##

## 2019/20 PSS CQUIN Scheme

## Indicator Template

## *[Section B to be completed before insertion in contracts.]*

## PSS3 Cystic Fibrosis Self-care (v2 revised 05 July 2019)

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| Indicator Name | ***Cystic Fibrosis: Supporting Self-care*** |
| 1. **SUMMARY of Indicator**
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| Indicator Sponsor (with email address) | *Dr Martin Wildman* *martin.wildman@sth.nhs.uk* |
| Improving Value Reference | *N/A* |
| Duration | One year. |
| CCG Complementarity | *N/A* |
|  **Problem to be addressed (maximum 150 words):*****[****Briefly characterise the shortfall in quality or efficiency that the indicator is designed to address; detailed evidence should be placed in section D1****]*** CF numbers are increasing by around 200 adults per year (equivalent to a new adult unit annually) with rapid cost increases for providers inevitable unless practice changes. A major driver of CF costs is hospital admissions for rescue therapy. Median adherence to the medicines that prevent exacerbations leading to hospital admission is 36%. Drugs that are not taken are ineffective so that poor adherence leads to lives that are disrupted and shortened by avoidable hospital admissions for expensive, risky rescue therapy. This CQUIN aims to support changes in clinician and patient behaviour that will transform CF care from an emphasis on clinician led reactive hospital based rescue to patient led community based prevention. These changes will save money and free up hospital beds to manage increasing numbers of adults with CF within the existing bed stock whilst enhancing patient quality of life.  |
| **Change sought:***[Specify what change in behaviour is sought in general terms, with detailed specification set out in section C4****.]*** A £2.4 million NIHR programme has developed a digital information technology platform, CFHealthHub (CFHH), that automatically collects adherence data, makes that data available to people with CF and their clinical teams to create a learning health system that transforms CF care through behaviour change interventions that create clinician and patient activation and support system wide medicines optimisation. Health economic modelling suggests that implementing a learning health system supporting an improvement collaborative that moves the system from rescue to prevention could potentially save around £100 million over 5 years across all adults with CF.**CFHealthHub: a multicomponent programme in continuous use since 2015 providing tools and behaviour change to move CF care from hospital based rescue to community based self-care by empowering prevention**

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| **Programme component** | **Shortfall in quality** | **Intervention components / behaviour change** | **System metrics**  | **Efficiency Impact** |
| **Learning Health System / improvement collaborative** | Adult CF centres lack standardised data to evaluate performance and mechanisms to share learning for improvement. | CFHealthHub (CFHH) provides data for shared learning via system wide clinician portal supported by improvement coaching & community of practice. | Automated capture of centre level adherence data allowing benchmarking across system. | On-going iterative Improvement cycles with real time data feedback indicating impact of cycles on behaviours and outcomes. |
| **Clinician activation** | Clinicians lack knowledge, skills and self-efficacy to support patient activation and habits of self-care. | CFHH provides tools to train clinicians in supporting patients. Intensive behaviour change training for key staff then cascades across system via improvement collaborative. | CFHH data capture via click analytics allows benchmarking & drives system change. | Clinicians develop the skills to shift care from expensive hospital based rescue to patient led community prevention. |
| **Patient activation** | Patients lack knowledge, skills and self-efficacy to sustain self-care. Median medication adherence 36%. | CFHH supports patients in building knowledge / skills & self-efficacy. Data feedback linked to implementation plans and coping plans drives formation of benign habits. | Automated adherence data sent to patients’ phones with behavioural prompts. | Increased adherence to preventative therapy reduces need for rescue. System savings £100 million over 5 years. |
| **Medicines optimisation**  | Over a typical 12-month period 65% of the year’s drugs are delivered but only 36% are taken. There are major variations in high cost drug use between centres. | CFHH data allows just in time drug delivery preventing waste so that the amount delivered will more closely match the amount taken. Real time adherence will data support appropriate aztreonam use and reduce variation. | Adherence data allows rational drug use by supporting just in time drug delivery. | Significant savings to commissioners from avoiding high cost drug waste and ensuring that transition to high cost drugs appropriate. |

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| 1. **CONTRACT SPECIFIC INFORMATION** *(for completion locally, using guidance in sections C below)*
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| **B1.Provider** (see Section C1 for applicability rules) | *[Insert name of provider ]* |
| **B2. Provider Specific Duration.** What will be the first Year of Indicator for this provider, and how many years are covered by this contract? | 2019/20 One year |
| **B3.Indicator Target Payment** (see Section C3 for rules to determine target payment) | Full compliance with this CQUIN indicator should achieve payment of: 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 indicator, are set out in Section C4.Relevant provider-specific variation, if any, is set out in this table.*[Adjust table as required for this indicator – or delete if no provider-specific information is required.]*

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| **Provider specific triggers** | **2019/20** |
| **Trigger 1:** |  |
| **Trigger 2** |  |
| **Trigger 3:** |  |
| **Trigger 4** |  |
| **Trigger 5** |  |
| **Trigger 6** |  |

