

IM2 Cystic Fibrosis Patient Adherence

Scheme Name	IM.ii Cystic Fibrosis Patient Adherence
Eligible Providers	2016/17 Pilot: Nottingham; Southampton (including for Poole patients); Sheffield 2017/20 Randomised Control Trial across 17 centres providing services for CF patients; the three pilot sites now piloting as Patient Observatories. All centres thereafter if successful.
Duration:	April 2016 – March 2020
Scheme Payment (% of CQUIN-applicable contract value available for this scheme)	CQUIN payment proportion [Locally Determined] should achieve payments for 2016/17 of c. £65,000 for the three pilot sites, with an additional sum (locally agreed) for Sheffield as coordinator. Target Value: Add locally CQUIN %: Add locally
Scheme Description	
<p>This scheme employs an electronic Cystic Fibrosis (CF) adherence indicator captured by an IT platform (CFHealthHub) to deliver a complex behavioural intervention that increases patient activation and adherence, thus delivering better patient outcomes and avoidance of costly escalations. Objective adherence is measured for high cost inhaled therapies collected via chipped nebulisers and displayed in CFHealthHub. CFHealthHub provides feedback to patients and clinicians about the adherence indicator in real time integrated into daily life and routine clinical care. CFHealthHub also provides a co-produced platform delivering a complex intervention designed to increase patient engagement by identifying barriers to patient activation and then using systematic behaviour change strategies to target barriers to patient activation.</p> <p>High cost inhaled therapies are prescribed in CF because randomised controlled trials have shown evidence of effectiveness in improving lung function and decreasing exacerbations. Inhaled medications can be considered to be preventative therapy that enables patients to self-manage in the community whilst working and attending school whereas intravenous antibiotics required to treat exacerbation can be considered to be rescue medications that typically require hospitalisation and will typically disrupt daily life. The benefits of inhaled therapies seen in RCTs are typically associated with adherence levels within RCTs of around 80%, whereas the median adherence rates in routine clinical practice are around 36%. Median adherence rates of only 36% for preventative therapy undermines therapy effectiveness and leads to avoidable hospital admissions. Medicine possession ratio data show that patients who collect less than 50% of their preventative therapy cost much more than those that collect 80% and the additional health care costs are related to unscheduled rescue care in hospital.</p> <p>Currently, routine clinical management in CF in the UK is carried out without knowledge of adherence. Without objective measures neither patients nor clinicians can reliably estimate adherence. This makes clinical encounters ineffective and may lead to important waste of resource: for example commissioning criteria allow escalation from bd tobramycin (approx. £7,000 per year) to tds aztreonam (approx. £12,000 per year) if</p>	

tobramycin is failing. With median adherence of 36% the most likely reason for tobramycin failure is non-adherence and switching to a tds drug will also fail waste money and not allow the clinician to focus on the more important issue of supporting patient engagement and activation. Embedding adherence data in every consultation has been found to be transformative in trailblazing sites.

The sums indicated (£65,000 for Southampton, for Nottingham, with additional funding for Sheffield recognising its coordinating role), as a proportion of CQUIN-applicable contract value, should provide the three providers piloting this scheme in 2016/17 with funding plus CQUIN incentive (of around 25%) to implement the pilot as specified below. Costs are justified in the Supporting Guidance section, below.

Measures & Payment Triggers

'16/17 Pilot.

The pilot requires the centres to deliver the pilot trial in their centres. The pilot study protocol is highly detailed and outlines what will be expected. Pilot centres will attract the CQUIN payment as long as

- they employ an interventionist who works with the research team according the protocol, and
- (through the interventionist) they provide recruited patients with chipped nebulisers and data transfer.

In addition, Sheffield as coordinator will pilot the development of an observatory, with the following deliverables:

- 1) Data observatory with measurement of adherence across a whole centre.
- 2) Data reports that show which patients are adhering and which are not to allow identification of at risk groups.
- 3) Data systems ready to accept Nottingham and Southampton in 2017 and to allow them to also receive centre level patient reports.
- 4) Data systems allowing Southampton, Sheffield and Nottingham to benchmark and compare.
- 5) An understanding of adherence changes within the majority of the Sheffield patients over the 12 month period.

Payment triggers for the RCT (from '17/18) are included in Supporting Guidance (below). However, the RCT methodology is under development, and adjustments may be made in advance of finalising the CQUIN scheme for '17/18.

Definitions

See supporting guidance below.

Partial achievement rules

None.

In Year Payment Phasing & Profiling

'16/17 Pilot

Hospitals will need the money to make appointments to support the programme and to recognise that the appointees will need to meet the evaluation team goals.

The centres will require this payment up front.

Rationale for inclusion

CFHealthHub is a platform that collects adherence data for high cost inhaled therapies. CFHealthHub, the focus of this scheme, provides a structured intervention to support patient activation by feeding back patient's adherence and linking this to problem solving and motivational interventions.

Health economic modelling suggests that, if an adherence intervention of modest effectiveness were to be implemented across the 6000 adults in the UK with CF, savings of more than £100 million might be expected over a 5 year time scale.

