NICE advice

CFHealthHub for managing cystic fibrosis during the COVID-19 pandemic

Medtech innovation briefing
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Summary

- The **technology** described in this briefing is CFHealthHub. It is a digital platform to help adults with cystic fibrosis (CF) manage their condition and monitor their medicine use.
- The **innovative aspects** are that it allows remote access to monitor medicines adherence. This is done by analysing usage data that is recorded and transmitted by the 2 most widely used nebulisers. This allows people to attend virtual clinics and supports people with CF while they are shielding from COVID-19. CFHealthHub also includes educational and behaviour change tools to support people to increase their knowledge, skills and confidence when managing their own health and care (patient activation).

- The intended **place in therapy** would be at home, linking adults with CF to their clinical teams in specialist care, for continuous monitoring and remote regular review appointments.
- The **main points from the evidence** summarised in this briefing are from 1 randomised feasibility study and 2 economic studies including a total of 46 adults with CF in England. The economic studies report that CFHealthHub is cost effective compared with standard care in adults with CF. The feasibility study reported that a full-sized randomised controlled trial (RCT) was feasible. An RCT of 607 people with CF across 19 UK CF centres was completed in 2019 and results are expected to be published later in 2020.
- **Key uncertainties** around the evidence or technology are that the RCT of CFHealthHub has not yet been published and so there is currently no comparative evidence showing its effectiveness. CFHealthHub cannot currently monitor adherence to oral therapies.
- The **cost** negotiated by CFHealthHub for the eTrack nebulisers is £1,600 per unit (excluding VAT), plus an additional annual data transfer charge of £191 per patient. Currently there is no charge for CF centres to use the CFHealthHub digital platform. From April 2021 the intervention developers expect to charge CF centres around £200 to £300 per person with CF, per year. This is to cover platform running costs. The **resource impact** would be in addition to standard care. Savings could be made by improving medicine adherence. This may reduce medicine wastage (estimated by the intervention developer to save around £1,300 per year, per person with CF) and lower the risk of exacerbations that lead to hospitalisation.

The technology

The CFHealthHub (CFHH programme universities) is a multi-faceted intervention that was co-produced by people with cystic fibrosis (CF) and clinical teams in CF centres. This aimed to create a digital health learning system to change the behaviour of both people with CF and clinical teams. It is designed to support medicines adherence and uses behaviour change techniques to promote patient activation in adults with CF. The intervention also aims to improve the way that CF centres deliver care. It comprises:

- eTrack rapid nebuliser (PARI Pharma GmBH). These are eFlow nebulisers that include a sensor that records the time, date and duration of each nebuliser use. These data are encrypted and sent by Bluetooth to the 2net Hub (Qualcomm Life). This transmits the data on to the CFHealthHub server using 2G (data transfer for mobile devices). Each CFHealthHub user has 1 eTrack nebuliser. This is used to give all of their nebulised CF treatments.

- The online CFHealthHub server, a secure cloud-hosted server that is managed by Manchester University.

- CFHealthHub online portal and app. This can be accessed by clinicians and patients using computers, tablets, or smartphones. It presents real-time data from the eTrack nebulisers. This allows daily and weekly adherence to nebulised CF medicine to be viewed by patients and their clinical team. Users can add their body weight and home-spirometry measurements to CFHealthHub, and these can also be viewed by their clinical teams. Spirometers with open application programming interfaces (APIs) are being added to the CFHealthHub system to allow remote lung function monitoring with automated data upload. The app also has educational content and evidence-based behaviour change tools to support people with CF to develop self-care habits.

- CFHealthHub is part of a digital learning health system that continually captures data to inform clinical teams about the quality of CF care they provide. This data is reviewed at weekly meetings of clinical teams in 16 CF centres who analyse how CFHealthHub is used within those teams and to improve the way that they deliver care. This enables a community of practices in the 16 CF centres to support continual improvement of both care delivery and of the CFHealthHub platform itself.

CFHealthHub can also be used with I-neb nebulisers (Philips). Data are not automatically transferred from the I-neb but instead can be manually downloaded at clinic visits. However, future developments to I-neb may allow automatic data transfer. Data from the I-neb and eTrack nebulisers are displayed to clinical teams in the same format. People using the eTrack nebuliser can switch off data transfer if they do not want data to be shared with their clinical teams.