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| **B5. Information Requirements** |
| **Obligations under the indicator 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** |
| * **Central costs must be transferred early in the first quarter** to allow central functions (the data management and analytics feedback framework which supports quality improvement across the system and allows the CFHealthHub platform to respond to learning during implementation) to be delivered from the beginning of the financial year.[[1]](#footnote-1)
* Trusts will be invoiced by Sheffield in April 2019 for these payments, which relate to Trigger 1; commissioners should therefore release advance payment for Trigger 1 on 1st April 2019. THIS ADVANCE PAYMENT WOULD NOT CONSTITUTE CONFIRMATION THAT THE TRIGGER PAYMENT WAS EARNED; IF THE TRUST IS NOT COMPLIANT WITH TRIGGER 1, THIS PAYMENT COULD BE CLAWED BACK AT RECONCILIATION.
* For the other payment triggers, the default arrangement may apply: half payment of target CQUIN payment each month, reconciliation end of year depending upon achievement. *[Specify variation of this approach if required]*
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| **C. INDICATOR SPECIFICATION GUIDE: STEP CHANGE INDICATORS** |
| **C1. Providers to whom Applicable** |
| **Nature of Adoption Ambition*:***  | All participating Adult Cystic Fibrosis Centres in England. |
| **List of Providers for whom Indicator is Applicable**  | *\*HIGHEST PRIORITY**Royal Brompton & Harefield NHS Foundation Trust (RT3)**Leeds Teaching Hospitals NHS Trust (RR8)**\*University Hospital Southampton NHS Foundation Trust (RHM) \*The Newcastle upon Tyne Hospitals NHS Foundation Trust (RTD)Kings College Hospital NHS Foundation Trust (RJZ)\*University Hospitals Bristol NHS Foundation Trust (RA7)Birmingham NHS Foundation Trust (RRK) (including Heart of England)\*Barts Health NHS Trust (R1H)\*Nottingham University Hospitals NHS Trust (RX1)\*Oxford University Hospitals NHS Trust (RTH)Frimley Health NHS Foundation Trust (RDU)\*Royal Devon and Exeter NHS Foundation Trust (RH8)\*University Hospitals of Leicester NHS Trust (RWE)\*Norfolk and Norwich University Hospitals NHS Foundation Trust (RM1)\*Sheffield Teaching Hospitals NHS Foundation Trust (RHQ)\*Plymouth Hospitals NHS Trust( RK9)\*York Teaching Hospital (RCB) (also serving Hull)\*University Hospital of North Midlands (Stoke) (RJE)University Hospital Lewisham (RJ2)**Blackpool Teaching Hospital (RXL)**Liverpool Heart and Chest (RBQ)* |
| **C2. Provider Specific Parameters** |
| **The indicator 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.)** | CF Registry data will be used to identify the patients in the centre with chronic pseudomonas (paper in press).Centres will be supported to recruit 50 to 75% of patients with chronic pseudomonas to the CFHealthHub platform by the end of year 1. Individual centres will vary in existing treatment regimens and devices, so some centres may extend use of chipped devices to patients without chronic pseudomonas. As such the suggestion that 50% to 75% of patients with chronic pseudomonas will receive chipped devices is flexible but there will be an expectation that interventionists allocate all the chipped devices that are provided in the CQUIN. Unlike in the randomised controlled trial, patients who have hybrid regimens with a wet nebuliser and a dry powder eg E-track for Dnase and dry powder for tobramycin can be recruited. |
| **3. Calculating the Target Payment for a Provider**  |
| **The target overall payment for this indicator (the payment if the requirements of the indicator are fully met, to be set in Section B3 above) should be calculated for each provider, according to the following algorithm:** **Table 1 sets out the payments per provider.** **Table 1**

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|   |   | **Total CQUIN payment**  |
| **RT3** | Royal Brompton & Harefield  | **£793,940** |
| **RR8** | Leeds Teaching Hospitals NHS Trust | **£617,300** |
| **RHM** | University Hospital Southampton  | **£450,900** |
| **RTD** | The Newcastle Upon Tyne Hospitals  | **£566,100** |
| **RJZ** | King's College Hospital  | **£438,100** |
| **RA7** | University Hospitals Bristol  | **£540,500** |
| **R1H** | Barts Health  | **£297,800** |
| **RX1** | Nottingham University Hospitals  | **£438,100** |
| **RTH** | Oxford University Hospitals  | **£297,800** |
| **RDU** | Frimley Health  | **£334,920** |
| **RH8** | Royal Devon And Exeter  | **£228,100** |
| **RWE** | University Hospitals Leicester  | **£240,900** |
| **RM1** | Norfolk And Norwich University Hospitals  | **£217,860** |
| **RK9** | Plymouth Hospitals  | **£202,500** |
| **RCB** | York Teaching Hospital  | **£228 100** |
| **RRK** | University Hospitals Birmingham  | **£540,500** |
| **RJE** | University Hospital of North Midlands  | **£297,800** |
| **RJ2** | Lewisham and Greenwich | **£234,500** |
| **RBQ** | Liverpool Heart and Chest | **£604,500** |
| **RXL** | Blackpool Teaching Hospital  | **£240,900** |
| **RHQ** | Sheffield Teaching Hospitals - *lead site* | **£463,700** |

**See Section D3 for the justification of the targeted payment, including justification of the costing of the indicator, which will underpin the payment.** |
| **C4. Payment Triggers and Partial Achievement Rules** |
| **Payment Triggers****The interventions or achievements required for payment under this CQUIN indicator are as follows:**

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| **Descriptions** | **First Year of Indicator** |
| **Trigger 1:** | Trust will provide evidence * that the interventionist is in post
* that the medicines optimisation lead is in post from 1st October 2019 for 12 months
* that central costs have been transferred to Sheffield Teaching Hospital for onward allocation to the academic partners delivering data analytic and support for national improvement collaborative workstreams. ***These payments are as set out in section D3, Table 4 by centre size and role. Payments should be made within six weeks of receipt of invoice from Sheffield Teaching Hospitals NHS Trust.***

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| **Trigger 2** | Clinical trials unit co-ordination team will provide evidence that the Pharmacist is providing 1 day per week of medicines optimisation support and is engaging in a weekly medicines optimisation call facilitated by a medicines optimisation project lead working as part of the central delivery team over seen by the University of Sheffield clinical trials unit. This should take place from October 2019 to Sept 2020. |
| **Trigger 3** | Trust will provide evidence that Etracks needed to deliver CFHH are ordered via Pari; Trust will provide evidence that data transfer fees are paid to Pari. This will be monitored by clinical trials unit. |
| **Trigger 4** | The clinical trials unit will use CF registry data to identify patients with chronic pseudomonas and CFHealthHub data will demonstrate that 50 to 75% of these patients are on CFHealthHub. However where setting up the 50 to 75% of chronic pseudomonas patients is inappropriate due to dry powder and other device use; this will be identified by the centre screening log maintained by clinical trials unit. In that case the trigger will be that all allocated Etracks are provided to other CF patients. |
| **Trigger 5** | Click analytics available from CFHH and checked by clinical trials unit will demonstrate that the clinical team access CFHealthHub adherence data and prescription data for all monitored patients every 8 to 12 weeks. |
| **Trigger 6** | Creation of a protocol using CFHealthHub to support medicines optimisation that takes account of local circumstances. The aim is to minimise waste by just in time drug delivery guided by actual adherence data and strategies to support drug escalation to aztreonam and Levofloxacin that takes account of adherence. The embedded pharmacist will have provided medicine possession ratio data for CF patients in the centre and be supported by CFHealthHub team to develop a local medicines optimisation protocol, work on this to begin October 2019 for completion Q2 2020. This protocol should be low maintenance so that it can eventually be delivered within existing resources by the regular CF team. The protocol will be adapted to be suitable to be embedded within routine care over the final 4 months of the CQUIN. |

