitioners.

It is particularly encouraging to note the improved outcomes for patients reviewed by the respiratory team as the higher pCO2 of COPD patients seen by the respiratory team would seem to suggest that they are looking after the sickest patients in whom one might expect to have a worse rather than better outcome.

Patients seen by the respiratory team were also more likely to be discharged via an early supported discharge scheme and have a slightly lower readmission rate. This is statistically significant even after adjusting for centre - which was the main determinant of access to an early supported discharge scheme.

The biggest impact of the discharge care bundle is likely to be on readmission rates. The only information available on this outcome was derived from the data submitted from Trusts based on hospital episode statistics. As bundles were completed in a relatively small proportion of the total number of patients discharged it is not surprising that no effect on this outcome was seen. Information on the 30 day readmission rate was not available at the individual patient level.

Review of COPD patient level data seemed to indicate differential management of patients based on their age. Patients over the age of 80 were less likely to have had a full care bundle delivered, they were less likely to have been reviewed by the respiratory team and were less likely to have received non-invasive ventilation. This may have been clinically appropriate as patients over the age of 80 had a lower pCO2 on admission.

Observation of different levels of intervention in older patients may not necessarily indicate clinically inappropriate care, as it is likely that older patients will have a greater number of comorbidities, which may influence the appropriateness of different interventions. In addition, older patients may also express different wishes about the levels of care they wish to receive. Nevertheless it is worrying to note that at discharge older patients were less likely to have had their inhaler technique checked, to have been considered for pulmonary rehabilitation, or to have been followed up after discharge. Older patients are less likely to be able to use their inhalers appropriately (16, 39, 40) and are thus in greater need of appropriate tuition and review of their inhaler devices prior to discharge. It is therefore hard to offer clinical decision making as a reason for the differentials in care older patients received at discharge. Clinicians must therefore be certain to ensure that care pathways are delivered according to clinical need and that these are not unduly influenced by age or other factors.

Finally. it is disappointing to note that only 2% of older smokers were referred to smoking cessation services, compared to 6.6% of younger smokers. Assessment and referral of all current smokers using medical services to a quit/smoking cessation programme must be the goal of all medical practitioners irrespective of the discipline in which they work.

10.2 Commentary on pneumonia care bundle results

There was a strong commitment from participating sites to implementing the CAP care bundle. Even with this determination, it took most sites over 6 months from the start of the pilot to put processes in place for CAP care bundle implementation.

Over the period of the pilot, patients in whom the CAP care bundle was delivered represented a minority of all the patients admitted with CAP.

Patients in whom the CAP care bundle was delivered were similar to patients who did not receive a care bundle in terms of disease severity at presentation.

Time to first antibiotic within 4 hours of admission was the key process measure that was significantly better in the group of patients in whom the CAP care bundle was applied (75% versus 66%). This process measure has been shown to be associated with improved clinical outcome, and underpins the potential for the CAP care bundle to lead to clinically meaningful changes.

Unexpectedly in-patient mortality was lower for patients in whom the CAP care bundle was applied (8.8% versus 13.6%). Whilst this finding was welcomed, this magnitude of reduction in mortality seems unlikely to be due solely to the improvements made in the time to first antibiotic. Care bundle implementation may have been associated with other quality of care processes, such as delivery of prophylaxis for venous thromboembolism, or earlier involvement of respiratory medicine specialists, that were not directly measured within the pilot project. Alternatively, a biased cohort of patients may have been unintentionally selected for CAP care bundle delivery; for instance, selection based on place of residence, functional status or time at presentation to hospital.

10.3 Effect of bundles on process reliability

Use of care bundles seemed to be associated with improved reliability of care in the pilot project. For patients with AECOPD, the likelihood of oxygen being prescribed, being assessed for non-invasive ventilation, and being reviewed by a respiratory specialist were all increased by receiving a care bundle. Patients who were not in receipt of a bundle also received elements of best care, but receipt of a bundle was associated with a 32% absolute increase in the likelihood of having four or more bundle elements administered. The strength of the association between the use of a care bundle and receipt of best care at discharge was even greater than the strength of association at hospital admission.

When comparing individual centres, it is encouraging to observe an almost linear relationship between the proportion of patients receiving a care bundle in each institution, and the likelihood of the key elements of care described in the bundle being delivered. The data suggests that receipt of a bundle is correlated with an improvement in the likelihood of receiving optimum care. The observation of the linear relationship between increased bundle delivery and increased reliability of care would seem to imply that this association may be causal(41).

10.4 Commentary on organisational elements of bundles pilot study

Review of the qualitative data collected from study participants highlights a number of positive elements associated with participation in a quality improvement project such as this. The work carried out on re-design of patient pathways in participating centres seems to have been associated with raising the profile of respiratory patients and their needs, and with an improvement in knowledge of staff with regard to the elements of best care.

Participants also seemed to value the opportunity to learn about quality improvement methodologies whilst refining problem-solving skills with colleagues.

