IM2 Cystic Fibrosis Patient Adherence (Adult)

Scheme Name	*IM2 Cystic Fibrosis Patient Adherence (Adult)*
Section A. SUMMARY of SCHEME	
QIPP Reference	*[QIPP reference if any : Add Locally]*
Duration	April 2016 to March 2019
Problem to be addressed 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. 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.	
Change sought The behaviour change that is sought is: 1) Improved adherence and self-management by patients, enabling better health outcomes and 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. The CFHealthHub software platform 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	
Section B. CONTRACT SPECIFIC INFORMATION *(for guidance on completion, see corresponding boxes in sections C below)*	
B1.Provider (see Section C1 for applicability rules)	*[Insert name of provider]*
B2. Provider Specific Parameters. What was or will be the first Year of Scheme for this provider, & how many years are covered by this contract? (See Section C2 for other provider-specific parameters that need to be set	2016/17[1], 2017/18, 2018/19 Two years

[1] I.e. scheme was contracted for first implementation in 2016/17 with Southampton, Nottingham and with Sheffield, and this template is setting out requirements for 2nd and perhaps 3rd year of scheme for those providers; for other providers this contract is for the 1st and 2nd year of participation in a pilot.

out for this scheme.)	
B3.Scheme Target Payment (see Section C3 for rules to determine target payment)	Full compliance with this CQUIN scheme should achieve payment of: *[set sum £s following the Setting Target Payment guide in section C3 for setting target payment according to the scale of service and the stretch set for the specific provider.]* Target Value: *[Add locally ££s]*

B4. Payment Triggers.

The Triggers, and the proportion of the target payment that each trigger determines, and any partial payment rules, for each year of the scheme are set out in Section C4. No local variation is appropriate.

B5. Information Requirements

Obligations under the scheme to report against achievement of the Triggers, to enable benchmarking, and to facilitate evaluation, are as set out in Section C5.

Final indicator reporting date for each year.	Month 12 Contract Flex reporting date as per contract. *[Vary if necessary.]*

B6. In Year Payment Phasing & Profiling

Default arrangement: half payment of target CQUIN payment each month, reconciliation end of each year depending upon achievement.

However, for the '17/18 trial, commissioners should note that

- *Hospitals will need money to make staff-appointments to support the programme.*
- *Equipment costs for each site per annum will be required in 1 month in advance of patient recruitment commencement within the RCT Sept 2017.*
- *The infrastructure costs of the central team developing and supporting CF Health Hub requires payment at the commencement of the year (April 17) to allow for this support to be redistributed via the sponsor.*

Section C. SCHEME SPECIFICATION GUIDE

C1. Applicable Providers

Nature of Adoption Ambition: "Universal Adoption" for designated Trial sites

C2. Provider Specific Parameters

The scheme requires the following parameters to be set for each provider in advance of contract, in order to determine precisely what is required of each provider, and/or to determine appropriate target payment (as per C3.)	• None

C3. Calculating the Target Payment for a Provider

The target overall payment for this scheme (the payment if the requirements of the scheme are fully met, to be set in Section B3 above) should be calculated for each provider, as follows:

	2017/18	**2018/19**
Sheffield (data observatory site and RCT co-ordination)	£360,000	£300,000

Nottingham, Southampton (data observatory sites)	£270,000	£195,000
Other Trusts (RCT sites)	£160,000	£220,000

See Section D3 for the justification of the targeted payment, including justification of the costing of the scheme, which will underpin the payment.

C4. Payment Triggers and Partial Achievement Rules

Payment Triggers

The interventions or achievements required for payment under this CQUIN scheme are as follows: (detailed breakdown of the costs are provided in the tables in section D3 below)

Payment Triggers:

Sheffield data observatory and RCT co-ordination

1) Interventionist staff must be funded and in post for 12 months for each CQUIN cycle.
2) The trial specified nebulizers, nebuliser handsets, communication hubs and monthly patient data-flow must be funded. This equipment and dataflow will be supported by the Trust under a framework agreement led by the Sponsor with the equipment provider.
3) Screening for eligibility for data observatory must be carried out on clinic population and eligible patients approached for recruitment with data presented on reasons for recruitment and non-recruitment to data observatory.
4) Staff funded to support data observatory and RCT must follow agreed protocols relating to data observatory and RCT.
5) Study specific Infrastructure support not incurred at sites (Treatment costs for CF health hub) will be recovered from sites as per the attached schedule B as a pass through payment at the commencement of the year.

Nottingham and Southampton data observatory sites

1) Interventionist staff must be funded and in post for 12 months for each CQUIN cycle.
2) The trial specified nebulizers, nebuliser handsets, communication hubs and monthly patient data-flow must be funded. This equipment and dataflow will be supported by the Trust under a framework agreement led by the Sponsor with the equipment .
3) Screening for eligibility for data observatory must be carried out on clinic population and eligible patients approached for recruitment with data presented on reasons for recruitment and non-recruitment to data observatory.
4) Staff funded to support data observatory must follow agreed protocols relating to data observatory.
5) Study specific Infrastructure support not incurred at sites (Treatment costs for CF health hub) will be recovered from sites as per the Table C as a pass through payment at the commencement of the year.

