

This is a repository copy of Implementing the use of objective medication adherence data in routine clinical practice via the digital CFHealthHub platform: situation analysis and strategy development using the theoretical domains framework.

White Rose Research Online URL for this paper: https://eprints.whiterose.ac.uk/178543/

Version: Submitted Version

Article:

Girling, C. orcid.org/0000-0003-4216-214X, Packham, A., Robinson, L. et al. (3 more authors) (Submitted: 2021) Implementing the use of objective medication adherence data in routine clinical practice via the digital CFHealthHub platform: situation analysis and strategy development using the theoretical domains framework. In Review. (Submitted)

10.21203/rs.3.rs-847358/v1

© 2021 The Authors. This work is licensed under a CC BY 4.0 License (https://creativecommons.org/licenses/by/4.0/).

Reuse

This article is distributed under the terms of the Creative Commons Attribution (CC BY) licence. This licence allows you to distribute, remix, tweak, and build upon the work, even commercially, as long as you credit the authors for the original work. More information and the full terms of the licence here: https://creativecommons.org/licenses/

Takedown

If you consider content in White Rose Research Online to be in breach of UK law, please notify us by emailing eprints@whiterose.ac.uk including the URL of the record and the reason for the withdrawal request.





Implementing the use of objective medication adherence data in routine clinical practice via the digital CFHealthHub platform: situation analysis and strategy development using the theoretical domains framework

Carla Girling (c.girling@sheffield.ac.uk)

The University of Sheffield Faculty of Medicine Dentistry and Health https://orcid.org/0000-0003-4216-

214X

Anna Packham

The University of Sheffield School of Health and Related Research

Louisa Robinson

The University of Sheffield School of Health and Related Research

Madelynne A Arden

Sheffield Hallam University

Daniel Hind

The University of Sheffield School of Health and Related Research

Martin J Wildman

Sheffield Teaching Hospitals NHS Foundation Trust

Research

Keywords: Cystic fibrosis, adherence, implementation, theoretical domains framework, intervention

Posted Date: September 7th, 2021

DOI: https://doi.org/10.21203/rs.3.rs-847358/v1

License: (a) This work is licensed under a Creative Commons Attribution 4.0 International License. Read Full License

Abstract

Background

Preventative inhaled treatments preserve lung function and reduce exacerbations in Cystic Fibrosis (CF). Self-reported adherence to these treatments is over-estimated. An online platform (CFHealthHub) has been developed with patients and clinicians to display real-time objective adherence data from dosecounting nebulisers, so that clinical teams can offer informed treatment support.

Methods

In this paper, we identify pre-implementation barriers to healthcare practitioners performing two key behaviours: accessing objective adherence data through the website CFHealthHub and discussing medication adherence with patients. We aimed to understand barriers during the pre-implementation phase, so that appropriate strategy could be developed for the scale up of implementing objective adherence data in 19 CF centres.

Thirteen semi-structured interviews were conducted with healthcare practitioners working in three UK CF centres. Qualitative data were coded using the Theoretical Domains Framework (TDF), which describes 14 validated domains to implementation behaviour change.

Results

Analysis indicated that an implementation strategy should address all 14 domains of the TDF to successfully support implementation. Participants did not report routines or habits for using objective adherence data in clinical care. Examples of salient barriers included skills, beliefs in consequences, and social influence and professional roles. The results also affirmed a requirement to address organisational barriers. Relevant behaviour change techniques were selected to develop implementation strategy modules using the behaviour change wheel approach to intervention development.

Conclusions

This paper demonstrates the value of applying the TDF at pre-implementation, to understand context and to support the development of a situationally relevant implementation strategy.

Contribution to the literature

• Research indicates that the implementation of healthcare innovations may be more likely to succeed when context and theory are taken into consideration.

• In this study, healthcare professionals identified barriers to two behaviours that were key to the implementation of a national Cystic Fibrosis (CF) healthcare innovation. By coding barriers to the Theoretical Domains Framework (TDF), a contextually relevant implementation strategy was developed, with a focus on clinician behaviour change.

• The study highlights the challenges CF teams face when implementing new remote monitoring of medication adherence, and provides an important opportunity to apply the TDF in the pre-implementation phase of a healthcare innovation.

Background

Cystic Fibrosis (CF) is a long-term condition affecting 10,000 people in the UK. Although survival in the UK is rising, people with cystic fibrosis (PWCF) typically die from lung damage at a median age of 47[1]. Preventative inhaled treatments preserve lung function by reducing infections [2-9]. Low adherence to these treatments is associated with exacerbations and decreases in lung function [10-15]. Despite the benefits of treatment, objectively-measured adherence to preventative inhaled treatments is between 30 to 50%[16, 17]. Subjective self-report measurements – the norm in routine practice – substantially overestimate adherence rates [16]. As a result, low adherence is largely invisible to care teams, who are therefore unable to provide appropriate support to those who need it.