The platform has 3 main purposes. Firstly, to support behavioural change that will improve adherence to their recommended medicines and promote patient activation. Secondly, to help clinicians to support people with CF to build good self-care habits, by giving them accurate data on how well they follow their schedule of prescribed medicine. Thirdly, to allow CF centres to track use of medicines, and seek support if medicines adherence rates are lower than average for their centre.

Since the start of the COVID-19 pandemic, a digital consent system has been developed to allow people with CF to be given access to CFHealthHub remotely, while shielding from COVID-19. Modifications have been also been made to allow virtual clinics to take place. The portal is being regularly adapted by centres using the platform to support people with CF and clinical teams during COVID-19.

Innovations

CFHealthHub enables remote monitoring and virtual clinics for people with CF. This is critical for CF monitoring during the COVID-19 pandemic because people with CF are classed as extremely vulnerable and are advised to avoid any risk of exposure to COVID-19.

The CFHealthHub platform includes educational and behaviour change material to promote patient activation and help improve people's self-care. This material has been co-produced by people with CF and their clinical teams. It is designed specifically for CFHealthHub using evidence-based behaviour change techniques.

Of the 24 adult CF centres in England, 16 are already offering CFHealthHub. There are 2 further centres in the process of joining the service.

Current care pathway

People with CF are described by the UK government as being clinically extremely vulnerable to COVID-19. Initially, people who are clinically extremely vulnerable were strongly advised to stay at home as much as possible. Advice was to keep visits outside to a minimum and maintain strict social distancing.

People with CF should minimise face-to-face contact to reduce the risk of infection. For people who still need to attend face-to-face appointments, existing arrangements to prevent cross-infection should include measures relating to COVID-19. Many CF services have provided home-spirometry equipment to patients for home-monitoring during the COVID-19 pandemic, and have arranged home collection of airway culture samples while people with CF are shielding.

Adults with CF should be in the care of a multidisciplinary team and have comprehensive annual reviews as well as regular reviews every 3 to 6 months.

Some treatments for CF involve a nebuliser to convert liquid medicine to an aerosol, which is inhaled. People with CF should be offered a mucoactive agent, with rhDNase (dornase alfa; recombinant human deoxyribonuclease) as the first choice of mucoactive agent. rhDNase is taken using a nebuliser, usually once per day. Antibiotics such as flucloxacillin, which is given orally or intravenously, or colistin, aminoglycosides or aztreonam, which are nebulised and inhaled, can be given to treat infections. CFHealthHub does not currently monitor the use of oral therapies.

The following publications have been identified as relevant to this care pathway:

- UK government guidance on shielding and protecting people defined on medical grounds as extremely vulnerable from COVID-19
- NICE's COVID-19 rapid guideline on cystic fibrosis
- NICE guideline on cystic fibrosis: diagnosis and management
- NHS England's policy statement on cystic fibrosis modulator therapies
- NHS England news NHS patients among first in Europe to benefit from landmark deal for cystic fibrosis treatment
- National Library of Quality Indicators adherence to nebulised therapy in cystic fibrosis
- National Library of Quality Indicators normative adherence to nebulised therapy in cystic fibrosis for patients with chronic pseudomonas acquisition

Population, setting and intended user

CFHealthHub is intended for adults with CF and CF teams in the NHS. This could include respiratory medicine and CF consultants, CF specialist nurses, physiotherapists and dietitians. The CFHealthHub developers are working on modifications to the platform for people aged 13 and over to use it. This work is expected to finish in 2021.

Clinical teams are given training to use CFHealthHub, which is free of charge. Training is given using an online programme that involves 4 sessions lasting 2 hours each. These sessions include advanced behaviour change techniques for the relevant leads in each centre. There are weekly meetings between all CF centres using CFHealthHub, and these include training issues. One-to-one mentoring is available for people experiencing complex issues and for people who want more training. Training is led by a professor of behaviour

change and a specialised CF physiotherapist.