A number of barriers to successful change in processes of care in the participating NHS organisations were identified. First, the way in which hospitals are organised seems to encourage "silo" working. Some of the project participants encountered difficulty motivating colleagues in emergency and acute medicine departments to engage with the project. This is surprising given the support of the Acute Medicine and Emergency Medicine Specialist Societies to protocol-based care in general.

The principal barrier was the lack of time which busy clinicians have to change pathways of care for patients – however highly motivated they may be. To optimise efficiency, busy clinicians need access to project management expertise and managerial time, but this was not forthcoming for the majority of participants. Organisations that were able to build teams incorporating these skills, with access to appropriate data and analyst time, appeared to be the most successful in embedding changes to patient pathways.

Some pitfalls were also observed. Few participating centres undertook process mapping prior to initiating changes in the way care was delivered. This is likely to result in failure to understand the whole patient pathway, and is ultimately likely to lead to a less successful outcome following implementation of care bundles.

In addition, the scale of the challenge associated with collecting patient level data on a large number of subjects can easily lead to project participants forgetting that the ultimate aim is better patient care not better data. It is also clear that where adequate resources are not directed towards collecting individual patient level data, there is ambiguity about whether changes in processes being made are indeed leading to improvements in the pathway as a whole.

The range of incentives for participating in the project was wide. Some centres were motivated by the need to improve clinical outcomes derived from historical audit or clinical performance data. Others worked in organisations that were incentivised by financial benefits offered by commissioning bodies. Opinions were mixed, but on the whole trusts offered the opportunity of increasing income in association with implementation of care bundles were, perhaps unsurprisingly, more willing to commit personnel and resources to assist clinicians in changing the pathways of care.

The key elements of success associated with successful changes in pathways of care seem to be:

- Alignment between the priorities of clinicians and managers with a focus on improving outcomes for patients.
- The measures incorporated in care bundles being accepted as evidence-based and as far as possible relatively uncontroversial. (Where this is not the case there is the danger that energy will be expended by clinicians on convincing peers about the clinical benefits of the bundle rather than working on their implementation).

Finally, it is clear that data collection can be one of the greatest barriers to service redesign if adequate resources are not dedicated to this aspect of quality improvement. The data collected must be broadly applicable, sensitive to change and agreed to be important by all participants. In addition data collection must be feasible and affordable, and based on existing data wherever possible.

10.5 Conclusion

Overall, the results from this pilot project are encouraging and suggest that wide implementation of the BTS CAP and COPD care bundles is practically feasible. The effectiveness of bundles in improving reliability and reducing unwarranted variability in care is also demonstrated. Further research already planned should allow conclusions to be drawn on whether this also leads to improved outcomes of care. However, analysis of patient level data seems to indicate that when focus is brought to bear on the organisation of care it is possible to show improved outcomes from an early stage of implementation. The patient level data also emphasises the importance of oxygen prescribing and provision of timely care. Finally, the value of respiratory specialist leadership of care is also demonstrated by the superior outcomes achieved when patients are seen by an appropriately trained practitioner.

11 Next Steps

The results of the BTS Pilot Care Bundle Project have provided sufficient support for a bundles approach to improving care in the NHS to allow a comprehensive assessment of COPD Bundles supported by a National Institute for Health Research (NIHR) Health Service & Delivery Research (HS&DR) grant. The project will be carried out by a well-established, multi-disciplinary team of researchers under the direction of Professor Sarah Purdy from the University of Bristol, and run jointly with BTS and a number of other organisations. The work is designed as a 'controlled before-and-after' study with nested case studies. The 36 month project will start in late 2014. The chosen study population will be adults admitted to hospital in England and Wales with a primary cause of acute exacerbation of COPD. The intervention under consideration is the delivery of care bundles at the point of admission and discharge.

Improving standards of care in the management of in-patients with pneumonia has been selected as a strategic priority for the British Thoracic Society with support from the National Clinical Director for Respiratory Medicine, and opportunities are being sought to spread implementation of this intervention more widely.

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Dr Gerrit Woltman, Consultant Respiratory Physician, University Hospitals of Leicester
Dr Swapna Mandal, Respiratory Research Registrar, St Thomas' Hospital, London

Project participants

Trust/Hospital	Project Lead	Team members
Abertawe Bro Morgannwg University Health Board: Morriston Hospital	Dr Emrys Evans	Craig Barker; Clinical Analyst Scott Pegler; Lead pharmacist Fiona Hughes; Assistant Head of Operations Integrated Medicine Respiratory Clinical Nurse Specialist and Ward Team Morriston Hospital
Aneurin Bevan Health Board: Royal Gwent Hospital Nevill Hall Hospital	Dr Patrick Flood-Page Dr Deborah Wales	Natalie Janes - RNS - Nevill Hall Hospital Sam Jones - RNS - Royal Gwent Hospital Joanne Powell - ABCi Project Support Pharmacy Royal Gwent Hospital and Nevill Hall Hospital Angela Haley Matthew Jones
Central Manchester Foundation Trust: Manchester Royal Infirmary	Dr Karthick Santhana	Shane O'Reilly Anne Humphreys Clare Challinor Jon Simpson Mark Woodhead Stuart Logan Yvonne Murray Elizabeth Parson
Epsom & St Helier University Hospitals NHS Trust:	Helen Parnell	Ginny Quirke; Sally Farmer; Claire Kearon; Sandra Bagirathan; Daniel Woosey; Sinthuja Sivarajah; Jo McCarthy; Patricia Lowe Shanthi Paramothayan; Jonathon Ratoff; Svitlana Romanova; Imran Elliahi; Desmond Deraujo Mohammed Al Khaddour Jairon Majdneya
George Eliot Hospital NHS Trust	Wendy Preston	Ruth Knowles Christine O'Brien Caroline Todd Laura Richards Tracy Corney

