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# CFHealthHub Data Observatory

**Submission date**
26/07/2017

**Recruitment status**
No longer recruiting

**Registration date**
02/08/2017

**Overall study status**
Completed

**Last Edited**
02/04/2024

**Condition category**
Respiratory

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

## Plain English summary of protocol

Background and study aims
Cystic Fibrosis (CF) is an inherited disease affecting 10000 people in the UK with an average age at death of 28 years in 2012. The lungs of people with CF (PWCF) are prone to infections. Daily physiotherapy and inhaled medications are needed to stay healthy. Around £30 million is spent annually on inhaled therapy but average adherence has been shown to be only 36%. Data suggest that adherence is better in younger children but of the most of the PWCF are now adults. PWCF who collect less than 50% of their medication cost the healthcare system significantly more than PWCF who collect more than 80% and most of the additional cost results from unscheduled emergency care and hospital admission. This unscheduled emergency care is distressing for PWCF and their families. Current research investigating whether adult PWCF can build successful, self-management, treatment habits using dose-counting nebulisers to collect adherence data, displaying this data on a website (CFHealthHub) and using a behaviour change toolkit, supported by a health professional, is ongoing. The aim of this study and the CFHealthHub is to help facilitate quality improvement projects using data from CFHealthHub about participants adherence and participant's relationship with the team. The study also aims to build an understanding of the process of implementing CFHH into routine practice.

Who can participate?
Adults aged 16 and older who are diagnosed with CF and use a nebuliser.

What does the study involve?
Participants receive a new chipped nebuliser, or have their existing nebuliser adapted to communicate with CFHealthHub. They are given a log in to the CFHealthHub system and shown how to use their device and the CFHealthHub website, by a member of their care team. This includes how to turn on and off data sharing with their clinical team. Participants are then able to use their nebuliser as normal, with the support of CFHealthHub. CFHealthHub automatically collects data on the participants' use of their chipped nebuliser, specifically the time of use and duration of inhalation. The data is stored in the secure CFHealthHub server. To provide a tailored CF toolkit participants will periodically complete a questionnaire about the challenges of taking their medication.

What are the possible benefits and risks of participating?
Participants may benefit from participating as the data could lead to changes in their CF care at their own health centre. Participants may find feedback available in the CFHealthHub useful to

understand their condition or form habits to take their medication. Participants may benefit from the treatment or therapy offered. There are no notable risks with participants, however, participants may have to give up some time to complete the consent visit.

Where is the study run from?
This study is being run by the University of Sheffield (UK) and takes place across seventeen hospitals in the UK.

When is the study starting and how long is it expected to run for?
January 2017 to March 2025

Who is funding the study?
NHS England CQUIN (UK)

Who is the main contact?
1. Sophie Farrell
sophie.farrell3@nhs.net
2. Dr Martin Wildman
martin.wildman3@nhs.net

### Study website
https://www.sheffield.ac.uk/scharr/sections/dts/ctru/cfhealthhub/dataobservatory

# Contact information

### Type(s)
Public

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Scientific

### Contact name
Dr Martin Wildman

### Contact details

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Clinical Lead in Service Improvement
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Sheffield Adult CF Centre
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## Additional identifiers

### EudraCT/CTIS number

### IRAS number
216782

### ClinicalTrials.gov number

### Secondary identifying numbers
IRAS 216782

## Study information

### Scientific Title
CFHealthHub Data Observatory: A Quality Improvement project and Trials within Cohort platform for Cystic Fibrosis

### Study objectives

Current study hypothesis as of 11/02/2020:
The aim of CFHealthHub data observatory is to explore the use of adherence data for quality improvement and as behavioural data within a cohort for future CF studies. The study also aims to build an understanding of the process of implementing CFHealthHub into routine clinical practice.

Previous study hypothesis:
The aim of CFHealthHub data observatory is to explore the use of adherence data for quality improvement and as behavioural data within a cohort for future CF studies.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
London-Brent Research Ethics Committee, 06/04/2017, ref: 17/LO/0032

## Study design
Current study design as of 11/02/2020:
A pragmatic development study which consists of an observational cohort study and a platform for quality improvement projects across the NHS.