Without access to objective adherence data for inhaled medications it is difficult for clinicians to identify whether a patient is deteriorating due to non-adherence or due to novel pathology which requires a change of treatment. To meet this challenge, we have worked with PWCF and healthcare practitioners to co-produce an online platform (CFHealthHub). CFHealthHub displays real time objective adherence data from dose counting nebulisers[18–21], allowing remote real time monitoring of patient adherence. A national implementation exercise is now underway, supported by NHS England commissioning for quality and innovation, in which objective adherence data will be embedded into routine CF care. In the first phase of this work, we have created a digital learning health system - a cohort study with research, implementation and quality improvement functions – in three UK CF centres (ISRCTN14464661).

Many innovations successful in a single centre or trial fail to be adopted across healthcare organisations[25], particularly when the innovation is not adapted to the specific context [26] in different units. As such, implementation programmes need to identify the factors that influence the performance of the key behaviours that enable implementation, situated within the context of the target healthcare provider. An understanding of the interactions between context and behaviour, used in combination with theory, has the potential to optimise implementation strategy development [27–31].

Identifying the most appropriate theory for a given behaviour and context is challenging and choosing one theory over another may result in key determinants of behaviour being missed [32]. The Theoretical Domains Framework (TDF) [23, 33, 34] is a synthesis of 33 different behaviour change theories, with 14 key domains that influence an individual's Capability, Opportunity and Motivation to perform a Behaviour (the COM-B model [35, 36]). To implement the use of objective adherence data in routine practice, clinical teams need to be able to perform two key behaviours #1) to routinely view patient's objective adherence data and #2) discuss objective adherence with the patient. These behaviours might be expected to be sustained long term if they become established in local routines, with the hope that they become habitual [37]. By identifying barriers and facilitators to performing the behaviours, through the identification of TDF domains, linked to COM-B, potential reasons for implementation failure can be anticipated, understood, and addressed in advance.

The behaviour change wheel (BCW) is a tool to enable the design of interventions using a systematic approach that is underpinned by the COM-B model. Here, we report a detailed situation analysis[38], which used the TDF to identify potential pre-implementation barriers and facilitators of the desirable behaviours and inform the development of an implementation strategy using the BCW [36, 39].

Methods Study Design

This was a qualitative study using semi-structured interview data.

Settings and participants

Participants (n=13) were healthcare practitioners from three participating CF centres, sampled from a combined multi-disciplinary team (MDT) of 125. A further seven healthcare practitioners were approached but were unable to participate due to time restrictions. At the time of this evaluation (April to August 2018), one centre had been involved in the development of CFHealthHub over 12 months and then started to use it in clinical practice and two of the three CF centres had taken part in a pilot trial of CFHealthHub as part of which one member of the MDT has been trained to use the CFHealthHub website and to deliver the intervention. All sites were therefore within the early stages of implementation. The CF population for the centres covered large geographical areas, across multiple counties. Each centre supported between 175 to 250 PWCF, at the time of the study.

We purposively sampled from the MDT based on centre and professional category (Table 2). Recruitment continued until the researchers determined that data saturation had been met, as defined by 'informational redundancy' [40], whereby no new comments were identified in the interviews.

Procedure

The study team contacted healthcare practitioners by email. All participants gave informed consent prior to the interview. Interviewers (CG, AP and DH) were known to three participants through wider project work but were not from the same institution. The interview topic guide (additional file 1) was based upon TDF constructs [39] focusing on the behaviour of accessing adherence data through CFHealthHub (#1) and discussing adherence with patients as part of routine practice (#2). Not all questions were relevant to all participants; for example, at the time of the interviews the use of data to benchmark quality of care between centres was not yet available to all members of the clinical team The interview guide was developed by investigators with expertise in behaviour change (MA) and Cystic Fibrosis (MW) and piloted

by one clinical member of staff. Interviews were conducted face to face or via a telephone. The duration of interviews was between 17 and 55 (mean 37) minutes. All interviews were digitally recorded and transcribed verbatim and imported into Nvivo 12 (QSR International).

Analysis

Transcripts were analysed using Framework analysis [41] based on the TDF. Two researchers doublecoded each interview; where fragments were coded to more than one domain these were cross-indexed. Researchers met regularly to discuss coding, data saturation and reach consensus on discrepancies.

Implementation strategy development

Based on the findings of the framework analysis, members of the team, including a respiratory physician (MW) and health psychologists (MA) developed an implementation strategy using the Behaviour Change Wheel (BCW) approach [36]. Firstly, a behavioural needs analysis was completed for the behaviours of routinely accessing objective adherence data (#1) and discussing adherence (#2) (table 1). Interview data, mapped to TDF domains, were used to perform a behavioural diagnosis for behaviour #1 and #2, allowing the researchers to identify what needs to change in order for the behaviours to be routinely performed. From here, intervention functions were identified. Intervention functions are broad categories, linked to the COM-B model. Within each intervention function there are multiple possible Behaviour Change Techniques (BCTs). To ensure context-based decisions on intervention content and delivery, the APEASE guidelines were applied to each of the nine potential intervention functions, specified in the BWC. This allowed the researchers to evaluate functions for affordability, practicality, effectiveness, acceptability, side effects/safety and equity. Having identified the barriers and relevant intervention functions, behaviour change techniques (BCTs) were selected. These are displayed as implementation 'strategy' modules.