The adherence indicator is generated by CFHealthHub from data from chipped nebulisers, with data displays co-produced with patients and clinicians. Data capture occurs automatically without interrupting the flow of routine care and without adding any burden. The adherence indicator is available in real time for patients and for clinicians to provide feedback, which is a strong driver of behaviour change.

The behaviour change that is sought is

- 1) Improved adherence and self-management by patients, enabling better health outcomes and a much less time off work and other life activities.
- 2) Change in clinical teams so that they devote time to delivering structured evidence based interventions to improve and to support patient activation that in turn supports adherence and self-management.
- 3) Change in the attitude of clinicians to the challenges of sustained adherence in clinical care. It is likely that patients will only share personal data with teams that have an appropriate and supportive attitude.

CFHealthHub supports this intervention by

- 1) Making the capture of adherence data automatic.
- 2) Making adherence data available at all clinical encounters.
- 3) Providing feedback of data to patients which will support behaviour change
- 4) Providing structured interventions to allow clinicians to support behaviour change in patients to increase adherence
- 5) Supporting the fidelity of interventions to increase patient activation through menus available within CFHealthHub
- 6) Providing unit level adherence data to allow units to understand their unit level adherence as a quality indicator

Link between behaviour change and outcome

Meta-analysis has demonstrated that feedback of adherence data can increase adherence by around 20% and a further 7% increase in adherence results if relatively simple behaviour change strategies such as problem solving are added. High cost inhaled therapies are effective in reducing exacerbations if they are adhered to. Hence improving adherence will be associated with a reduced need for hospitalisation for intravenous antibiotics. The planned 20 centre RCT evaluation is designed to establish the relationship between the process of adherence and the outcome of reduced exacerbations. Once this relationship is established, adherence can be used as a quality indicator. The NIHR programme team are working with HSCIC to establish adherence as a UK quality indicator.

Data Sources, Frequency and responsibility for collection and reporting	
2016/17 Pilot	
The Clinical trials unit at Sheffield School of Health and Related Research (SchARR) will monitor involvement of centres in the trial and will be able to confirm to commissioners that the pilot centres have taken part in all the evaluation activities. Data sources for RCT (from '17/18) are discussed in the additional information supporting this CQUIN.	
Baseline period/ date & Value	n/a. for pilot year
Final indicator period/date	n/a. for pilot year
Final indicator reporting date	n/a. for pilot year
CQUIN Exit Route <i>How will the change including any performance requirements be sustained once the CQUIN indicator has been retired?</i>	The UK CF Registry is currently used for commissioning in CF. Once the evaluation phase is completed, we will report unit level adherence in the CF registry as an important quality indicator that will be routinely collected by CFHealthHub and regular feedback and benchmarking of unit level adherence in the CF registry reports will drive continued use of CFHealthHub to support adherence in clinical care. Financial savings from improved adherence, which support the continuation of the programme, are shared between commissioners and providers. Providers continue to benefit from implementing strategies to increase patient activation since patients require less unscheduled rescue care. Costs will in due course feed through into the CF year of care tariff.

Supporting Guidance and References

Costs

Costs will be incurred in the pilot year ('16/17) of circa £50,000 per centre (with additional costs for Sheffield). (The CQUIN payments exceed these figures by c.25% so to provide an incentive for participation – as is the norm for CQUIN schemes.) Details as follows:

May 2016 to April 2017

Costs include 0.52 of a band 6 interventionist for 12 months in each centre, the provision of 64 chipped nebulisers and the data transfer and peripherals and a hand held computer tablet per centre.

The funding for the interventionist post will need to be made available in a timely fashion so that the individual can be appointed and trained to allow the trial to start on time. The appointed individual will need to work closely with the NIHR research team and observe the research protocols.

Some savings expected from reduced exacerbations may be expected within the pilot but the amount is modest as only 32 patients are included in each pilot site .The emphasis within the pilot is to iterate the intervention further by involving additional hospital teams and patients in co-producing the intervention, intervention manual and data presentation within CFHealthHub.

There are some additional costs at Sheffield in excess of the other pilot sites, which will be reflected in a higher Target CQUIN payment.

Specific additional costs at Sheffield:

(i) Senior input to run the national CQUIN programme including both the NIHR evaluation and the data observatory

(ii) Project manager and support officer (a) to co-ordinate establishing framework and governance structures of data observatory including information governance and ethics, (b) to co-ordinate contracting with all the centres that will enter the RCT in Sept 2017 (c) to co-ordinate the move of Nottingham and Southampton into the data observatory in May 2017

(iii) Programming from Farr Institute Manchester to provide metrics within data observatory:

Cost £25,000

(iv) Funding the Phillips to establish I-Neb connectivity >> Cost £15,000

Further details of the intentions for future years are set out in the Annex, based on the NIHR Evaluation and expected rollout:

- Stage 1 March 2015 to April 2016: Intervention development and co-production
- Stage 2 May 2016 to April 2017: Pilot Trial in 2 additional centres
- Stage 3 July 2017 to October 2019: Fully powered Trial.
- Stage 4 September 2019 onwards: Rollout to all CF centres