Other Trusts (RCT sites)

1) Interventional staff must be funded and in post for 12 months for each CQUIN cycle.
2) The trial specified nebulizers, nebuliser handsets, communication hubs and monthly patient data-flow must be funded. This equipment and dataflow will be supported by the Trust under a framework agreement led by the Sponsor with the equipment .
3) Screening for eligibility for randomised controlled trial (RCT) must be carried out on clinic population and eligible patients approached for recruitment with data presented on reasons for recruitment and non-recruitment to RCT. Target recruitment as an average is 35 per site.

4) Staff funded to support RCT must follow agreed protocols relating to delivering RCT.

5) Study specific Infrastructure support not incurred at site (Treatment costs for CF health hub) will be recovered from sites as per the Table A as a pass through payment as the commencement of the year.

Definitions

Not applicable

C5. Information Flows: for benchmarking, for evaluation, and for reporting against the triggers.

Information for Benchmarking

The clinical trials unit at University of Sheffield will support the information flows to support benchmarking. This will include data captured from CFHealthHub which will be provided to participating centres and collects process data documenting engagement with the data observatory and RCT.

In addition structured training will be provided to the staff employed by the CQUIN and this training will involve structured fidelity measures which will assess competency and delivery of the roles that deliver the RCT and data observatory.

For centres within the RCT the clinical trials unit will collect data to ensure that trial procedures are followed and this will include trial monitoring visits that will provide data to allow trusts to satisfy the criteria to trigger CQUIN payments.

Information for Evaluation

Data for evaluation will come from CFHealthHub that collects data on the use of CFHealthHub to support people with CF and also data on the use of CFHealthHub to support day to day management of PWCF in clinics. These data will be processed by the clinical trials unit and provided back to units to allow evaluation.

Information Governance

CFHealthHub has been developed to meet all the relevant information governance standards. Formal ethical approvals through the national ethical governance procedures will govern the conduct of both the RCT and data observatory.

People with CF (PWCF) the RCT will receive information allowing them to sign consent forms to ensure that all data use has explicit consent. In addition all PWCF who enter the RCT will retain control of their data and data will only be shared with their permission and within the permitted uses authorised by the ethics approval relating to the RCT.

PWCF entering the data observatory will also be fully informed and sign consent forms to ensure that they agree to any use of their data. Just as in the RCT PWCF will retain control of their data and decide how it is shared.

Reporting of Achievement against Triggers

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 2017/18) are discussed in the additional information supporting this CQUIN. The CQUIN will be delivered and evaluated within a structured framework that allows testing of the intervention within an RCT, mixed methods process evaluation of both clinician and patient experience and a formal health economic analysis . Details can be found at https://www.sheffield.ac.uk/scharr/sections/dts/ctru/actif

Reporting Template requirement

C6. Supporting Guidance and References

RCT

An intervention and research guide outlines the role of staff employed in each trust. In addition face to face training will be delivered over 2 days at the beginning of the RCT and further telephone support will always be available. Staff will complete competency assessments and there is virtual training available to all staff.

Data observatory

Training and support will mirror the training in the RCT.

Section D. SCHEME JUSTIFICATION

D1. Evidence and Rationale for Inclusion

Evidence Supporting Intervention Sought

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. CFHealthHub also feeds back aggregated CF centre level adherence and engagement data that will support quality improvement at centre and system level.

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.

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 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. 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:

7) Making the capture of adherence data automatic.
8) Making adherence data available at all clinical encounters.
9) Providing feedback of data to patients which will support behaviour change
10) Providing structured interventions to allow clinicians to support behaviour change in patients to increase adherence
11) Supporting the fidelity of interventions to increase patient activation through menus available within CFHealthHub
12) 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.

Rationale of Use of CQUIN incentive

Scheme will generate financial benefits for commissioners as well as providers – on top of

improved patient outcomes. It is therefore appropriate for commissioners to fund it.

D2. Setting Scheme Duration and Exit Route

The UK CF Registry is currently used to support 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.

D3. Justification of Size of Target Payment

The target payment is based upon a detailed costing of the requirements falling upon the trial participants, and upon the three centres who have implemented the scheme in 2016/17 and are graduating to become Data Repositories, and upon Sheffield as programme coordinator, so as to ensure payment of at least 150% of average costs incurred. This site costing necessarily includes a site share of the infrastructure support for central teams that are incurred outside of each Trust supporting CF Health hub development. This is shown in the detailed tables A, B and C.