Ethics

After review from the study's Patient and Public Involvement group, ethical approval was obtained from London-Brent Research Ethics Committee (ref 17/L0/0032).

Results

We present a summary of data by theoretical domains, ordered by the umbrella concepts, capability opportunity and motivation (Table 3) before discussing the development of the implementation strategy. We have combined the data for the two behaviours of focus.

Domains related to capability

Overall, participants had some **knowledge** of the concept of nebuliser adherence, both in relation to the challenges of nebuliser adherence and the impact on lung health. The disparity between subjectively reported and objectively measured adherence was also frequently reported. By comparison, **knowledge** about CFHealthHub was variable between centres and healthcare practitioners; some consultants were unaware of patient facing CFHealthHub content but were aware that the platform displays adherence data. The most engaged participants demonstrated a more insightful understanding, describing patient-specific content and its use for both patients and healthcare practitioners:

"...so it's a monitoring tool I'd say as well as supportive tool for adherence" (S01F04).

Most participants reported no formal training in using CFHealthHub, or in how to discuss adherence with PWCF. Participants used **skills** from their professional training when discussing adherence with patients:

"...I do it, I suppose in my own counselling type way..." (S01F01).

Furthermore, skills and training influenced participants' willingness to discuss adherence. Participants with backgrounds in counselling and training in motivational interviewing reported this as a facilitator for discussing adherence. Participants reported remembering (**memory**), paying **attention** and **decision processes** in using adherence data as effortful. Discussing adherence with a PWCF was only done when prompted by conversations with PWCF in clinic appointments, for example during changes in prescribed medication. Even when adherence was remembered, participants did not necessarily access the objective data from CFHealthHub. No one reported formal **behavioural regulation** strategies to ensure adherence was discussed with PWCF. Where CFHealthHub was accessed as a team, this was during MDT meetings and was driven by specific individuals (see opportunity).

Domains related to opportunity

TDF domains relating to both **physical** and **social opportunity** featured prominently in the sample. Participants described the physical barriers relevant to their centre's **environment**, such as the availability of clinic rooms in which to deliver adherence support. Access to computers and the internet also impeded the ability to open the objective adherence data on CFHealthHub. All participants described time as being a significant barrier for talking to PWCF about medication adherence (#2) and opening the objective adherence data at meetings or with colleagues (#1):

"...meetings are quite quick and then there are other things that we need to talk about and we don't necessarily have time to factor in the adherence in it in a detailed way". (S01F02)

Participants thought that physiotherapists and nurses had more contact time with patients than consultants, and therefore had more time to use CFHealthHub (links to professional role).

In addition, all centres reported that limited staff capacity, particularly during the winter months, was a barrier to both behaviours. However, participants did note that CFHealthHub would make accessing adherence data easier than previous systems[1]. At least one influential figure, or "CFHealthHub Champion" from each centre was identified. A factor that appeared to be associated with **social influences** was how passionate the individual was about CFHealthHub. Participants also felt that doctors and consultants had the most influence in centres and were an important factor in the adoption of adherence data into practice. Some participants reported feeling that they were not individually able to implement change in their centre; they believed change would require team effort.

Domains related to motivation

Professional role featured heavily as a theme in determining who accessed CFHealthHub and which individuals in a centre provided adherence support to patients. Those who reported they did access the objective adherence data on CFHealthHub and have adherence discussions did so because *"it is part of my job isn't it?"* (*S03F01*). Each team reported an individual as being responsible for opening adherence data. This meant that the behaviour of opening adherence data fell down when the individual was unavailable *"We planned having it in every MDT meeting, … we feel slightly guilty when [name] isn't here 'cause she's the one who usually sets that for us" (S01F02).*

Participants reported the **goal** that CFHealthHub would be used routinely in MDT meetings, but had varying levels of **intentions** to use CFHealthHub. Physiotherapists reported that they intended to access adherence, whereas Consultants generally stated they might access adherence data themselves or through a colleague. However, Consultants report that they did not have intentions of performing the second behaviour of delivering adherence support.

"I don't think I use it with patients, cause I don't think I have the time to sit and use it with patients; plus it's mainly delivered probably by the physios (yeah) at the moment in our service, or [name] might be working with one or two. So, because that you already know that they're doing with it, I'll talk about their adherence, but I'm not gonna, I don't sit down with (and open it up)" (S01F05).