A mixed-methods process evaluation that will be repeated yearly from 2018 to 2020 and will follow MRC process evaluation guidelines to explore the activities and outputs documented on the logic model, specifically to identify the barriers and pathways to implementation.

Previous study design:
A pragmatic development study which consists of an observational cohort study and a platform for quality improvement projects across the NHS.

## Primary study design
Observational

## Secondary study design
Cohort study

## Study setting(s)
Hospital

## Study type(s)
Other

## Participant information sheet
Available to download from the study website https://www.sheffield.ac.uk/scharr/sections/dts/ctru/cfhealthhub/dataobservatoryfolder/dataobservatory

## Health condition(s) or problem(s) studied
Cystic Fibrosis

## Interventions
CFHealthHub is an online portal which displays adherence data and provides behaviour change resources and tools for people with Cystic Fibrosis (PWCF), these tools used alongside trained

CF health professionals support changes in patient self-management (nebuliser adherence). It is available on-line via computers, tablets or mobile phones. Previous research has focused on the development of an adherence intervention for PWCF (CFHealthHub) and is subject to ongoing evaluation. These work packages have been supported by an NIHR applied programme grants (Reference RP-PG-1212-20015).

The Data Observatory facilitates quality improvement projects, which act as an intervention within the CF team. These QI projects utilise the Clinical Microsystem methodology developed by the Dartmouth Institute, USA (Nelson, Bataldan and Godfrey 2007) and adopted by the Sheffield Microsystem Coaching Academy (MCA). The Sheffield MCA (http://www.sheffieldmca.org.uk) approach advocates that complex health systems can be reduced to smaller building blocks called 'microsystems' where multidisciplinary teams deliver healthcare to patients. At each microsystem a number of QI projects may occur but the implementation requires the completion of four phases; Assessment, Diagnose, Treatment and Standardise, where tools such as assessment using the 5 P's (Purpose, Patients, Professionals, Processes, Patterns) process mapping, time series measurements, Plan Do Study Act (PDSA) cycles are utilised until the change idea has been adapted or has become embedded into the microsystem.

Participants who consent to take part in the study will receive a new chipped nebuliser, or have their existing nebuliser adapted to communicate with CFHealthHub. They will be given a log in to the CFHealthHub system and shown how to use their device and the CFHealthHub website, by a member of their care team. This includes how to turn on and off data sharing with their clinical team. Participants will then be able to use their nebuliser as normal, with the support of CFHealthHub.
CFHealthHub automatically collects data on the participants use of their chipped nebuliser, specifically the time of use and duration of inhalation. The data is stored in the secure CFHealthHub server.

To provide a tailored CF toolkit participant's periodically complete a questionnaire about the challenges of taking their medication, which is entered by a member of staff into CFHealthHub, at a clinic appointment or review.

Members of the CF team will be able to view the adherence data for participants who have data sharing switched on, and identify if any participants could benefit from the behavioural intervention that is currently being tested in an RCT. The Data Observatory will not be measuring the effectiveness of this intervention. Instead, CFHealthHub will help facilitate quality improvement projects using data from CFHealthHub about participants adherence and participant's relationship with the team.

## Intervention Type
Behavioural

## Primary outcome measure
Current primary outcome measure as of 11/02/2020:
Objective nebuliser adherence measured using adherence information stored in the CFHealthHub system. Three-monthly and annual adherence for each individual will be calculated as unadjusted adherence, normative adherence (Hoo, 2016) and total nebuliser used per week.

Previous primary outcome measure:
Sophisticated normative adherence as defined by Hoo (2016)

## Secondary outcome measures

Current secondary outcome measures as of 13/02/2020:
1. Lung function assessed by FEV1 captured on CFHealthHub at baseline and every clinical encounter
2. Process data (prescription checks, duration of inhalation) is measured using data recorded on CFHealthHub at baseline and every clinical encounter
3. The rate of consent as measured by the number of completed consent forms. Rate of follow up is measured by the number of completed follow-up questionnaires, data sharing is available by extracting the number of participants with data sharing switched on or off on the CFHealthHub system.