Costs

Technology costs

- eTrack rapid nebulisers are purchased by the CF service from PARI, at a negotiated cost of £1,600 per unit. This includes 12 months of data transfer costs and consumables. Each patient uses a single nebuliser unit for all their nebulised medicines, with interchangeable nebuliser heads that are specific for each medicine used. Each nebuliser unit is expected to last 5 years.
- Data transfer charge paid by each CF service to PARI is £191 per patient every year, from year 2.
- Access to CFHealthHub is a not-for-profit online platform that is currently free of charge. From April 2021, costs will be charged to services to cover running costs. This is estimated to be around £300 per patient every year, although costs will fall as more people start using the platform.

Costs of standard care

The resource impact would be in addition to standard care. Standard care involves using nebulisers to give mucoactive agents, as well as advanced molecular therapies. The standard care tariff for CF varies depending on the severity of the person's illness. The 2018/19 reference costs range from £4,288 to £52,855 per year (excluding CF transmembrane conductance regulator [CFTR] modulator therapies and nebulisers). Currently, eTRack and eFlow nebulisers are excluded from the tariff and are purchased by CF centres or by people with CF. I-neb nebulisers are provided free of charge to CF centres, and are paid for by NHS England.

Resource consequences

The charging structure means that the cost of CFHealthHub differs between the first year, which includes the capital costs for the eTrack nebulisers, and is lower in later years. From April 2021, the costs of running the platform will be added.

To use CFHealthHub each user needs an eTrack rapid nebuliser, at a one-off charge of £1,600 per unit. There is also a yearly data transfer fee to PARI which is £191 per year from year 2. CFHealthHub is currently free of charge but is expected to increase to £300 per year from April 2021. This results in ongoing costs of £0 per year in year 1 (£300 per year from April 2021) and £191 per year from year 2 onwards (£491 from April 2022). There will also be some resource costs in medical time taken to examine data on CFHealthHub.

The cost of current care includes a nebuliser, medicines and staff costs for regular consultations to monitor care. For adults, these are recommended every 3 to 6 months. The level of contact will be affected by the severity of the person's condition and involve multidisciplinary teams. The COVID-19 pandemic has prevented many regular reviews from taking place.

CFHealthHub could be cost saving if it reduces the time it takes for medical staff to monitor people with CF. There could also be cost savings from improvements in medicines adherence, both in improved outcomes (resulting in fewer hospital admissions and reduced use of rescue therapies) and reduced medicine waste. The intervention developer has estimated that CFHealthHub could lead to additional savings of around £1,300 per patient every year because of reducing medicine waste.

A preliminary economic analysis by Tappenden et al. (2017) included an economic model that used assumptions on the effectiveness of CFHealthHub. The analysis was done from an NHS perspective. It found that CFHealthHub was dominant, meaning it was both cost saving (£64,078 per patient) and improved quality-adjusted life years (by 0.19) over an average treatment lifetime. The costs savings resulted from improvements in medicines adherence and preventing CF symptoms from worsening. This led to reduced hospitalisations and rescue interventions.

Regulatory information

The eTrack controller was CE marked as a class II medical device in 2015. The 2net Hub is not classed as a medical device. The CFHealthHub digital platform is not in the remit for CE marking but complies with General Data Protection Regulations.

Equality considerations

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination

and fostering good relations between people with particular protected characteristics and others.

Patient-facing digital health technologies such as the CFHealthHub online portal and CFHealthHub apps may be unsuitable for people with visual or cognitive impairment, problems with manual dexterity or learning disabilities. Disability is a protected characteristic under the Equality Act.

Access to internet-enabled devices, access to the internet and user engagement with the technology may be more difficult for the people in deprived communities. Socioeconomic status is not a characteristic and so is not protected under the Equality Act 2010 but factors affecting access to care delivered using digital devices should be considered.

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the interim process and methods statement. This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

Published evidence

There are 3 studies summarised in this briefing, including a total of 46 patients.

These studies include 1 feasibility study for a randomised controlled trial (RCT) and 2 economic studies (1 published as an abstract only).

The clinical evidence and its strengths and limitations is summarised in the overall assessment of the evidence.

Overall assessment of the evidence

CFHealthHub was first launched in 2015 and is still at an early stage of evidence generation. This means there is limited published evidence showing its effectiveness. The only comparative effectiveness evidence is from a feasibility RCT, which was only powered to show the feasibility of a larger RCT and not to report clinical outcomes.