Participants discussed a range of **beliefs about** the power of adherence data and CFHealthHub and the **consequences** of using these tools. Although these was a consensus that using CFHealthHub and discussing adherence could improve patient care and could increase adherence, participants felt this would be limited to certain groups of patients or that they would see small incremental changes "...*If you get people who are at 30% up to 40% that's good and if you get people who are at 55% up to 65% that's good and that's where I think the benefit's going to be" (S02F03).* In addition, healthcare practitioners believed that adherence data would not be helpful for patients with complicated home lives. The circumstances and their willingness to engage with adherence were also reported as barriers to supporting adherence, suggesting that they were reluctant to discuss this with everyone.

"I suppose both depending on what sort of place they're in at that time, how their mood is... Some people we're building relationships with when they first come to us and we don't want to be heavy..." (S01F01)

Some participants perceived negative **consequences**. These participants were concerned objective adherence data could become a tool for "telling off" patients. This belief was influenced by the knowledge that that the clinical team hadn't received adequate training in accessing and using adherence data. This was thought to impact on the **capability** of the team to use the data in a positive, patient centred way.

"... I think without the right training and support with the team is that actually it could then be used in a negative way with the patient. So actually as a tool to tell patients off ..." (S03F01).

Participants received some **reinforcement** for using CFHealthHub. Viewing improvement in patient's adherence was felt to be rewarding. Participants also reported positive **emotions** when seeing improvements in PWCF adherence.

[insert table 3]

Implementation strategy development

All 14 domains were relevant to routinely access objective adherence data (#1); six were relevant to discussing adherence with patients (#2) (Table 4 and 5). Intervention functions defined in the BCW were considered in relation to the behavioural needs assessment (Table 1) and reported barriers (Table 4 and 5). Discussions around the implementation intervention considered the needs of different professional roles, with the reported barriers to performing each of the behaviours. The intervention functions were evaluated using the APEASE guidelines, which led to the rejection of three intervention functions, as likely to be impractical (restriction), ineffective (incentivisation) or unacceptable (coercion), see table 6 for specific reasoning. Table 7 provides more detail on the selected proposed intervention functions that would go on to help identify suitable BCTs. Six intervention functions were selected by the researchers as suitable (training, education, environmental restructuring, enablement, modelling and persuasion), based on the needs assessment (Table 1). The intervention functions were further defined, leading to the selection of 31 specific functions for routinely accessing objective adherence data (#1) and 12 for discussing adherence (#2) (Table 7). Each BCT was discussed in relation to the two behaviours and identified barriers. This led to the identification of BCTs that the researchers deemed useful. The practicality, resources and expertise from the central study team were also considered when selecting and grouping the BCTs into potential implementation modules (Tables 8 and 9).

Implementation strategy modules

Tables 8 (#1) and 9 (#2) demonstrate how intervention functions, identified from barriers reported in interview data, link to proposed BCTs. On this basis, we have put together the following modules:

Educational/Training package

(#1) To address the varied training and education barriers to routinely using objective adherence data, a face to face and online educational training package would be provided, with the aim to provide practical support, such as instructions on how to perform the behaviours and information about others approval of the behaviour, for example local endorsement by members of the clinical team. As participants reported a varied understanding of the relevance of objective adherence data to CF care, the training package would focus on presenting information about the consequences of non-adherence for the PWCF and the relevant impact on the clinical team. To address social influence barriers such as lack of senior management support, it is important that a Consultant Physician provides demonstrations of the behaviour during these sessions and endorses accessing adherence data (#1), alongside credible sources of information and the opportunity to rehearse the behaviours.

(#2) The same module principals should be applied, however focused on delivering non-judgemental conversations and behaviour change techniques, as described in CFHealthHub intervention development [42, 43].

Quality Improvement Cycles

(#1) Quality improvement (QI) methods were identified as a potential strategy to address centre specific barriers and provide feedback on the frequency of the performance of the behaviours at an individual and centre level. QI can be used to perform a number of BCTs (see table 8) and is adaptable to individual centre context [44]. The implementation will use The Dartmouth Institute QI methodology, allowing the BCT problem solving, through process mapping and Plan Do Study Act (PDSA) cycles. These techniques will allow small behavioural experiments for change to be implemented, measured (providing feedback) and revised as required. As well as supporting centres to address environmental issues and improving the efficiency of the team, this strategy could be used to address specific concerns. For example, where the belief in prescription accuracy is a barrier, then the team would use quality improvement PDSA cycles to address their centre prescription processes and integrate updating CFHealthHub prescriptions that drive adherence data accuracy, into current practices. QI should be data driven [45, 46] to provide measurable feedback. To overcome the lack of behavioural regulation, healthcare practitioners should be given feedback on their own performance of behaviour #1 through frequency of website clicks into objective adherence data, collected as part of PDSA cycles.

(#2) Relevant CFHealthHub page clicks should be fed back to healthcare practitioners delivering adherence discussions. Barriers identified such as clinic space and time can be addressed through QI cycles, in the way described for #1.