Project participants

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Heart of England NHS Foundation Trust: Birmingham Heartlands Hospital	Dr Alice Turner	Rachel Knightly Tim Spruell Clare Cartlidge Tracie Stuart Amy Hoare
James Paget University Hospital NHS Foundation Trust: James Paget University Hospital	Dr Anna Blackburn	Heather Matthews Maria Hunter Sharon Boothby Douglas Jones Gary Wakeley, Information Analyst Stacie Morgan Mathew Gilbert Amber Woodcock Emma McCarthy Ionut Badescu Diviya Sritheran Tamara Tasjic
Medway Foundation NHS Trust: Medway Maritime Hospital	Dr Lisa Vincent Smith	Kay MacKay Learieann Alexander
North Bristol NHS Trust	Dr James Calvert	Jane Ashford, Specialist Nurse Sophie Rudman, Staff Nurse Melanie Chalder

Project participants

Royal Liverpool and Broadgreen University Hospitals NHS Trust: Royal Liverpool University Hospital	Dr Justine Hadcroft	Anthony Duffy Paul Jones Sally Jones Sarah Byrne Sinead Fletcher Tracy Perry Stephen Lloyd
Royal Cornwall Hospital NHS Trust	Dr Jonathan Myers	Ian Moyle; Clinical Matron Sarah Wonnacott; Sister Wellington Ward
St George's Healthcare NHS Trust: St George's Hospital	Samantha Prigmore	Michael Pollard
Taunton and Somerset NHS Foundation Trust: Musgrove Park Hospital	Dr Sarah Foster	Robert Stone Consultant Respiratory Physician Alex Parker ACCS Trainee Dinesh Shrikrishna Specialist Registrar Respiratory Greg Nicholls Foundation Year One Trainee Peter Lewis Deputy Chief Executive Joanne Watson Clinical Director Improvement Network
University Hospitals of Bristol NHS Foundation Trust: Bristol Royal Infirmary	Dr Nabil Jarad	Ros Badman Lucinda Foy Stuart Metcalfe Kate Ford
University Hospitals of Leicester NHS Trust: Glenfield General Hospital	Dr Ruwani Rupesinghe	Catherine Free Gerrit Woltmann Caroline Stanford - Information Analyst Tim Lessells - Acting Assistant Audit Facilitator
University Hospitals Southampton NHS Trust	Dr Zoe Pond	Sophie Fletcher Lis Mayhew-Arnold
Whittington Health: Whittington Hospital	Dr Sara Lock	Kelly Collins Sarah Crook Kevin Gilbride
Worcestershire Acute Hospitals NHS Trust: Worcestershire Royal Hospital	Dr Catherine Moore Dr Elaine Bevan-Smith	Clare Hooper Sarah Deacon
Yeovil District Hospital	Sister Sheila Leeman	Rajendra Sinha - Consultant; Kate Brookman - Senior Respiratory Nurse Specialist; Janet Fallon - Specialist Registrar; Charlotte Mitchell - Clinical Governance Assistant
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Dr Christine Bucknall, BTS Audit Programme Director

Dr James Calvert, BTS Professional and Organisational Standards Committee

Professor Derek Bell, Imperial College

Dr Robert Berg, Royal Derby Hospital

Catherine Blackaby, Lung Improvement Programme

Dr Jerry Brown, Chair BTS Lung Infection SAG

Jan Cassidy, Respiratory Programme Manager, East of England

Dr Edward Cetti, East Surrey Hospital

Professor Peter Davey, Lead Clinician for Clinical Quality Improvement, Dundee

Dr Sarah Elkin, St Mary's Hospital, London

Dr Annika Graham, Huddersfield Royal Infirmary

Dr Toby Hillman, Whipps Cross Hospital

Cathy Howe, Programme Lead for Acute Care, NIHR CLAHRC

Lianne Jongepier, Anglian Community Enterprise

Dr Wei Shen Lim, Nottingham City Hospital, CAP audit lead

Dr Gillian Lowrey, Royal Derby Hospital

Dr George Mabeza, Royal Derby Hospital

Dr Hannah Morgan, East Grinstead Hospital

Samantha Prigmore, St George's Hospital, London

Professor Monica Spiteri, University Hospital of North Staffordshire

Dr Rob Stone, Musgrove Park Hospital

Catherine Thompson, Lung Improvement Programme

Dr Mark Woodhead, Manchester Royal Infirmary

Sally Welham, BTS

British Thoracic Society
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