Previous secondary outcome measures as of 11/02/2020:
1. Lung function assessed by FEV1 on spirometry
2. Process data (prescription checks, duration of inhalation) is measured using data recorded on CFHealthHub
3. The rate of consent as measured by the number of completed consent forms. Rate of follow up is measured by the number of completed follow-up questionnaires, data sharing is available by extracting the number of participants with data sharing switched on or off on the CFHealthHub system.

Previous secondary outcome measures:
1. Unadjusted adherence is measured using adherence information stored in the CFHealthHub system
2. Simple normative adherence is measured using the CFHealthHub system
3. Process data (prescription checks, duration of inhalation) is measured using data recorded on CFHealthHub
4. The rate of consent as measured by the number of completed consent forms. Rate of follow up is measured by the number of completed follow-up questionnaires, data sharing is available by extracting the number of participants with data sharing switched on or off on the CFHealthHub system.

### Overall study start date
09/01/2017

### Completion date
31/03/2025

## Eligibility

### Key inclusion criteria
1. Diagnosed with CF and with data within the CF registry
2. Aged 16 years and above
3. Taking inhaled mucolytics or antibiotics via a chipped nebuliser (e.g. eTrack or I-Neb) or able and willing to take via eTrack or I-Neb

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit

16 Years

### Sex
Both

### Target number of participants
To date, there are seventeen confirmed CQUIN (2019/2020) centres across England taking part in the CFHealthHub Learning Health System. Across such CF centres, 899 patients are providing real-time objective adherence data, with the intention that there could be as many as 2000 patients accessing adherence support and contributing data for quality improvement and medicines optimisation projects. As a long-term recruitment goal, it is anticipated that all patients using nebulisers with electronic monitoring capabilities will eventually join the data observatory resulting in 5000 to 6000 adults with CF to be included.

### Key exclusion criteria
Lacking in capacity to give informed consent

### Date of first enrolment
25/05/2017

### Date of final enrolment
31/03/2025

## Locations

### Countries of recruitment
England

United Kingdom

Wales

### Study participating centre
### Sheffield Teaching Hospital NHS Foundation Trust
Cystic Fibrosis Centre
Northern General Hospital
Herries Rd
Sheffield
United Kingdom
S5 7AU

### Study participating centre
### Nottingham University Hospital NHS Trust
East Midlands Cystic Fibrosis Adult CF Centre
Nottingham University Hospitals NHS Trust City Hospital campus
Hucknall Road
Nottingham

United Kingdom
NG5 1PB

**Study participating centre**
**University Hospital Southampton NHS Foundation Trust**
Adult cystic fibrosis service
level C,
West Wing
Southampton General Hospital
Tremona Rd
Southampton
United Kingdom
SO16 6YD

**Study participating centre**
**Frimley Park Hospital**
Frimley Health NHS Foundation Trust
Portsmouth Rd
Frimley
Camberley
United Kingdom
GU16 7UJ

**Study participating centre**
**The Royal Victoria Infirmary**
Cystic Fibrosis Department, Respiratory Medicine
Newcastle Upon Tyne Hospitals NHS Foundation Trust
Queen Victoria Rd
Newcastle upon Tyne
United Kingdom
NE1 4LP

**Study participating centre**
**Norfolk and Norwich University Hospital**
Respiratory Medicine
East Block
Level 3
Norfolk and Norwich University Hospitals NHS Foundation Trust
Colney Lane
Norwich
United Kingdom
NR4 7UY

**Study participating centre**
**Royal Stoke University Hospital**
North West Midlands Cystic Fibrosis Centre
Children's Outpatients Department
University Hospitals of North Midlands NHS Trust
Newcastle Road
Stoke-on-Trent
United Kingdom
ST4 6QG

**Study participating centre**
**John Radcliffe Hospital**
Oxford Adult Cystic Fibrosis Centre (OACFC)
Ward 5D
Level 5
John Radcliffe Hospital
Headley way
Headington
Oxford
United Kingdom
OX3 9DU

**Study participating centre**
**St Bartholomew's Hospital**
Ward 4E
Cystic Fibrosis Unit
Department of Respiratory Medicine
4th Floor
KGV Building
West Smithfield
London
United Kingdom
EC1A 7BE

**Study participating centre**
**Royal Cornwall Hospital**
The Lighthouse
Royal Cornwall Hospitals NHS Trust
Treliske
Truro
United Kingdom
TR1 3LQ

