Smart asthma:

Real-world implementation of connected devices in the UK to reduce asthma attacks

Contents

Foreword

My first major event as Chief Executive at Asthma UK was the launch of the National Review of Asthma Deaths (NRAD) in 2014.

This seminal report highlighted the tragedy of two out of three deaths from asthma attacks being entirely preventable if simple routine care was implemented. After six months in post, having attended many meetings with the respiratory community, policymakers, and industry, it felt inevitable that basic care could not be consistently delivered by the NHS. But when hardened journalists at the press conference were shocked by the findings of the NRAD report, I resolved never to accept that people with asthma will have their care compromised and their lives put at risk.

Of course, nobody wants poor care to be the norm. However, we haven't yet found the best ways of making the basics of asthma management and self-management clinically effective, accessible to those without expert knowledge, affordable in a system of stretched resources, and acceptable to the wide variety of people with asthma. Continuing with the refrain of "if only" – if only GPs had more time in appointments, if only there was more training, if only patients did exactly what they were told, if only people had a spare five minutes a day – is pointless. We need to design around reality, not aspiration.

The reality of managing asthma is that it is messy, unpredictable, complicated, delivered at huge scale, yet entirely personal to each person with asthma. And crucially, unless someone is struggling for breath, it's unlikely to be the most important thing on the to-do list of their life. These are the underpinning principles for any redesign of how we deliver basic asthma care – solutions need to be discreet, personalised and intuitive, and need to require less from the person with asthma, rather than more.

Without newly available technologies and the ubiquity of smartphones, significant change would likely be just a pipedream. However, with new sensors, cloud data services, risk algorithms, telehealth solutions and mobile apps we have the opportunity to radically redesign asthma care.

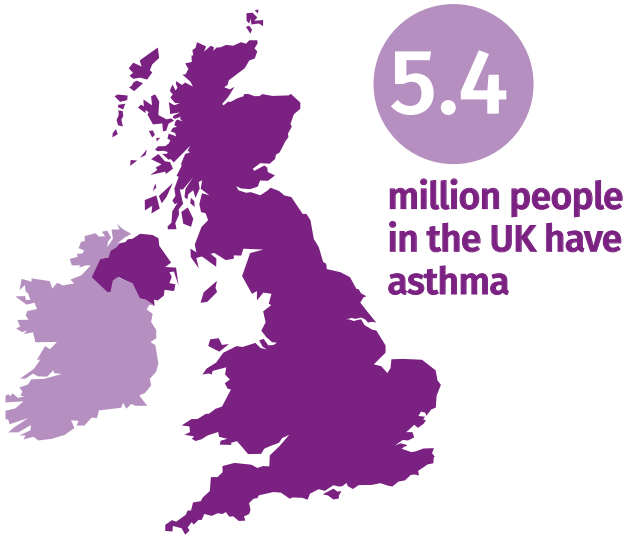
Asthma UK is determined to play a pivotal role in speeding up the adoption of such technologies – and, conversely, slowing them down if there are dangers they bring new care challenges or will not deliver real benefits for the majority of people with asthma. How we choose to implement asthma digital health in the NHS in the next five years is likely to set the direction for the next 20 to 30 years. In the same way, the model used to introduce inhalers in the 1980s – asthma reviews – is still the model dominant today, although it is sub-optimal in practice.

We need to design around reality, not aspiration.

This report sets out the opportunities and possible pitfalls as we digitise asthma. We have consulted industry, expert clinicians, eminent academics and policy specialists in the course of developing this report. We know that to make new technology stick it must help healthcare system efficiency and allow providers to make a fair profit. However, our overriding and unapologetic duty is driving improvement for the 5.4 million people in the UK with asthma, and the families who have lost a loved one as a result of a failure in asthma care.

It is for these people's sake that the recommendations in this report should be seriously debated and considered, and the future implementation of digital asthma care taken up at the highest levels of the NHS.

Kay Boycott
Chief Executive



Executive summary

Care for the 5.4 million people with asthma in the UK has seen no significant improvement in recent years, despite the widespread availability of treatments that are effective for the majority. New ways of delivering asthma care are urgently needed.

Asthma technology to drive NHS innovation

Connected devices for asthma are becoming increasingly available – particularly smart inhalers which can objectively track, monitor and prompt medication use. Initial research suggests a willingness among the asthma population to carry a connected device.[13] There is therefore a major opportunity for people with asthma, healthcare professionals and the NHS to use data from these devices over the coming decade to improve asthma outcomes in the UK. However, there could be adverse and costly effects if these technologies are not developed and rolled out thoughtfully.