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| **Percentages of Target Payment per Payment Trigger****The following table sets out the proportion of the Target payment that is payable on achievement of each of the Payment Triggers.**

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| **Percentages of Target Payment per Trigger** | **Large Provider****(over 180 CF patients)** | **Medium Provider**  | **Small Provider** |
| **Trigger 1** | 70% | 60% | 50% |
| **Trigger 2** | 5% | 5% | 5% |
| **Trigger 3** | 5% | 5% | 5% |
| **Trigger 4** | 10% | 15% | 20% |
| **Trigger 5** | 5% | 10% | 15% |
| **Trigger 6** | 5% | 5% | 5% |
| **TOTAL** | 100% | 100% | 100% |

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| **Partial achievement rules****Year One****Trigger 1: all-or-nothing****Trigger 2: all-or-nothing****Trigger 3: strictly-proportional****Trigger 4: strictly-proportional:****75% patients 🡪 full payment****50% patients 🡪 two thirds payment****25% patients 🡪 one third payment****Trigger 5: strictly-proportional****Trigger 6: all-or-nothing****No payments for any trigger until Trigger 1 (parts 1 and 3) is met.** |
| **Definitions** |
| **C5. Information Flows: for benchmarking, for evaluation, and for reporting against the triggers.**  |
| **Reporting of Achievement against Triggers:** |
| Financial flows will be reported by Sheffield teaching hospitals and the University of Sheffield Clinical trials unit**.** The Clinical trials unit supporting the programme will monitor all targets in real time and remain in close contact with NHS England specialised commissioning, an approach that led to timely delivery of the programme in the first 3 years of the CF CQUIN.Employment and engagement of the interventionists will be monitored by Sheffield university clinical trials unit with the delivery of the interventions monitored by click analytics from CFHealthHub and reported by Sheffield University clinical trials unit.Set up of patients on E-tracks will be reported by Sheffield University clinical trials unit. |
| **Information for Benchmarking:** |
| Click analytics outputs from CFHealthHub demonstrating the use of adherence data by the clinical team will be provided by the clinical trials unit to allow centres to understand the extent to which adherence data is being used in consultations.Adherence levels in centres will also be provided; however it is recognised that the adherence metric is still in development and will not be sufficiently mature to definitively support benchmarking in 2019/2020 but will provide a metric that will support shared learning around variation in adherence rates between centres. Some of that learning will triangulate data with the CF registry and help centres to understand how effectively they are supporting their most difficult to reach patients.  |
| **Information Governance:** |
| All patients using CFHealthHub have signed consent forms that provide explicit consent to share pseudonymised CFHealthHub data at centre level and national level. London-Brent Research Ethics Committee reference 17-LO-0032 IRAS ID: 216782 Clinical Trials Gateway reference ISRCTN 14464661 All processes are GDPR compliant. |
| **Reporting Template requirement:** |
| **N/A** |
| **C6. Supporting Guidance and References** |
| **Further details on implementation, and references to documents that will support implementation:****N/A** |

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| **D. Indicator Justification and Evaluation** |
| **D1. Evidence and Rationale for Inclusion**  |
| **Recognition of the need for digital systems iteratively co-produced with patients and clinicians and implemented at scale**There is an emerging policy imperative seeking to drive the development and integration of digital systems at scale that optimise clinical care by creating integrated services that make care more efficient and more humane. In addition, there is recognition that patient activation in long term conditions reduces unscheduled care. CFHealthHub uses a digital platform to support both patient and clinician activation. Typically, such systems are developed in single centres and scale poorly across whole disease areas. Over the past 5 years the methodologists and researchers that make up the CFHealthHub group have worked with people with CF and their clinical teams to co-produce a digital platform CFHealthHub that moves CF care from clinician driven, resource intense hospital based rescue to patient led community based self-management enabled by behaviour change strategies that support the relevant knowledge skills and self-efficacy in both patients (patient activation) and clinicians (clinician activation) . The good news is that this work has the potential both to generate significant learning relevant to many long-term conditions and to save as much as £100 million in adults with CF over 5 years. The system has been in continuous use since 2015, has been implemented at scale and is currently in use in over 80% of CF units in England, Wales, Scotland and Northern Ireland.**Achievements to date and how the 2019 CQUIN will leverage those achievements for patient benefit and the wider NHS**It is important to make clear that this CQUIN builds on over £3 million in investment to date and that all the milestones and goals of a national programme have been achieved and this provides a unique opportunity to consolidate system wide success. The programme is running to time and target and the 2019 CQUIN builds on a programme that is appreciated by patients and clinicians and is an exemplar of the digital aspirations of the new 10 year NHS plan.Implementing innovations within the NHS is notoriously difficult. This programme has taken a strategic, sequential, cumulative approach involving co-production and capacity building in a multi-faceted programme. Notable milestones that have been achieved to date include;* 14 months of co-production of a patient facing platform available via mobiles and other platforms with patients driving the process and providing feedback to experts in mixed methods process evaluation independent of the clinical teams.
* Similar success over 18 months for clinician facing platform
* Extensive training of dedicated interventionists in 22 (80%) of UK adult CF centres. This training involved face to face training, pass/fail assessments, on-going taping of intervention delivery with fidelity testing and feedback all supported by weekly group calls to share expertise. The staff who have been trained provide the “boots on the ground” who will cascade the digital behaviour change programme to the rest of the staff in UK CF centres.
* This programme demonstrates successful introduction of a digital platform at scale in 80% of UK CF units with multiple improvement cycles leading to more than 100 software upgrades in response to clinician and patient feedback. The 2019 CQUIN will consolidate this success.