Cystic Fibrosis Improvement Collaborative as an improvement support module

Creating an improvement collaborative would link CF centres into a community of practice and provide a platform for sharing past successes and learning from across the CF healthcare system that can solve

implementation barriers using ideas that have worked elsewhere. For example, interview data indicated that there were barriers to lack of support across senior management and colleagues (#1 and #2). Participants also reported concerns that adherence support (#2) was only suitable for PWCF without complicated home lives, and this belief hindered healthcare professional's motivation to discuss adherence. Taking these issues to the collaborative for consideration, would allow information about what others think of the behaviour, including how PWCF perceive their care teams using their data (#1) and supporting adherence (#2) to be provided. This would also enable healthcare practitioners to view both behaviours being performed.

Planning, Routine and Habits

(#1) Lack of routine and habit was reported by all centres and as such made performing both behaviours effortful and unreliable. Healthcare practitioners lacking established routines or habits for regularly accessing adherence data on CFHealthHub, could be identified through website click analytics and self-report. Support would be provided to set achievable targets, focusing on frequency of accessing adherence data. Healthcare professional would be supported to identify prompts or cues in the environment for the behaviour and then action plan performing the behaviour. Prompting rehearsal and repetition in the same context is thought to support habit formation. By supporting healthcare practitioners to build robust habits to behaviour #1, barriers related to 'forgetting' and the effort involved in opening CFHealthHub at clinical encounters could be addressed.

(#2) Healthcare practitioners would be supported by CFHealthHub champion to plan when and where they would deliver adherence discussions. It is not expected that 'habits' would be created in discussing adherence, as replicability of the behaviour in similar situations is thought to be unlikely.

[1] The previous system required multiple steps and did not allow the PWCF or clinician to see the data before the consultation. The device had to be brought to clinic, put into a docking device, the data downloaded and the clinician to manually calculate adherence based on prescription. They would then report back to the PWCF during the clinic appointment.

Discussion

Median adherence in Cystic Fibrosis is 30% but without measuring adherence clinical teams cannot determine which patients are deteriorating due to non-adherence and which are deteriorating due to novel pathology. This paper identified the barriers and facilitators for CF healthcare practitioners to implement two behaviours, #1 accessing objective adherence data from the website and #2 discussing adherence with PWCF as part of routine clinical care, through interviews with CF specialist healthcare practitioners. The barriers for each behaviour were mapped to intervention functions and BCTs, using the behaviour change wheel (BCW) [36] which formed the basis of an implementation strategy. As well as identifying the challenges facing CF teams, this paper provides an example of the use of the TDF and BCW to systematically identify facilitators and barriers and derive implementation strategies.

The key goal of successful implementation is to select strategies that are appropriate for the organisations and stakeholders [47]. Although methods such as quality improvement, can be effective in implementing change at a local setting, it is not likely to be sufficient to ensure new practices diffuse or scale up across organisations[48]. Changing routine clinical practice in CF also involves behaviour change at the level of the healthcare practitioner. Therefore, an implementation intervention must be aimed at the needs of the individuals, rather than relying on system change only.

Habit or routine offers a sustainable mechanism for behaviour change in healthcare practitioners [49, 50]. Once established, a routine of accessing adherence data (behaviour #1) might create the habit that would lead to automaticity that would override the requirement for future motivation [51] and may be resilient in the face of increased work related stressors [52]. The implementation package seeks to address fundamental barriers to behaviour #1. If barriers are removed and the behaviour is successfully repeated the establishment of a routine or habit will reduce the burden of behaviour #1 and repetition will be more likely [53].

The same implementation strategy modules can be applied to the complex behaviour of discussing adherence with patients (#2). It is not expected that 'habit' would be relevant to behaviour #2, as healthcare practitioners are required to make a judgement about the suitability and content of the discussion on a per person basis. However, planning for the behaviour #2 is important to enable the team to identify who, where and when adherence discussions will be delivered. We hypothesise that reducing the barriers described in this paper could be sufficient to enable increases in adherence discussions within routine practice. Future research should aim to address this question.

While the interviews were conducted on a relatively small number of participants at a limited number of centres, given the narrow study aim, specificity of the sample and the use of established theory [54], the number of interviews is likely adequate to understand common barriers to programme implementation. Multiple coding using a validated framework[34, 55] with the input of an experienced health psychologist increases the trustworthiness of the findings.

Together, the three sites function as a 'scalable unit' which can be used to assess the necessary requirements for best-practice implementation, and to test the processes and infrastructure needed to achieve full-scale integration of the intervention[56]. A further 19 NHS Trusts expressed an interest in implementing CFHealthHub from June 2019. Conducting this analysis at the outset of the preimplementation has maximised the opportunity to formulate an implementation strategy that will be applicable during scale up[57]. The next step will be to test this empirically devised implementation strategy and identify the elements which succeed or fail.

Conclusion

We have devised an implementation strategy to increase and sustain two target behaviours, opening objective adherence data and initiating adherence discussions, both of which are required for implementing the web application 'CFHealthHub'. The study identified potential pre-implementation

facilitators and barriers, reported by CF healthcare practitioners and sensitive to local context. The resulting implementation strategy was developed using the TDF and BCW, demonstrating that the TDF can be used to develop implementation strategies. The success of this specific implementation intervention will be evaluated in future longitudinal research in up to 19 UK CF centres.

