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Admission and discharge care bundles for COPD

Submission date 08/01/2015	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 11/02/2015	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 07/03/2023	**Condition category** Respiratory	[_] Individual participant data

Plain English summary of protocol

Background and study aims
Avoiding unnecessary use of hospital services is one of the biggest challenges currently facing the NHS. Chronic obstructive pulmonary disease (COPD) is one of the most common lung diseases in the United Kingdom and accounts for 10% of hospital admissions each year. Nearly a third of these patients are readmitted to hospital within 28 days of discharge. COPD care bundles could play a key role in resolving the issue of unplanned admissions. Care bundles are a way of ensuring that staff provide a coordinated package of care to patients with COPD when they arrive at and are sent home from hospital. This study aims to evaluate the effectiveness of care bundles as a means of improving hospital care and reducing re-admissions for patients with COPD.

Who can participate?
This study will include a group of up to 20 hospitals in England and Wales who have already agreed to implement the COPD care bundles, and up to 20 ‘comparator’ hospitals who will not be delivering them.

What does the study involve?
By comparing how many patients are readmitted to each type of hospital over a two-year period, and what happens to patients during their stay, we will be able to assess how successful COPD care bundles are. More specifically, we will look at the number of patients admitted with COPD, the number of deaths of COPD patients while in hospital, the number of days spent in hospital by patients with COPD, the proportion of patients with COPD who are readmitted, the number of COPD patients seen and discharged from A&E, levels of satisfaction in patients with COPD, how patients with COPD are managed in hospital, and how much it costs to care for a patient with COPD in hospital and after discharge. Most of the information needed for this study is routinely collected by hospitals in the course of their own management activity.

What are the possible benefits and risks of participating?
The benefit of taking part in the study for either NHS Trusts or individual patients is the opportunity to participate in a national high-quality evaluation of service delivery which will provide new evidence on the effectiveness of an aspect of NHS care provision. The risks of participation are minimal.

Where is the study run from?
University of Bristol (UK)

When is the study starting and how long is it expected to run for?
May 2014 to August 2017

Who is funding the study?
NIHR Health Services and Delivery Research (UK)

Who is the main contact?
Prof. Sarah Purdy
sarah.purdy@bristol.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Sarah Purdy

Contact details
School of Social and Community Medicine
University of Bristol
Canynge Hall
39 Whatley Road
Bristol
United Kingdom
BS8 2PS
-
sarah.purdy@bristol.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
17828

Study information

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

Study objectives

This research seeks to evaluate the effectiveness of care bundles (i.e., a co-ordinated package of care) as a means of improving hospital care and reducing re-admissions for patients with chronic obstructive pulmonary disease (COPD).

More details can be found at: http://www.nets.nihr.ac.uk/projects/hsdr/1213053
July 2014 V1 protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0003/129792/PRO-12-130-53.pdf
April 2016 V2 protocol: see additional files

Ethics approval required
Old ethics approval format

Ethics approval(s)
Frenchay REC, 12/09/2014, ref: 14/SW/1057

Study design
Non-randomised; Observational: before-and-after, controlled; Design type: Mixed method - quantitative and qualitative

Primary study design
Observational

Secondary study design
Mixed method - quantitative and qualitative

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Respiratory disorders; Subtopic: Respiratory (all Subtopics); Disease: Respiratory

Interventions
The intervention is the delivery of a COPD care bundle at either the point of admission to or discharge from hospital.

Intervention Type
Other

Primary outcome measure
COPD re-admission rates; Timepoint(s): 28 days post-discharge

Secondary outcome measures
1. Compliance with delivery of COPD care bundles; Timepoint(s): 12 months pre- and post-
2. COPD re-admission rates; Timepoint(s): 90-days post-hospital discharge

3. Costs of in-patient medications and procedures; Timepoint(s): 12 months pre-and post-
4. In-hospital mortality; Timepoint(s): 12-months pre- and post-
5. Length of stay for patients with COPD; Timepoint(s): at end of 12-month data collection
6. Mortality; Timepoint(s): 90-day post-hospital discharge
7. Overall re-admission rates; Timepoint(s): 28-days post-hospital discharge
8. Time taken to deliver COPD care bundles; Timepoint(s): post-admission or pre-discharge
9. Total number of COPD admissions; Timepoint(s): monthly
10. Total number of patients for whom COPD care bundle used; Timepoint(s): 12-months post-hospital data collection

As with the primary outcome, the secondary outcomes of the study will be measured for a 12-month period pre-and post- a particular index date. This index date is the date upon which an individual implementation site i.e. NHS Trust began to deliver its COPD care bundle or, in the case of comparator sites, the date upon which an individual site's matched implementation site began to deliver its COPD care bundle. This approach will ensure that data are collected during the same ‘before’ and ‘after’ period for matched implementation and comparator sites.

12/12/2016: "Patient and carer experience; Timepoint(s): at end of 12-month data collection" outcome removed from April 2016 protocol.

Overall study start date
01/05/2014

Completion date
31/08/2017

Eligibility

Key inclusion criteria
1. People over 18 years of age admitted to an acute hospital with COPD
2. Primary cause of admission is COPD (ICD10 diagnostic codes J41-44)
Target Gender: Male & Female ; Lower Age Limit 18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 76; UK Sample Size: 76; Description: 60 patients + 16 trusts. Study comprised of 3 levels of research. Level 1 is not consenting and uses publicly available data. Level 2 is 'consents' at a trust level and will recruit 'up to 16' trusts and level 3 is patient-consented case studies and aims to recruit 10 patients per site from 'up to 6 sites'. May also

include some patient carers and healthcare professionals where available. Mixed method study combining both quantitative and qualitative approaches - no formal sample size calculation. Total final enrolment was 14 trusts and 55 participants for the qualitative study.

Total final enrolment
69

Key exclusion criteria
1. People admitted to hospital with COPD where this is not the primary cause of admission
2. Elective admissions for COPD

Date of first enrolment
01/02/2015

Date of final enrolment
31/07/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Bristol
School of Social and Community Medicine
Canynge Hall
39 Whatley Road
Bristol
United Kingdom
BS8 2PS

Sponsor information

Organisation
University of Bristol

Sponsor details
c/o Christine Nileshwar
Senate House
Tyndall Avenue
Bristol

England
United Kingdom
BS8 1TH

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Government

Funder Name
Health Services and Delivery Research Programme (Grant Codes: HS&DR/12/130/53)

Alternative Name(s)
Health Services and Delivery Research (HS&DR) Programme, NIHR Health Services and Delivery Research (HS&DR) Programme, NIHR Health Services and Delivery Research Programme, HS&DR Programme, HS&DR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date
01/11/2017

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	25/02/2016		Yes	No
Protocol file	version v2.0	30/04/2016	02/03/2017	No	No
Results article	results	01/06/2019	24/02/2020	Yes	No
Results article		25/03/2020	07/03/2023	Yes	No
Results article		30/05/2019	07/03/2023	Yes	No
HRA research summary			28/06/2023	No	No