The programme is designed to shift CF care from clinician led reactive hospital based rescue to patient led community based prevention. This requires transformation in knowledge, skills and self-efficacy (clinician and patient activation) and this process has made startling progress over the past 24 months with objective measures of intervention delivery and fidelity showing continuous improvement. This evidence is available in transcripts and fidelity scores and measures of intervention delivery. In order for this expertise (that currently sits within a small group of trained staff) the next phase of the programme needs to provide the resource that will allow the trained interventionists to cascade training to the remainder of centre MDTs. This is what the 2019 CQUIN will achieve. It is following this next phase that profound changes in CF care will be expected. If the CQUIN is not made available the investment over the past years will not reach its potential and the savings will not be seen. To highlight the potential of the programme we start with a patient story.**A patient story in a CF unit without CFHealthHub**Jane turned up for an unscheduled clinic visit with her mum. This was unusual since as an independent 24-year-old Jane usually came to clinic alone. When the doctor entered the clinic room Jane was looking at the floor, her mum on the edge of her seat anxious and scared. Over the previous 12 weeks Jane had become increasingly breathless. After work she was exhausted and went straight to bed. She was losing weight and her lung function was down by 14%. The doctor took a brief history. Jane was using colomycin alternating with tobramycin and not quite sure how much she was taking. The doctor ordered a blood sugar series, sputum culture, chest x-ray and some bloods, admitted her to hospital for 14 days of intravenous antibiotics and swapped twice daily colomycin for three times daily aztreonam.**A Patient story in a centre with CFHealthHub** The graph below shows data which is available in real time to patients’ mobiles and to the clinical team in centres using CFHealthHub. 6 months before the clinic visit Jane had been taking 17 nebulisers a week, but in the 3 months leading up to clinic this had fallen to 5 per week.C:\Users\Zhe Hui\Documents\My documents\(3) ST4\Cystic Fibrosis\PhD stuff\2014 NIHR application\RDS presentation 131121\z context change decline.png*\*This is a composite patient story using illustrative data to maintain confidentiality***The power of real time data: patients at home no longer out of sight out of mind**Review of CFHealthHub data for all centre patients at the weekly team meeting in April identified Jane’s change in adherence to preventative therapy. Phone support to Jane followed by a home visit enabled problem solving and supported self-care. Adherence recovered. The crisis out-patient visit was avoided. There was no costly escalation from twice daily colomycin (circa £1.1K per annum) to thrice daily aztreonam (circa £12K per annum) no need for a 14-day hospital admission costing around £2.5K and no month of terror where Jane was sure that her CF had progressed and that her death might be approaching.**Why CF centres are being offered the CQUIN? What is the problem and how does CFHealthHub solve the problem?**Median adherence to preventative therapy in CF is around 35% resulting in increased hospital admissions for rescue therapy which is disruptive and hazardous. CFHealthHub is a system wide digital platform supporting a multi-component intervention targeting both patients and their clinic teams. Simply considering the 3000 adults with chronic pseudomonas CFHealthHub is expected to save around £49.5 million over 5 years. In order for these benefits to become available GDPR legislation requires that patients are consented to use CFHealthHub and system change requires that the necessary equipment is provided along with cascaded training so that units reach a tipping point where clinical care shifts from hospital-based rescue to community-based prevention. The CQUIN enables the creation of a CF wide improvement collaborative that will drive the necessary change that is already well advanced in the units already in the improvement collaborative (Southampton, Nottingham and Sheffield).**Evidence supporting intervention** • Median adherence to preventative therapy in people with CF (PWCF) is 36% (Daniels et al Chest 2011; 140:425–432). • When adherence to preventative therapy in PWCF is poor exacerbations increase along with health care costs which are predominantly driven by hospital admissions for rescue therapy (Quittner et al Chest 2014;146:142 -151). * Health economic modelling suggests that interventions in adults with CF that improve adherence have the potential to save £49.5 million in just the 2,979 adults with chronic pseudomonas over a 5-year period .Savings might be closer to £100 million if modelled across all 6000 adults with CF (Tappenden et al PharmacoEconomics 2017; 35:647–659).
* Patients who have the knowledge, skills and self-efficacy to self-manage and maintain self-management over time despite the challenge of changing circumstances have been shown to have better outcomes including a reduced need for unscheduled care (Kinney et al Patient Educ Couns 2015; 98:545-552.)
* Meta-analysis has demonstrated that feedback of adherence data alongside cognitive-educational components can increase adherence by around 20% (Demonceau et al Drugs 2013; 73:545–562).
* Habit is important to sustain self-care, with studies suggesting that habit may be a better predictor of long-term medication adherence than conscious motivational factors (Phillips et al J Behav Med 2016; 39:1076–1091).
* Studies among PWCF have shown that high adherers have higher habit scores than low adherers (Hoo et al Thorax 2018;[Epub ahead of print], Hoo et al Health Psychol Behav Med 2017;5:299–316)

 * Meta-analysis level data shows implementation plans to be effective in supporting behavioural enactment which is a building block of habit formation. (Gollwitzer, P. M., & Sheeran, P. (2006). Advances in Experimental Social Psychology, 38, 69)
* The Lind alliance identified that simplifying the burden of care was the first priority for people with CF. Since habits are automatic behaviours, this has the consequence that sustained behaviours driven by habit are associated with much less burden than behaviours driven by will power and attention (Lind Alliance Thorax 2017;0:1–3.doi:10.1136/thoraxjnl-2017-210473)

**How does the CF CQUIN deliver patient and clinician activation leading to sustained self-management that moves CF care from expensive and disruptive clinician led hospital-based rescue to patient led community-based prevention? Scheme characteristics*** This scheme uses CFHealthHub a digital platform successfully deployed across 80% of adult CF units to deliver a complex behavioural intervention that increases clinician activation, patient activation and adherence, thus delivering better patient outcomes and avoiding costly hospital admissions.
* CFHealthHub provides a patient facing dashboard co-produced with patients over 14 months and a clinician facing dashboard co-produced with clinicians within 3 centres over 18 months.

• CFHealthHub has now been in continuous use since 2015 and is presently in use in more than 80% of adult CF units in the UK(22 out the 27 ) , and is popular with both patients and clinical teams. * In addition to collecting adherence data the platform provides click analytics monitoring intervention delivery so that teams can be supported to focus on the components of the intervention that are known to be powerful such as the creation of implementation and coping plans.
* The CQUIN will allow implementation of this digitally supported improvement collaborative across adult CF units by supporting the staff that will recruit and consent patients and enable those staff to cascade training to the clinical team. The CQUIN will also provide sufficient equipment so that CFHealthHub data is available for the majority of patients ensuring that the system achieves tipping point and adherence support becomes embedded in usual care.