Smart inhalers for an evolving NHS have the potential to support:

- Digital transformation of health services
- Management of long-term conditions at scale
- Enhanced supported self-management
- Risk stratification and management according to need
- Personalised approaches to care
- Reductions in avoidable emergency admissions
- Improvements in patient safety
- Improvements in patient quality of life
- New discoveries through data-driven academic research

Challenge 1: *The technical capability to introduce connected devices to address key issues in asthma care (such as adherence) is already here, though this does not imply that ideal care pathways, processes and devices yet exist.*

A focus on new approaches for asthma

Asthma is very common, total medication costs are high, and adverse outcomes are largely preventable.[6,9,18] The use of digital technologies like smart inhalers could save the NHS time and resources at a time of unprecedented financial pressure. In contrast, continued suboptimal asthma management will have long-term effects in failing to reduce preventable harm. Tailoring treatment to manage an individual's asthma "pattern" requires significantly greater monitoring than is currently achieved through infrequent healthcare practitioner review.

Challenge 2: *Asthma represents an ideal opportunity for the thoughtful widespread rollout of connected technologies.*

Realising the UK's competitive innovation model

The UK is a global leader in academic and commercial research, and through the NHS can co-develop, test and commercialise innovation at scale. Given that 85% of asthma cases are treated within primary care, there is significant potential to develop connected technologies that utilise the electronic health records provided through primary care. Smart inhaler developers have initially focused on the United States market, which risks these connected devices evolving without seizing on the benefits of the UK's health system and expertise.

Challenge 3: *The UK is ideally placed to lead on the development and strategic implementation of connected technologies for asthma.*

Future-proofing connected devices for asthma

The persistent and successful use of connected devices will rely on modernisation of clinical and administrative practice. As devices like smart inhalers become increasingly used, clinicians will need to adapt to use the data collected as a core part of their assessment and monitoring – helping to support their management of patients and informing face-to-face consultations. This will also require different approaches to procurement. Commissioners will no longer be purchasing just medication in the form of inhalers, but also other components to make the whole system work – such as the sensors, cloud services, user mobile apps and clinical support systems. How these are sold and priced from the start could have far-reaching impacts on models of implementation.

Challenge 4: *Widespread use of connected technologies will happen very soon. We must have a clear plan to ensure they are safe, effective and good value for money for all, and to enable rapid access and uptake.*

User-centred design of technology

Digital devices to support self-management have experienced setbacks in being accepted by users.[41] The development of connected technologies for asthma must ensure the variety of the patient population is reflected.

Challenge 5: *Involving people with asthma in the development of connected technologies and related systems will result in greater use and longevity of products.*

Supporting clinician care

Asthma is a variable condition, and people with asthma often do not seek support or assessment at times of need or increased risk. Annual asthma reviews are not always of use to patients,[11] and their volume currently contributes substantially to the already-stretched provision of primary care services. The use of data from connected devices will challenge this current approach and could enable fewer face-to-face consultations and more personalised care according to need. Connected devices will allow clinicians to manage asthma at scale and facilitate true risk stratification. By alerting patients and clinicians when symptoms require specific action, smart inhalers could help reduce the complacency that current systems encourage, and facilitate a shift to greater self-care and self-activation. Engagement with clinicians is crucial in helping ensure that the data collected through connected devices to help inform asthma care are appropriate, timely, robust, and correctly interpreted.

Challenge 6: *Developing technologies with clinicians will result in more useful and efficacious products, and potentially better use of clinician time.*

Ensuring compatibility across the NHS

Little work has been done to determine how apps and devices will link to NHS systems in a standard manner and make interoperability the norm. This is crucial for data to be used to make clinical decisions or to automate management steps. With over 90 inhalers on the market and many people with asthma prescribed at least two, people with asthma must also be able to switch between their inhaled treatments (or use multiple treatments) seamlessly, and without being tied to a particular mobile health offering or needing multiple apps.

Challenge 7: *Accounting for the needs of healthcare providers and current systems when developing new technologies will increase their volume and breadth of use.*

Research opportunities and challenges

Current research on connected technologies in asthma to date suggests:

- There is clear imperative to undertake a programme of research relating to newer connected technologies.
- People with airways disease appear to generally accept and interact with connected devices.
- Data from smart inhalers can provide clinically relevant insights.