Abbreviations

BCT – Behaviour Change Technique BCW – Behaviour Change Wheel CF- Cystic Fibrosis COM-B – The Capability Opportunity Motivation Behaviour model MDT – Multidisciplinary Team NHS – National Health Service PWCF – People With Cystic Fibrosis TDF – Theoretical Domain Framework UK – United Kingdom

Declarations

Ethics, consent and permissions

Written informed consent was obtained prior to participation.

Ethical approval

The study received ethical approval from the London Brent Research Ethics Committee (17/LO/0032).

Consent for publication

Not applicable.

Availability of data and materials

The datasets generated and analysed during the current study are not publicly available due to the potential to identify participants, but are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

Funding

CFHealthHub is funded by NHS England Commissioning for Quality and Innovation (CQUIN). The funding body did not have a role in the design, conduct or decision to publish this study.

Authors Contributions

CG (Study Manager), AP and LR (Research Assistants) drafted the report with input from MW (Consultant Respiratory Physician) and MA (Professor of Health Psychology). The following designed the research: CG, MA, MW. The following were involved in the acquisition of data: DH (Assistant Director of Clinical Trials Research Unit), AP, CG. The following were involved in the analysis and interpretation of the data: AP, CG, LR, MA, MW. All authors were involved in the final approval of the version to be published.

Acknowledgements

We would like to thank all patients and clinicians who have been involved in the development and testing of CFHealthHub and without whom CFHealthHub would not be possible.

References

1. Charman, Susan., McClenaghan, Elliot., Cosgriff, Rebecca., Lee, Andrew., Carr S. *UK Cystic Fibrosis Registry Annual data report 2018*, https://www.cysticfibrosis.org.uk/sites/default/files/2020-12/2018 (2019, accessed 11 May 2021).

2. Agent P, Parrott H. Inhaled therapy in cystic fibrosis: agents, devices and regimens. *Breathe* 2015; 11: 111–118.

3. Southern KW, Barker PM, Solis-Moya A, et al. Macrolide antibiotics for cystic fibrosis. In: Southern KW (ed) *Cochrane Database of Systematic Reviews*. Chichester, UK: John Wiley & Sons, Ltd, 2011. Epub ahead of print December 2011. DOI: 10.1002/14651858.CD002203.pub3.

4. Ramsey BW, Davies J, McElvaney NG, et al. A CFTR Potentiator in Patients with Cystic Fibrosis and the *G551D* Mutation. *N Engl J Med* 2011; 365: 1663–1672.

5. McCoy KS, Quittner AL, Oermann CM, et al. Inhaled aztreonam lysine for chronic airway Pseudomonas aeruginosa in cystic fibrosis. *Am J Respir Crit Care Med* 2008; 178: 921–8.

6. Ryan G, Mukhopadhyay S, Singh M. Nebulised anti-pseudomonal antibiotics for cystic fibrosis. In: Ryan G (ed) *Cochrane Database of Systematic Reviews*. Chichester, UK: John Wiley & Sons, Ltd, 2003. Epub ahead of print July 2003. DOI: 10.1002/14651858.CD001021. 7. Jones AP, Wallis C. Dornase alfa for cystic fibrosis. In: Jones AP (ed) *Cochrane Database of Systematic Reviews*. Chichester, UK: John Wiley & Sons, Ltd, 2010. Epub ahead of print March 2010. DOI: 10.1002/14651858.CD001127.pub2.

8. Wark P, McDonald VM. Nebulised hypertonic saline for cystic fibrosis. In: Wark P (ed) *Cochrane Database of Systematic Reviews*. Chichester, UK: John Wiley & Sons, Ltd, 2009. Epub ahead of print April 2009. DOI: 10.1002/14651858.CD001506.pub3.

9. Ryan G, Singh M, Dwan K. Inhaled antibiotics for long-term therapy in cystic fibrosis. *Cochrane database Syst Rev* 2011; CD001021.

10. Mayer-Hamblett N, Rosenfeld M, Emerson J, et al. Developing Cystic Fibrosis Lung Transplant Referral Criteria Using Predictors of 2-Year Mortality. *Am J Respir Crit Care Med* 2002; 166: 1550–1555.

11. Quittner AL, Zhang J, Marynchenko M, et al. Pulmonary medication adherence and health-care use in cystic fibrosis. *Chest* 2014; 146: 142–151.

12. Nasr SZ, Chou W, Villa KF, et al. Adherence to dornase alfa treatment among commercially insured patients with cystic fibrosis. *J Med Econ* 2013; 16: 801–808.

13. Briesacher BA, Quittner AL, Saiman L, et al. Adherence with tobramycin inhaled solution and health care utilization. *BMC Pulm Med* 2011; 11: 5.

14. Wertz DA, Chang C-L, Stephenson JJ, et al. Economic impact of tobramycin in patients with cystic fibrosis in a managed care population. *J Med Econ* 2011; 14: 759–68.