**Summary of the changes of behaviour that will occur within the CQUIN** 1) Change in the skills, tools and data available to clinical teams enabling them to target structured, evidence-based interventions to support patient activation that in turn supports adherence and self-management. 2) Change in the skills, tools and data available to patients enabling patients to create the habits and routines to support habitual sustained self-care resulting in improved adherence to preventative therapy and consequent fall in the need for expensive treatment escalation and hospital admission.**The CQUIN supports the creation of a digital learning health system that enables a community of practice to transform CF care via the following changes in practice:**1. Embedding the CFHealthHub digital platform across adult CF units making the capture of adherence data automatic and routine across all adult CF centres and at all clinical encounters. Clinician activation will achieve a tipping point ensuring that the system pays attention to prevention/patient activation in all clinics and consultations when most patients with chronic pseudomonas are active on CFHealthHub. Once this point is reached, clinicians have the system open and running in all meetings and seeing poor levels of adherence is a behavioural prompt that drives clinician activation.

2) Providing feedback of data to patients alongside structured behaviour change strategies including implementation and coping plans that will support behaviour change aimed at habit formation and sustained behaviour change.3) Providing unit level adherence data to allow units to start to benchmark across the whole system supporting sharing of good practice within an improvement collaborative with alternate week improvement calls and quarterly improvement collaborative meetings.**Real time objective adherence data for high cost inhaled therapies allows continuous medicines optimisation**1. Commissioning guidelines allow patients deteriorating on cheaper first inhaled therapies to be escalated to aztreonam and levofloxacin at £12k per patient per year. CFHealthHub provides objective adherence data to ensure treatment failure is not due to poor adherence
2. Medicine possession ratio for wet nebulisers is around 65% but time & date stamped data indicate that only around 35% of drugs are actually used. CFHealthHub can support the development of systems that harmonize drug delivery with actual drug use saving significant sums of money.

**Summary**• System change is notoriously difficult to achieve. • This CQUIN draws on a comprehensive programme pulling together experienced health services researchers, behavioural scientists, information technologists and improvement scientists to leverage a system wide digital platform that uses state of the art behavioural science linked to real time objective data capture and feedback to empower self-care in long term conditions by creating patient and clinician activation in terms of knowledge, skills and self-efficacy in delivering sustained prevention. • Potential savings of up to £100 million are possible with the counterfactual of non-adoption leading to inevitable cost increases and demoralisation. |
| **Rationale of Use of CQUIN incentive*** *the costs of the behaviour change, and the stretch involved beyond standard service quality, net of cost savings accruing to providers*

**CQUIN as an instrument is justified if net costs beyond normal service requirements are incurred by providers whilst benefits and cost savings accrue to patients and commissioners.**This CQUIN leverages £2.6 million of investment from NIHR that has brought together staff from six universities and has created a technology platform that has now been in use at scale since 2015. It builds on three previous years of CQUIN investment and will take the programme to a state where it will be sustainable by reaching an implementation tipping point. If a similar programme had been developed by a private sector technology company the costs to the NHS would have been much greater and on-going implementation would have extracted profit from the NHS. If the on-going CQUIN funding from 2019 is not available the three year CQUIN funding and five year NIHR funding will not leave a legacy and the potential to save £100 million will be lost.**The rationale of the CF CQUIN is to create a learning health system that moves CF care from rescue to prevention via behaviour change accompanied by key metrics that drive change and monitor progress**. **RCT evidence demonstrates that adequate prevention prevents the need for rescue but that median use of prevention is only 36%**. The CQUIN incentive funds1. The CFHealthHub platform that automatically collects data that provides date and time stamped data indicating the extent to which patients are reaching target levels of preventative therapy. If these targets are met RCT evidence tells us that exacerbation rates will fall, quality of life and lung function will improve (Ryan et al Cochrane Database Syst Rev 2011;3:CD001021 , Wark & McDonald Cochrane Database Syst Rev 2009;2:CD001506 3 Yang et al Cochrane Database Syst Rev 2016;4:CD001127).
2. CFHealthHub programmers working at Farr University of Manchester who will ensure that the metrics required by centres are made available initially as bespoke reports and subsequently as routine system-wide menus within CFHealthHub
3. The central expertise within the national programme team to provide training for a behaviour change lead in each centre to embed CFHealthHub and drive the learning health system and weekly system-wide support to create a community of practice across all adult centres.
4. Salary for the behaviour change lead to ensure that they have the protected time to build capacity, habits and routine in the local system so that when the posts finish in 2021, expertise around prevention is embedded in routine care.
5. Medicines optimisation programme that develops modules within CFHealthHub to support medicines optimisation in individual centres and develops the local expertise to make medicines optimisation part of routine care.
* *the benefits accruing to patients*

**Enduring benefits accruing to patients*** CFHealthHub is projected to support patients in moving from hospital led rescue to patient led community self-care with a consequent reduction in the number exacerbations requiring intravenous antibiotic courses used per year by an average of 50% per patient (Tappenden et al PharmacoEconomics 2017;35:647-659) Intravenous antibiotics are disruptive, hence this is a major benefit to patients by avoiding disruption to work, education and family life. The reduction of exacerbations is an important benefit to patients since exacerbations accelerate lung function decline which reduces quality of life and survival. (Bhatt Eur Respir Rev 2013;22:205-216)
* CFHealthHub is projected both to save money and to deliver lifetime 0.19 QALYs increase per patient (Tappenden et al PharmacoEconomics 2017;35:647-659) )
* *cost-savings accruing to commissioners (NHS E, CCGs, other]*

**Enduring whole-system savings*** For the 3,000 adult patients with chronic pseudomonas, CFHealthHub is projected to deliver enduring whole system savings of:
	+ £8.7 million per annum (approx. £2,900 per patient)
	+ 25,000 bed days per annum

**Enduring benefits to commissioners*** Quantitative enduring benefits:
	+ Patient and clinician activation creating savings to providers by switching care from rescue to prevention: It is feasible that a proportion[[2]](#footnote-2) of the projected £10.6m in annual enduring savings arising from reduced hospitalisations might eventually inform a reworking of the tariff to allow some of the savings to reach commissioners.
	+ Medicines optimisation: £2.1m per annum. This comes from savings in the high cost inhaled therapies otherwise delivered to patients who are adhering poorly.
	+ Intelligent commissioning supporting medicines optimisation: potential enduring savings related to optimising escalation to new generation inhaled antibiotics run to the hundreds of thousands per annum. Further research is required to quantify these savings.