**Study participating centre**
**Royal Devon and Exeter Hospital**
Q235
Level 2
Royal Devon and Exeter Hospital NHS Foundation Trust
Barrack Road
Exeter
United Kingdom
EX2 5DW

**Study participating centre**
**Heartlands Hospital**
Ward 26
University Hospitals Birmingham NHS Foundation Trust
Bordesley
Green East
Birmingham
United Kingdom
B9 5SS

**Study participating centre**
**Bristol Royal Infirmary**
Medical Research Unit
Zone B501
University Hospitals Bristol NHS Foundation Trust
Marlborough Street
Bristol
United Kingdom
BS2 8HW

**Study participating centre**
**Glenfield Hospital**
Respiratory Bioemedical Research Unit 3
University Hospitals of Leicester NHS Foundation Trust
Groby Rd
Leicester
United Kingdom
LE3 9QP

**Study participating centre**
**Derriford Hospital**
Chest Clinic

Level 6
University Hospitals Plymouth NHS Trust
Plymouth
United Kingdom
PL6 8DH

**Study participating centre**
**University Hospital Llandough (UHL)**
The All Wales Cystic Fibrosis Centre
University Hospital of Wales
Penlan Road
Llandough
Cardiff
United Kingdom
CF64 2XX

**Study participating centre**
**York Hospital**
Learning and Research Centre
York Teaching Hospital NHS Foundation Trust
Wigginton Road
York
United Kingdom
YO31 8HE

# Sponsor information

**Organisation**
Sheffield Teaching Hospitals NHS Foundation Trust

**Sponsor details**
Royal Hallamshire Hospital
Glossop Road
Sheffield
England
United Kingdom
S10 2JF

**Sponsor type**
Hospital/treatment centre

**ROR**
https://ror.org/018hjpz25

# Funder(s)

### Funder type
Government

### Funder Name
NHS England CQUIN funding

# Results and Publications

### Publication and dissemination plan
Current publication and dissemination plan as of 11/02/2020:
Planned publication in a high-impact peer-reviewed journal. Additional documentation is available to download from the study website: https://www.sheffield.ac.uk/scharr/sections/dts/ctru/cfhealthhub/dataobservatory

### Intention to publish date
31/03/2026

### Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr Martin Wildman (Chief Investigator), martin.wildman3@nhs.net. The data-sets are available throughout the duration of the Data Observatory. Data available will include real-time adherence data. At present the study team are refining what information will be helpful for future research, therefore contacting the study team to discuss any requests is advised. Data will only be available from participants who have consented to participate in the trials within cohorts platform. All future research using the Data Observatory platform must be ethically approved. The Data Observatory is suitable for future randomised controlled trials. However, there are two levels of consent for the trials within cohorts platform, consent to:
1. Pseudonymised data within CFHealthHub to be used for future research related to CF which has been ethically approved
2. Be included for selection in future research studies which have been ethically approved. If the participant meets the desired characteristics for the study they may be selected by chance to receive a new treatment. If they are not selected to receive the new treatment then they consent to sharing pseudonymised data without further notification. If they are selected to receive the new treatment they understand that they will be contacted and will have the opportunity to decline participation in the new study.

Previous publication and dissemination plan:
Planned publication in a high-impact peer reviewed journal. Additional documentation is available to download from the study website https://www.sheffield.ac.uk/scharr/sections/dts/ctru/cfhealthhub/dataobservatory

IPD sharing statement:
The datasets generated during and/or analysed during the current study will be available upon request from Dr Martin Wildman (Chief Investigator), martin.wildman@sth.nhs.uk. The data-sets

are available throughout the duration of the Data Observatory. Data available will include real-time adherence data. At present the study team are refining what information will be helpful for future research, therefore contacting the study team to discuss any requests is advised. Data will only be available from participants who have consented to participate in the trials within cohorts platform. All future research using the Data Observatory platform must be ethically approved. The Data Observatory is suitable for future randomised controlled trials. However, there are two levels of consent for the trials within cohorts platform, consent to:
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## IPD sharing plan summary

Available on request

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Protocol file | version v9.0 | 19/03/2020 | 01/06/2020 | No | No |
| HRA research summary | | | 28/06/2023 | No | No |