The costing is as follows:

CF HealthHub				
Provisional estmates for Donald Franklin and Ursula Peaple - 10th September 2016 v21 ERF				
Required NHS England CQUIN Support April 2017-June 2020				
	12m	12m		39 months
Summary as at 17/008/2016: Provisional figures will be changing as estimates confirmed	**2017-18**	**2018-19**		**April 2017-Jun 2020 Total**
A. Total Sheffield CQUIN for patients as participants within Data Observatory	£ 241,749	£ 196,999		£ 695,848
B. Total CQUIN costs for Nottingham as participants in Data Observatory	£ 179,779	£ 128,953		£ 412,465
C. Total CQUIN costs for Southampton / Poole as participants in Data Observatory	£ 179,779	£ 128,953		£ 412,465
D. Total CQUIN costs for **PER SITE** in RCT/ Data Observatory unit recruiting 35 patients (for initial 17 centres)	£ 106,923	£ 145,353		£ 497,767
E. Total Costs RCT/ Data observatory 17 centres + Sheffield + Pilot sites -39 months				**£ 9,982,808**
F. Total CQUIN site cost for additional patients for 35 patients per site > 20 sites	£ 90,873	£ 72,113		£ 299,515

Table A Details of Costs for RCT sites : Cost per Site (Year 1 and 2)

For 17-18 and 18-19 CQUIN 17 RCT Sites		
NHS Finanical Year	**2017-18**	**2017-19**
Year ending	**31/03/2018**	**31/03/2019**
No completed month costs	**12m**	**12m**
Equipment costs	31,366	16,803
eFlow data transfer expenses	940	5,447
Interventionist	27,071	40,606
Interventionist travel to Patient Homes	1,787	1,434
Quality improvement travel for Interventionis	-	1,825
Total Interventionist / Nebuliser Equipment and data flow Trust Incurred Costs	**61,163**	**66,115**
Central expenses for Infrastructure not RCT Trust incurred Costs	45,760	79,238
Cost per Site	**£ 106,923**	**£ 145,353**

NB : Additional funding from Research Grant to support Interventionist will be part of non-commercial agreement with sites

Table B Details Costs for Sheffield Site Data Observatory and RCT co-ordination (Years 2 and 3)

Sheffield Data Observatory Patients			
NHS Finanical Year	**2017-18**	**2018-19**	**Total**
Year ending	**31/03/2018**	**31/03/2019**	
No completed month costs	**12m**	**12m**	
Equipment costs	112,023	-	112,023
eFlow data transfer expenses	14,454	23,958	38,412
4 x PAs for Senior Investigator	46,260	46,260	92,520
Intrventionist Sheffield	3,408	42,753	46,161
Microsystems Coaching Academy	13,728	14,313	28,041
Central expenses for Infrastructure	51,876	69,715	121,591
B. Total Sheffield CQUIN	**£ 241,749**	**£ 196,999**	**£ 438,748**

NB Additional funding from NIHR Programme Grant to support Interventionist will be part of non-commercial agreement with sites

Table C Details of Cost for Nottingham and Southampton/Poole Sites : Cost per site

Per Site Costs for Nottingham and Southampton and Poole Data Observatory		
NHS Finanical Year	**2017-18**	**2017-19**
Year ending	**31/03/2018**	**31/03/2019**
No completed month costs	**12m**	**12m**
Equipment costs	89,618	-
eFlow data transfer expenses	8,039	17,279
Interventionist	49,332	52,000
Interventionist travel to patient homes	4,175	5,250
Quality improvement travel and accommodation for Interventionist	6,692	7,300
Central expenses for Infrastructure not RCT Trust incurred Costs	21,924	47,124
Total Nottingham and Southampton Site Expenses for CQUIN	**£ 179,779**	**£ 128,953**

Additional funding from NIHR Programme Grant and service support costs from local Clinical Research Networks to support 1.0 wte Interventionist will be available in 2017-18 and 2018-19 NHS Financial years.

Allowing the standard 50% CQUIN premium, this would give CQUIN payments as set out in section C3.

D4. Evaluation

The scheme is being evaluated as part of an NIHR Research Grant

Appendix: Providers

	From	Confirmed Y/N
Sheffield	current	
Nottingham	current	Y
Southampton	current	Y
Birmingham Heartlands	17/18	Y
Bristol	17/18	tbc
Cambridge Papworth	17/18	tbc
Royal Devon & Exeter	17/18	tbc
Frimley Park	17/18	tbc
Hull/York (service merging)	17/18	tbc
Leeds		tbc
Leicester	17/18	tbc
Liverpool	17/18	tbc
Barts	17/18	tbc
Kings College London	17/18	Y
Royal Brompton	17/18	tbc
UHSM	17/18	tbc (were going to be in pilot)
Newcastle	17/18	Y
UHNM (Stoke)	17/18	tbc
Norfolk & Norwich	17/18	tbc
Oxford	17/18	Y in principle
Plymouth	17/18	tbc