**Table 2**

|  |
| --- |
| **Long-term enduring benefits for the 3,000 patients with chronic pseudomonas** |
|  | **Whole system** | **Commissioners** | **Providers** |
| **Financial Impacts** |
| CFHealthHub | -£1.0m | £0 | -£1.0m |
| Additional inhaled drug costs [3] | -£3.0m | -£3.0m | £0 |
| Reduced hospitalisations (patient and clinician activation) | £10.6m | £0 | £10.6m |
| Medicines optimisation | £2.1m | £2.1m | £0 |
| Intelligent commissioning [4] | *Further research required* |
| *Tariff band change [5]* |  | *£4.3m* | *-£4.3m* |
|  |  |
| **Annual enduring net savings** | **> £8.7m** | **> £3.4m** | **£5.3m** |
| **Long run impact (as tariffs adjust to lower costs) [6]** | **> £8.7m** | **> £8.7m** | **0** |

Notes1. This table has been based on 3,000 patients with chronic pseudomonas which is the closest round figure to the 2,979 patients considered in Tappenden et al PharmacoEconomics (2017) 35; 647-659 and offers a helpful approximation to the current number of English patients with chronic pseudomonas.
2. These potential enduring net savings may be exceeded in the long-run because of the increasing life expectancy of the UK CF population. The UK adult CF population will inevitably grow by a third within a decade. CFHealthHub builds the learning health system to mitigate the costs of this growth.
3. CFHealthHub is likely to deliver substantial savings without a corresponding increase in expenditure on high-cost drugs because while increased adherence equates to increased drug use, even with the 28% increase in national adherence considered to underpin the Tappenden health economic model the resultant new national adherence level of 61% would be below the current best estimate for the medicine possession ratio of 63%. See figure 1 below. The table assumes, that 60% of the increased utilisation is offset by the improve waste avoidance that the system facilitates.
4. Potential enduring savings run to the hundreds of thousands per annum. Further research is required to quantify these savings.
5. As patients increase their adherence they should move to a lower tariff band. The timing of this tariff band change will lag the other savings by a year, because it is based on annual reporting of data within the CF registry. Based on modelling by Tappenden, the average tariff band change is £1,421 per patient. This tariff shift might be expected to persist.
6. In due course, reduced costs to providers should feed through into reduced reference cost returns and reduced tariffs, freeing resources for commissioners.

*C:\Users\Dave\AppData\Local\Temp\ScreenClip.png***Figure 1 Medicines possession ratio and objective medication use** (adherence of 35% in figure 1 is the objective adherence rates measured by chipped devices)**Medicines optimisation**The medicine possession ratio for high cost inhaled therapy in adults in the UK is reported as 63% (White et al Eur Respir J 2017; 49: 1600987) whereas actual objectively measured adherence is reported as 36% (Daniels et al CHEST 2011; 140(2):425–432). As homecare companies deliver a greater proportion of medicines there is the possibility of waste. CFHealthHub will develop modules to support the use of time and date stamped drug use data to guide homecare deliveries so that the MPR approaches actual use thus avoiding waste. This CFHealthHub functionality will also support patients in the Lind alliance survey priority of simplifying the administration of medications to ensure just in time availability.Based on initial analysis with CF pharmacists participating in the data observatory, the annual enduring saving is modelled at £708 per patient.**Adherence data supporting intelligent commissioning around new generation antibiotics**New generation inhaled antibiotics (Aztreonam and Levofloxacin) cost in the region of £12K per patient per year whereas colomycin costs in the region of £1.1K per annum. Specialised commissioning guidance suggests that patients should only escalate to the more expensive new generation inhaled antibiotics if patients cannot tolerate the first line antibiotics or are deteriorating. However, given that median adherence to inhaled antibiotics is in the region of 36%, a significant amount of treatment failure is likely to result from non-adherence. In the context of non-adherence, escalation from a twice daily £2k per annum drug to a more complex thrice daily regime with £12k per year drug is unlikely to deliver patient benefit. Reducing inappropriate variation in the use of high cost third and fourth line medication might save hundreds of thousands per annum. CFHealthHub can automatically provide adherence data to support escalation decisions. Aztreonam was introduced into the UK in January 2015 and the annual spend in England in 2016/17 was in the region of £5.5 million which probably represents an additional cost of £3 million per year resulting from aztreonam replacing the cheaper alternatives. If adherence is invisible, it is impossible to be sure how often escalation might be avoided by adherence support for the cheaper regimen.**Timing of savings**In 2019-20 the medicines optimisation work will be focused on developing simple protocols that can be delivered as part of routine care once the development phase carried out in the CQUIN is completed.**Table 3: Example showing the potential progression of savings for a centre of 150 patients with CF of whom 60 are patients with Chronic Psuedomonas****The 2022-23 savings represent the *enduring* annual savings.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|   |  **2019-20**  |  **2020-21**  |  **2021-22**  |  **2022-23**  |
|   | **31/03/2020** | **31/03/2021** | **31/03/2022** | **31/03/2023** |
|   |  **12m**  |  **12m**  |  **12m**  |  **12m**  |
|  |  |  |  |  |
|  **Whole System Financial Impacts**  |
|  **Annual savings**  | **-130,372**  | **129,986**  | **176,052**  | **176,052**  |
|  **Bed days saved**  | **128**  | **357**  | **510**  | **510**  |
|  |  |  |  |  |
|  **Financial Impacts: Provider**  |
|  CFHealthHub  | -190,000  | -19,980  | -19,980  | -19,980  |
|  Tariff band change  | 0 | -21,315  | -59,682  | -85,260  |
|  Reduced hospitalisations  | 53,190  | 148,932  | 212,760  | 212,760  |
|  **Annual savings**  | **-136,810**  | **107,637**  | **133,098**  | **107,520**  |
|  |  |  |  |  |
|  **Financial Impacts: Commissioner**  |
|  Additional inhaled drug costs\*  | -14,802  | -41,446  | -59,208  | -59,208  |
|  Tariff band change  | -  | 21,315  | 59,682  | 85,260  |
|  Medicines optimisation  | 21,240  | 42,480  | 42,480  | 42,480  |
|  Intelligent commissioning  | -  | -  | -  | -  |
|  **Annual savings**  | **6,438**  | **22,349**  | **42,954**  | **68,532**  |