However, key research gaps are yet to be addressed and could hinder success unless addressed in full. Filling these gaps will require industry, the NHS, and academia to work together in partnership.

Challenge 8: *Realising the potential of connected technologies will require investment in a significant programme of research – including basic information such as accuracy, robustness, user experience and clinical outcomes.*

Main action points

For government and decision-making bodies

There is an overall need to prioritise this area. Creating facilitative conditions for connected technologies has the potential to create wealth and employment in the UK.

The health technology appraisal system across the UK needs to be efficient to ensure that it is an attractive first market destination for smart inhaler companies looking to introduce their products.

The promise of connected technologies will not be realised unless substantial work is done on data standards and interoperability with NHS systems. It is crucial this work starts as soon as possible.

An industrial grand challenge for asthma management could seek to harness device and drug-based monitoring technologies, combined with patient data, aimed at automating asthma care where this could be appropriate.

Clear technical standards for smart inhalers will ensure consumers receive devices that are robust and accurate, and collect clinically meaningful data. The creation of standards against which organisations like NICE can appraise new products is overdue.

Researchers will need access to data-enabled populations at sufficient size and representation to enable cost-effectiveness testing and development of implementation models for smart inhalers.

There is currently a lack of clarity over the funding structure for connected devices in the UK and limited understanding of how this will align with developers' business models. The elucidation of this by NHSE will facilitate innovation and allow healthcare providers to co-ordinate their plans for future services to maximise progress and minimise waste.

For healthcare organisations

- Connected devices will form an essential component of systems in the UK that reduce the burden on care settings. Healthcare providers need to come to a consensus as to what data they require about and from new technologies to effectively deploy them.
- "Internet of Things" technologies generate very large amounts of data in a continuous stream. Healthcare providers need to plan how these data are to be stored and meaningfully integrated into electronic patient records, and settle questions about who owns the data.
- Deploying new technologies is likely to increase short-term costs. Providers will need to work with health economists to determine what models are likely to be sustainable and where initial priorities for asthma lie.

For healthcare professionals

- Developers often lack an understanding of the measurements useful to clinicians and how they are best presented. Therefore, healthcare professionals and their professional bodies should begin the process of agreeing the desirable attributes of clinically useful connected devices for asthma.
- Smart inhalers and other connected devices are available, and may soon be in widespread use in the UK. Clinicians should give thought now as to how these new data streams can be most usefully and safely integrated into their usual schedule and how resources may be redeployed to maximise their use.
- Clinicians should also consider how these new data streams can be included into existing clinical decision-making systems for asthma.

For industry

- The effectiveness and longevity of connected technologies depends on their co-creation with end-users, clinicians, and providers. Developers will need to demonstrate clear engagement with these groups before products are considered for use in the UK.
- People with asthma usually have more than one medicine, and drugs or devices are often changed because of asthma's variability. Stand-alone solutions that are not readily compatible with other systems will not be successful.
- The provision of connected devices and related devices is costly and potentially harmful. The standard of evidence required before their deployment in the UK is much higher than for lifestyle products such as activity monitors. Developers must consider building studies into their budgets and timelines.

For researchers and research funders

- The efficiency and effectiveness benefits of deploying connected technologies for asthma will not be realised in a safe and timely manner without co-ordinated, high-quality research. Research funders can provide leadership in this area and should consider directed calls.
- In a competitive UK marketplace, it is likely that specific products for asthma will be tested against standard care. Additional research is therefore required to investigate the underlying principles of what elements of connected technologies are beneficial for which measures in which populations.
- The healthcare value of incorporating data from connected devices into self-management, risk scoring, and clinical decision making is uncertain. Future research should include consideration both effectiveness and cost-effectiveness.

Smart inhalers and other connected devices are available, and may soon be in widespread use in the UK. Clinicians should give thought now as to how these new data streams can be most usefully and safely integrated into their usual schedule

Aim

Asthma UK's ***Connected Asthma*** report identified areas of digital technology that could potentially transform asthma care. The aim of this report is to highlight specific opportunities for the widespread deployment of connected technologies for asthma in the UK, how this could be facilitated, and the potential barriers to deployment – with a focus on smart inhalers.
The deployment of connected technologies for asthma is inevitable, with market analysts predicting these will make a multi-million-dollar contribution to asthma's multi-billion-dollar medicines market in the next five years.[1] This report highlights asthma-specific opportunities to positively influence clinical and economic outcomes in the UK. It also shows how asthma could provide a template for other conditions and a rich source of data for research in precision medicine and learning health systems. The report describes the risk of smart devices being costly, frustrating and even harmful if deployment is not thoughtful and inclusive.