The full-scale RCT of 607 people with cystic fibrosis (CF) having usual care or CFHealthHub completed in 2019 and is expected to publish later in 2020. The setting and primary outcomes for this trial will be highly relevant to the NHS. They will include clinical outcomes around medicines adherence and the rates of exacerbations. The results of this RCT will also inform the economic modelling that has been done to examine the cost effectiveness of CFHealthHub, which has relied on assumptions about its effectiveness. Another study in preparation for publication in 2020 is an analysis of the cost savings associated with medicines optimisation using CFHealthHub. This study analyses the costs of 330 people with CF in 13 CF centres. This will help to support the model-based cost analyses by providing evidence of real-world costs saved.

Hind et al. 2019

Study size, design and location

A randomised feasibility study of 64 adults with CF in 2 CF centres in England. The aim was to see whether the full-scale RCT (due to publish later in 2020) was feasible.

Intervention and comparator(s)

There were 33 people randomised to have care using CFHealthHub and 31 randomised to have usual care, which was typically face-to-face reviews every 3 months. Each person in the control group used a nebuliser that recorded its use, but these data were not available to people in this group.

Key outcomes

Primary recruitment and retention were satisfactory. Over the 5-month study, no statistically significant differences in the rate of exacerbations was seen between groups. However, the study was not powered to detect these.

Strengths and limitations

There is limited reporting of user outcomes because this is a feasibility study for a larger RCT.

Tappenden et al. (2019)

Study size, design and location

A model-based cost utility analysis of the potential cost-effectiveness of CFHealthHub using a state-transition model.

Intervention and comparator(s)

CFHealthHub compared with costs of standard care.

Key outcomes

In the model, CFHealthHub was assumed to reduce the number of days that people with CF needed intravenous antibiotics to treat infections with *Pseudomonas aeruginosa*. It was assumed that CFHealthHub would reduce exacerbations by 1 per person every year, when each exacerbation needs 14 days of home or hospital intravenous antibiotic treatment.

The study concluded that if CFHealthHub is effective then it will produce an additional 0.19 quality-adjusted life years and cost savings of £64,000 per patient every year. Over 5 years this could generate costs savings of £49.5 million.

Strengths and limitations

This study uses assumptions about the effectiveness of CFHealthHub and so should be viewed with caution. The authors intend to update the model with the real effectiveness data from the ongoing RCT.

Sadler et al. (2016)

Study size, design and location

Conference abstract describing a model-based cost utility analysis.

Intervention and comparator(s)

CFHealthHub compared with standard care. The study used a Markov model from the

NICE technology appraisal guidance on colistimethate sodium and tobramycin dry powders for inhalation for treating pseudomonas lung infection in cystic fibrosis. The model was modified to estimate the incremental cost effectiveness of CFHealthHub. Sensitivity analyses were done to explore uncertainties in the assumptions about CFHealthHub, including its clinical effectiveness.

Key outcomes

All analyses showed that CFHealthHub would produce health gains and costs savings compared with standard care. Over 5 years, CFHealthHub was expected to generate cost savings of £17,852 per patient. This is equivalent to £106.5 million for the 5,864 adults with CF in the UK.

Strengths and limitations

Because this is a conference abstract, there is very limited reporting of the methodology used in the analysis. The sources for the clinical-effectiveness data in the modelling are not given.

Recent and ongoing studies

- A randomised controlled trial and parallel process evaluation to determine whether CFHealthHub, an intervention to help cystic fibrosis (CF) patients build better treatment habits, offers any benefit over usual care to adults with CF. ISRCTN55504164. Status: completed but not yet reported. Indication: CF. Device: CFHealthHub. Start date: Autumn 2017. Completed June 2019, publication of results expected 2020. Country: UK. Population: adults aged 16 and over with CF who use a nebuliser.
- CFHealthHub Data Observatory. ISRCTN14464661. Status: ongoing. Indication: CF. Device: CFHealthHub. Start date: January 2017. Expected end date: March 2025. Country: UK. Population: adults aged 16 and over with CF who use a nebuliser.

Expert comments

Comments on this technology were invited from clinical experts working in the field and relevant patient organisations. The comments received are individual opinions and do not

represent NICE's view.