\* Arising from increased adherenceNotes – 1. As noted above, the timing of any tariff band change will lag the other savings by a year, because it is based on annual reporting of data within the CF registry and will occur if and when improvements in adherence reduce the need for hospital admissions for IVs that will reduce service pressures and create savings for providers in terms of bed days and drug costs.
2. For simplicity and consistency, we have only considered patients with Chronic Pseudomonas although other patients with CF would also be likely beneficiaries were they to use CFHH.
3. Savings are conservative. We have assumed a gradual realisation of savings since increased adherence may take a while to stabilise lung health. This is illustrated in graph below where medicines optimisation gains occur more quickly. The local 8a pharmacist is expected to create local protocols to embed recurrent savings by the end of 2019/20 CQUIN.
 |
| **D2. Indicator Duration and Exit Route** |
| **The appropriate duration of an indicator depends upon how long CQUIN support is required before the change in behaviour sought can be embedded in services specification or otherwise.**The exit route is that CFHealthHub will sustain the benefits for patients, providers and commissioners through the incorporation of a special purpose, independent not for profit legacy vehicle. This vehicle will ensure the continuation of the infrastructure required to deliver the CFHealthHub digital platform for system wide use. This is the approach identified by an options appraisal performed for NIHR and supported in principle by the CFHealthHub intellectual property holders who are working with the CFHealthHub principal investigator to achieve this exit route. The enduring savings to the provider (see table 3) support a revenue model for CFHealthHub whereby providers invest a modest proportion of those savings to sustain the system-wide infrastructure and data transfer while retaining the net savings. For 3,000 patients providers would retain £4.8m per annum[[3]](#footnote-3) after an investment of £1m per annum (approximately £333 per patient) to sustain CFHealthHub for their patients. It is important to set the £333 per patient per annum in context. A single patient escalated from tobramycin to aztreonam cost an additional £5000 per annum and a single admission for rescue intravenous antibiotics costs in the region of £3000. As is typical with platform business models, CFHealthHub experiences increasing returns to scale as the number of users increases. Increasing the number of patients for whom CFHealthHub is available not only scales the benefits and extends the learning, it increases the per patient return on investment. |
| **D3. Justification of Size of Target Payment** |
| **The evidence and assumptions upon which the target payment was based, so as to ensure payment of at least 150% of average costs (net of any savings or reimbursements under other mechanisms), is as follows:****Table 4 CQUIN investment per site**

|  |
| --- |
| **Per site CQUIN investment: NHS financial year ending 31/3/2020** |
| Number of years site has been in improvement collaborative by 2020 | **1** | **3** |
| Site category | **Small**  | **Medium**  | **Large** |
| Role |  |  |  | **Southampton/Nottingham**  | **Lead site** |
| eTrack data transfer expenses for existing CFHH patients |  £ 6,834  |  £ 11,716  |  £ 11,716  |  £ 26,361  |  £ 26,361  |
| Behaviour change specialist (Band 7) and co-ordinating roles |  £ 43,955  |  £ 54,944  |  £ 54,944  |  £ 54,944  |  £ 161,024  |
| Behaviour change specialist travel to patient homes |  £ 5,250  |  £ 7,250  |  £ 10,000  |  £ 10,000  |  £ 10,000  |
| Quality improvement travel and accommodation for behaviour change team |  £ 7,000  |  £ 9,000  |  £ 10,000  |  £ 10,000  |  £ 10,000  |
| Establishing local systems expertise in medicines optimisation (Band 8a Pharmacist or CF MDT member able to deliver medicines optimisation) |  £ 12,260  |  £ 12,260  |  £ 12,260  |  £ 12,260  |  £ 12,260  |
| ***Expenses to be invoiced under Trigger 1 for transfer to lead site for distribution to clinical trials unit and university of Manchester to deliver digital platform, evaluation and data to participating centres.*** |  ***£ 59,701***  |  ***£ 94,830***  |  ***£ 176,080***  |  ***£ 161,435***  |  ***£ 55,355*** |
| **Total per site CQUIN investment** |  **£ 135,000**  |  **£ 190,000**  |  **£ 275,000**  |  **£ 275,000**  |  **£ 275,000**  |

|  |  |  |
| --- | --- | --- |
| **Site category** | **Number of CF registry patients****(Registry data 2017)** | **Sites** |
| 1 | Under 115 | Cornwall/PlymouthExeterLeicesterNorfolkYork (including patients in Hull)LewishamManchester (for Blackpool) |
| 2 | 115 to 180 | BartsFrimleyOxfordUHNM (Stoke) |
| 3 | Above 180 | BirminghamBristolBromptonKingsLeedsNewcastleNottingham (in 3rd year of improvement collective)Southampton (in 3rd year of improvement collective)Sheffield (in 3rd year of improvement collective – lead site)Liverpool |

**Table 5 sets out the parameters that determine payments, which are set out provider by provider in Table 6.**

|  |  |
| --- | --- |
| **Table 5. CQUIN payment parameters** |  |
| Large centre estimated costs | £275,000 |
| Medium centre estimated costs | £190,000 |
| Small centre estimated costs | £135,000 |
| CQUIN premium  | 50% |
| E-track cost for one year\*(includes heads and data transfer) | £1,280 |