15. Eakin MN, Bilderback A, Boyle MP, et al. Longitudinal association between medication adherence and lung health in people with cystic fibrosis. *J Cyst Fibros* 2011; 10: 258.

16. Conway D, Peckham T, Daniels L, et al.Electronic Monitoring of Nebulizers Self-Report and Clinician Report vs Accurate Assessment of Adherence. 2011; 140: 425–432.

17. Modi AC, Lim CS, Yu N, et al. A multi-method assessment of treatment adherence for children with cystic fibrosis B,BB. Epub ahead of print 2006. DOI: 10.1016/j.jcf.2006.03.002.

18. Hoo ZH, Curley R, Campbell MJ, et al. Accurate reporting of adherence to inhaled therapies in adults with cystic fibrosis: Methods to calculate "normative adherence". *Patient Prefer Adherence* 2016; 10: 887–900.

19. Hoo ZH, Campbell MJ, Curley R, et al. Do cystic fibrosis centres with the lowest FEV 1 still use the least amount of intravenous antibiotics? A registry-based comparison of intravenous antibiotic use among adult CF centres in the UK. *J Cyst Fibros* 2017; 1–8.

20. Campbell MJ, Curley R, Wildman MJ. An empirical method to cluster objective nebulizer adherence data among adults with cystic fibrosis. *Patient Prefer Adherence* 2017; 11: 631–642.

21. Hoo ZH, Boote J, Wildman MJ, et al. Determinants of objective adherence to nebulised medications among adults with cystic fibrosis: an exploratory mixed methods study comparing low and high adherers. *Heal Psychol Behav Med* 2017; 5: 299–316.

22. Arden MA, Hutchings M, Whelan P, et al. Development of an intervention to increase adherence to nebuliser treatment in adults with cystic fibrosis: . DOI: 10.1186/s40814-020-00739-2.

23. Michie S, Van Stralen MM, West R. Implementation Science The behaviour change wheel: A new method for characterising and designing behaviour change interventions Michie et al. The behaviour change wheel: A new method for characterising and designing behaviour change interventions. Epub ahead of print 2011. DOI: 10.1186/1748-5908-6-42.

24. Hind D, Drabble SJ, Arden MA, et al. Feasibility study for supporting medication adherence for adults with Cystic Fibrosis: mixed-methods process evaluation. 10. Epub ahead of print 2020. DOI: 10.1136/bmjopen-2020-039089.

25. Ross J, Stevenson F, Lau R, et al. Factors that influence the implementation of e-health: A systematic review of systematic reviews (an update). *Implement Sci*, 11. Epub ahead of print 2016. DOI: 10.1186/s13012-016-0510-7.

26. Wiltsey Stirman S, Kimberly J, Cook N, et al. The sustainability of new programs and innovations: a review of the empirical literature and recommendations for future research. *Implement Sci*, 7. Epub ahead of print 2012. DOI: 10.1186/1748-5908-7-17.

27. Michie S, Prestwich A. Are interventions theory-based? Development of a theory coding scheme. *Heal Psychol* 2010; 29: 1–8.

28. Powell BJ, Beidas RS, Lewis CC, et al. Methods to Improve the Selection and Tailoring of Implementation Strategies. *J Behav Heal Serv Res* 2015; 177–194.

29. Waltz TJ, Powell BJ, Fernández ME, et al. Choosing implementation strategies to address contextual barriers: diversity in recommendations and future directions.DOI: 10.1186/s13012-019-0892-4.

30. Liang L, Bernhardsson S, Vernooij RWM, et al.Use of theory to plan or evaluate guideline implementation among physicians: a scoping review. *Implement Sci* 2017; 12: 26.

31. Damschroder LJ. Clarity out of chaos: Use of theory in implementation research. *Psychiatry Res*. Epub ahead of print June 2019. DOI: 10.1016/j.psychres.2019.06.036.

32. Patey AM, Islam R, Francis JJ, et al. *Anesthesiologists' and surgeons' perceptions about routine preoperative testing in low-risk patients: application of the Theoretical Domains Framework (TDF) to identify* *factors that influence physicians' decisions to order pre-operative tests*. Epub ahead of print 2012. DOI: 10.1186/1748-5908-7-52.

33. Lipworth W, Taylor N, Braithwaite J. *Can the theoretical domains framework account for the implementation of clinical quality interventions?*, http://www.biomedcentral.com/1472-6963/13/530 (2013, accessed 16 October 2018).

34. Cane J, O'Connor D, Michie S. Validation of the theoretical domains framework for use in behaviour change and implementation research. *Implement Sci* 2012; 7: 37.

35. Michie S, van Stralen MM, West R. The behaviour change wheel: A new method for characterising and designing behaviour change interventions. *Implement Sci* 2011; 6: 42.

36. Michie S, Atkins L, West R. *The Behaviour Change Wheel: A Guide To Designing Interventions*. Sutton: Silverback Publishing, 2014.