All 4 experts were familiar with CFHealthHub and 2 use it in their centre.

Level of innovation

One of the experts found CFHealthHub to be highly innovative because it reports how well a person is taking their medicines to both the person and their clinical team. This helps discussion about improving how well people take their medicines and self-manage their cystic fibrosis (CF). Another expert noted that virtual monitoring of people with CF during the COVID-19 pandemic is now very common, but still described CFHealthHub as novel. One expert noted that while there are other apps and data collection systems on the market, CFHealthHub was the only system that works with both of the most commonly used nebulisers (I-neb and eTrack). Others need manual data input rather than automatic data collection. One expert stated that CFHealthHub was not a major innovation because using nebulisers that can monitor how well people take their medicines is not new. However, another expert noted that the optional linking of data to the patient's clinical team was novel. There were 2 experts who noted that the innovative aspect of CFHealthHub is the included behaviour change tools.

Potential patient impact

All 4 experts acknowledged that there is a lack of evidence to show the effectiveness of CFHealthHub. They noted that the results of the upcoming RCT will be essential to prove its effect. One of the experts noted that evidence is needed to prove that CFHealthHub improves medicines adherence and that this is linked to improvements in patient outcomes such as exacerbation rates.

All 4 experts noted that using CFHealthHub could offer benefits to patients. Of the experts, 3 stated that they would expect the benefits of CFHealthHub to be improving medicines adherence. Two experts added that CFHealthHub has improved clinical consultations by enabling discussions about this. One noted that patients often overestimate how well they stick to their medicine plans, and having an honest discussion about the data was helpful. An expert reflected that these discussions included how the patient may be struggling with the burden of treatment, how they fit treatment around their everyday activities, and how the CF team can support them in this. They noted that CFHealthHub may be particularly useful for people with CF who are transitioning from

paediatric to adult care and gradually taking over responsibility for their treatment from their parents.

An expert stated that while some people engage well with CFHealthHub (about 60% adults with CF in their centre), others have found it to be intimidating and have declined engaging with the system. The expert liked the fact that the patients are in control of this decision, rather than their clinical team, and patients could remove themselves from the system if they wish.

Potential system impact

Of the experts, 3 acknowledged that there is currently a lack of published evidence to support the claimed system benefits of CFHealthHub.

All 4 experts noted that (if proven effective) CFHealthHub may lead to system benefits. Benefits included reducing hospital admissions, reducing the need for intravenous antibiotic treatment, and reduced medicine waste. One expert was sceptical that these benefits would be realised in practice. Three experts considered that CFHealthHub would present an additional cost to standard care. One expert thought using CFHealthHub would be unlikely to need additional staffing and was likely to improve the way that medicines adherence was assessed.

General comments

One of the experts noted that the introduction of new CF transmembrane conductance regulator (CFTR) modulator therapies is changing the care landscape of CF. This means many people with CF may move away from having nebulised therapy. Two experts noted that there was currently a lack of evidence to correlate medicines adherence with improvements in longer-term patient outcomes. Another expert noted that some people with CF use dry powder inhalers instead of nebulised therapies, and so CFHealthHub would not automatically track these.

Expert commentators

The following clinicians contributed to this briefing:

- Professor Iolo Doull, consultant respiratory paediatrician, deputy medical director, Children's Hospital for Wales, Cardiff, Welsh Health Specialised Services. Did not declare any interests.
- Professor Martin Walshaw, consultant respiratory physician, Liverpool Heart and Chest Hospital. Did not declare any interests.
- Dr Stephen J Bourke, consultant physician, Newcastle Adult cystic fibrosis (CF) Centre, Royal Victoria Infirmary. Dr Bourke's CF centre contributed patients to the CFHealthHub randomised controlled trial and participates in the CFHealthHub data observatory. All centres that participated in these studies had CQUIN funding for their trust to fund an interventionist. No personal financial or other interests declared.
- Ms Nicola MacDuff, advanced clinical nurse specialist, Adult CF Service, Royal Wolverhampton NHS Trust. Ms MacDuff is working with Roche on a presentation for the digital European CF Society conference in September 2020. Ms MacDuff is also providing comments on patient information leaflets for Gilead.

Development of this briefing

This briefing was developed by NICE. The interim process and methods statement sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

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