\*E-tracks have a warranty for two years. In year two and onwards costs would simply include data transfer at circa 144 euros per patient and any replacement heads that might be required. Patients on Vantobra, Aztreonam and Levofloxacin receive free heads bundled with the drugs.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|   |  **Table 6** |  Size of CF Centre | **CQUIN (A)** | **50% CQUIN premium (B)** | ***Number of Etracks needed*** | **Etrack costs** **(C)** | **Total CQUIN payment (A+B+C)** |
| **RT3** | Royal Brompton & Harefield  | Large | £275,000 | £137,500 | *298* | £381,440 | **£793,940** |
| **RR8** | Leeds Teaching Hospitals NHS Trust | Large | £275,000 | £137,500 | *160* | £204,800 | **£617,300** |
| **RHM** | University Hospital Southampton  | Large | £275,000 | £137,500 | *30* | £38,400 | **£450,900** |
| **RTD** | The Newcastle Upon Tyne Hospitals  | Large | £275,000 | £137,500 | *120* | £153,600 | **£566,100** |
| **RJZ** | King's College Hospital  | Large | £275,000 | £137,500 | *20* | £25,600 | **£438,100** |
| **RA7** | University Hospitals Bristol  | Large | £275,000 | £137,500 | *100* | £128,000 | **£540,500** |
| **R1H** | Barts Health  | Medium | £190,000 | £95,000 | *10* | £12,800 | **£297,800** |
| **RX1** | Nottingham University Hospitals  | Large | £275,000 | £137,500 | *20* | £25,600 | **£438,100** |
| **RTH** | Oxford University Hospitals  | Medium | £190,000 | £95,000 | *10* | £12,800 | **£297,800** |
| **RDU** | Frimley Health  | Medium | £190,000 | £95,000 | *39* | £49,920 | **£334,920** |
| **RH8** | Royal Devon And Exeter  | Small | £135,000 | £67,500 | *20* | £25,600 | **£228,100** |
| **RWE** | University Hospitals Leicester  | Small | £135,000 | £67,500 | *30* | £38,400 | **£240,900** |
| **RM1** | Norfolk And Norwich University Hospitals  | Small | £135,000 | £67,500 | *12* | £15,360 | **£217,860** |
| **RK9** | Plymouth Hospitals  | Small | £135,000 | £67,500 | *0* | £0 | **£202,500** |
| **RCB** | York Teaching Hospitals  | Small | £135,000 | £67,500 | *20* | £25,600 | **£228 100** |
| **RRK** | University Hospitals Birmingham  | Large | £275,000 | £137,500 | *100* | £128,000 | **£540,500** |
| **RJE** | University Hospital of North Midlands (Stoke) | Medium | £190,000 | £95,000 | *10* | £12,800 | **£297,800** |
| **RBQ** | Liverpool Heart and Chest  | Large  | £275,000 | £137,500 | *150* | £192,000 | **£604,500** |
| **RJ2** | Lewisham and Greenwich | Small | £135,000 | £67,500 | *25* | £32,000 | **£234,500** |
| **RXL** | Blackpool Teaching Hospital  | Small | £135,000 | £67,500 | *30* | £32,000 | **£240,900** |
| **RHQ** | Sheffield Teaching Hospitals - *lead site* | Large | £275,000 | £137,500 | *40* | £51,200 | **£463,700** |

 |
| **D4. Evaluation: Approach, data and resources** |
| **Evaluation Approach:** **Summary**Randomised Controlled Trial, mixed methods process evaluation and formal health economic evaluation reports late 2019. Involves 600 patients and 19 centres.On-going Learning health system evaluation reporting centre level and benchmarked system level metrics with process evaluation of system implementation. Currently includes 3 centres and around 400 patients and from 2019 will include up to 20 centres. Learning health system provides a constant flow of real time metrics to support evaluation. **Methods of evaluation**The CFHealthHub programme has been designed as a Learning health system in which metrics are continually collected to allow on-going evaluation, iteration and redesign for improvement. The metrics are fed back to the users of the system in a co-produced clinician facing dashboard and clinicians are then supported to reengineer service delivery via evidence based frameworks that support change intended to create improvement and then further on-going collection of metrics allowing participants to understand whether improvement has occurred. Patients receive data about adherence linked to behaviour change interventions around habit formation that allows evaluation to support them to improve habits of self-care. Generation of metrics is a key system attribute. The Microsystems approach to quality improvement supports system improvement in the light of evaluation and the COMB model and habit formation supports the behaviour change necessary to enable individuals within the system to change.It is important to bear in mind that since meta-analysis of randomised controlled trials have already demonstrated that the process of taking inhaled preventative therapy improves outcome metrics which measure adherence to inhaled preventative therapy become valid quality indicators and the system will continually provide these data thus generating real time evaluation ((Ryan et al Cochrane Database Syst Rev 2011;3:CD001021 , Wark & McDonald Cochrane Database Syst Rev 2009;2:CD001506 3 Yang et al Cochrane Database Syst Rev 2016;4:CD001127).  |
| **Information for Evaluation** | *[Information flows required for evaluation should be referenced here, building on those set out at C5]*CFHealthHub is a digital platform explicitly designed to collect metrics for evaluation that also support behaviour change in clinicians and patients. National Ethics approvals already exist allowing patients to share data for the purposes of evaluation with work planned to allow HES data linkage with appropriate consent in 2019/20. An important task of the local behaviour change specialist is to ensure appropriate patient consent for this routine data capture.Adherence to inhaled therapy is a metric routinely available within CFHealthHub. The adherence metric is also being used in the development of a UK national indicator via the NHS Digital Indicator Library process. Click analytics around key behaviour change processes of care such as the use of adherence data during clinic visits and the creation of implementation plans and coping plans by people with CF are routine outputs of CFHealthHub. |
| **Resources for Evaluation** | Personnel involved in evaluation include staff at University of Sheffield and University of Manchester and are costed with the CQUIN as the central costs involved in delivering the learning health system.  |

1. Central costs deliver digital platform expertise from the Centre for Health Informatics University of Manchester, behaviour change expertise from The Behavioural Sciences Consortium (Sheffield Hallam) and Improvement collaborative/ National Ethics /Trials support from the Clinical trials unit University of Sheffield. This technical support is necessary to enable system wide digital platform implementation, data sharing and improvement work. These partners have all vested intellectual property to the NHS and provide the expertise necessary for system wide digital innovation. [↑](#footnote-ref-1)
2. While in the short-run the savings from reduced hospitalisations accrue to the provider, In the long-run, as Table 3 shows, providers will receive enduring net savings after paying NHSE to enable CFHealthHub to exist (see Exit Route in D2 below). Bearing in mind the substantial whole-system savings and the prevailing split, there is the option for the commissioner to receive some of those benefits. [↑](#footnote-ref-2)
3. Bearing in mind the substantial whole-system savings and the prevailing split, there is the option for the commissioner to receive some of those benefits. [↑](#footnote-ref-3)