37. Nilsen P, Roback K, Broström A, et al. *Creatures of habit: accounting for the role of habit in implementation research on clinical behaviour change*, http://www.implementationscience.com/content/7/1/53 (2012, accessed 26 April 2019).

38. Funnell SC, Rogers PJ. Developing a Theory of Change. In: Funnell SC, Rogers PJ (eds) *Purposeful Progam Theory*. San Francisco, CA: Jossey-Bass, 2011, pp. 149–240.

39. West R, Michie S. Applying the Behaviour Change Wheel A very brief guide, https://www.ucl.ac.uk/behaviour-change/files/bcw-summary.pdf (accessed 10 November 2017).

40. Grady M. *Qualitative and action research: A practitioner handbook*. Phi Delta Kappa International, https://books.google.com/books?hl=en&lr=&id=JOr3-A3LbwC&oi=fnd&pg=PA1&dg=Grady+MP.+Qualitative+and+Action+Research:+A+Practitioner+Handbook.

+Bloomington:+Phi+Delta+Kappa+Educational+Foundation%3B+1998.+%5BGoogle+Scholar

%5D+%5BRef+list%5D&ots=hCSST5jAKZ&sig=fZS4e8aWOtcrEcpPn95ymjx8M38 (1998, accessed 16 November 2020).

41. Bryman A. BRG. *Analyzing Qualitative Data*. London: Routledge. Epub ahead of print 9 September 1994. DOI: 10.4324/9780203413081.

42. Hind D, Drabble SJ, Arden MA, et al. Supporting medication adherence for adults with cystic fibrosis: a randomised feasibility study.DOI: 10.1186/s12890-019-0834-6.

43. Arden MA, Drabble SJ, O'Cathain A, et al.WS16.1 ACtiF study: understanding adherence to nebuliser treatment in adults with cystic fibrosis using the Theoretical Domains Framework. *J Cyst Fibros* 2016; 15: S26.

44. Godfrey MM, Oliver BJ. Accelerating the rate of improvement in cystic fibrosis care: Contributions and insights of the learning and leadership collaborative. *BMJ Qual Saf* 2014; 23 Suppl 1: i23–i32.

45. Marshall M, Pronovost P, Dixon-Woods M. Promotion of improvement as a science. *Lancet* 2013; 381: 419–421.

46. Dixon-Woods M, Martin GP. Does quality improvement improve quality? *Futur Hosp J* 2016; 3: 191–194.

47. Braithwaite J, Marks D, Taylor N. Harnessing implementation science to improve care quality and patient safety: a systematic review of targeted literature. *Int J Qual Heal Care* 2014; 26: 321–329.

48. Groene O, Lombarts MJMH, Klazinga N, et al. Is patient-centredness in European hospitals related to existing quality improvement strategies? Analysis of a cross-sectional survey (MARQuIS study). DOI: 10.1136/qshc.2008.029397.

49. Gardner B, Rebar AL, Gardner B, et al.Habit Formation and Behavior Change. In: *Psychology*. Oxford University Press. Epub ahead of print 15 January 2019. DOI: 10.1093/obo/9780199828340-0232.

50. Potthoff S, Rasul O, Sniehotta FF, et al. The relationship between habit and healthcare professional behaviour in clinical practice: a systematic review and meta-analysis. *Health Psychol Rev* 2019; 1–18.

51. Gardner B, Rebar AL, Gardner B, et al. Habit Formation and Behavior Change. In: *Psychology*. Oxford University Press, 2019. Epub ahead of print January 2019. DOI: 10.1093/obo/9780199828340-0232.

52. Hofmann W, Friese M, Wiers RW. Impulsive versus reflective influences on health behavior: a theoretical framework and empirical review. *Health Psychol Rev* 2009; 2: 111–137.

53. Carey RN, Connell LE, Johnston M, et al. Behavior Change Techniques and Their Mechanisms of Action: A Synthesis of Links Described in Published Intervention Literature. *Ann Behav Med* 2018; 1–15.

54. Malterud K, Siersma VD, Guassora AD. Sample Size in Qualitative Interview Studies: Guided by Information Power. *Qual Health Res* 2015; 1–8.

55. Atkins L, Francis J, Islam R, et al. A guide to using the Theoretical Domains Framework of behaviour change to investigate implementation problems. *Implement Sci* 2017; 12: 107–112.

56. Barker PM, Reid A, Schall MW. A framework for scaling up health interventions: lessons from largescale improvement initiatives in Africa. *Implement Sci* 2015; 11: 12.

57. Barker PM, Reid A, Schall MW. A framework for scaling up health interventions: lessons from largescale improvement initiatives in Africa. Epub ahead of print 2016. DOI: 10.1186/s13012-016-0374-x.

Tables

Due to technical limitations, Table 1 to 9 are only available as a download in the Supplemental Files section.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- Tables1to9.docx
- AdditionalFile1TopicGuidev1.126Feb18.docx
- ISSMCOREQChecklist.pdf