The key themes of the report are:

1

Co-production
Working together to create more effective interventions

2

Research
Understanding how best to develop and deploy newer technologies in the real world

3

Co-ordinated implementation
Ensuring connected technologies are available when and where they are beneficial

Introduction

Asthma affects millions of people in the United Kingdom (UK), regardless of age, sex, ethnicity and geography. It is also a major and growing global health and economic issue.[2-4] There are over 300 million people with asthma globally, a number expected to rise by 100 million by 2025.[5,6]

Despite the widespread availability of an increasing variety of efficacious treatments for asthma in the UK, rates of admissions and deaths remain at a plateau.[7,8] Two-thirds of asthma deaths are preventable,[9] and the ***majority of adult admissions*** occur in people of working age. For the majority of people with asthma, existing treatments are effective if taken regularly. However, adherence is highly variable – around half of people with asthma do not take their medication as prescribed. These figures suggest that rather than simply offering incrementally better medicines, we need new ways of delivering asthma care and activating patient self-management.

300 million
people have asthma globally today

This is set to rise
400 million
by 2025

Given the scale of the problem, national collaborative strategies (such as have proven successful in Finland[10]) are required. New standard frameworks of management must acknowledge the range of people who have asthma, particularly those at risk of poor outcomes. They must also recognise the fact that the current mainstay of asthma care, the asthma review, does not appear fit for purpose: as many as two-thirds of people do not attend this review,[11] with more not receiving the basic elements of care or not perceiving the value.[12] Strategies must also recognise the significant changes in the availability and capability of connected technologies, and their potential to drive clinical change. By the nature of asthma demographics, a substantial proportion of people with asthma are likely to be engaged with, and readily accepting of, newer technologies, and initial research suggests that many are willing to carry connected devices.[13] In addition, Asthma UK's profiling work using geodemographic and health data has indicated that people in some of the highest risk segments are also the most likely to have the latest technology.

Around half of people with asthma do not take their medication as prescribed

As many as two-thirds of people do not attend their asthma review

Among people with asthma, there is also greater scope to improve morbidity through better self-management than for most other common chronic conditions, as its evidence base for self-management support is extensive and of high quality.[14] This suggests asthma should be prioritised as one of the first conditions for the rollout of connected devices.

Section One:

Developing connected technologies for asthma

The availability of technology

Over the past decade, the increase in the volume and range of everyday electronic devices has been remarkable. The number, capability and robustness of sensors, processors, and data systems continues to increase whilst costs fall. "Smart" inhalers are an example of such a technology (figure 1). They have progressed from prototypes that are an exercise in engineering and computer science, to medical research tools and commercial products. Relatively new enterprises are the subject of ***large-scale investment from pharmaceutical companies*** which are now planning and conducting effectiveness studies with their specific devices. Given the advanced state and falling cost of these technologies, they will be incorporated into routinely issued inhalers. This move is likely to also include generic medicines such as salbutamol as companies seek a larger share of the multi-billion-dollar market for inhaled respiratory products.

There is therefore a major opportunity for people with asthma, healthcare professionals and the National Health Service (NHS) to use data from devices that are already in existence to improve asthma outcomes over the coming decade.

There is a significant risk, as with any new technology, that partial adoption of multiple systems leads to complexity and errors without widespread health gains. This issue is already apparent in the smartphone health app sector.[15] Of the large and increasing number of competing commercial offerings available, many (including those for asthma) are of low quality, particularly those that are most widely used.[16] The market for smart inhalers is ripe to expand, and given the potential profits to be made it is quite possible that we will see devices being sold that are insufficiently robust, accurate, clinically relevant, or able to link to existing systems. Clinicians and managers may be swayed by impressive new technologies in their enthusiasm to offer these devices to people with asthma. However, decades of technology implementation in healthcare has shown that the benefits will only be realised if investment is put into processes and skills training relating to an overall care pathway.

Challenge 1: *The technical capability to introduce connected devices to address key issues in asthma care (such as adherence) is already here, though this does not imply that ideal care pathways, processes and devices yet exist.*

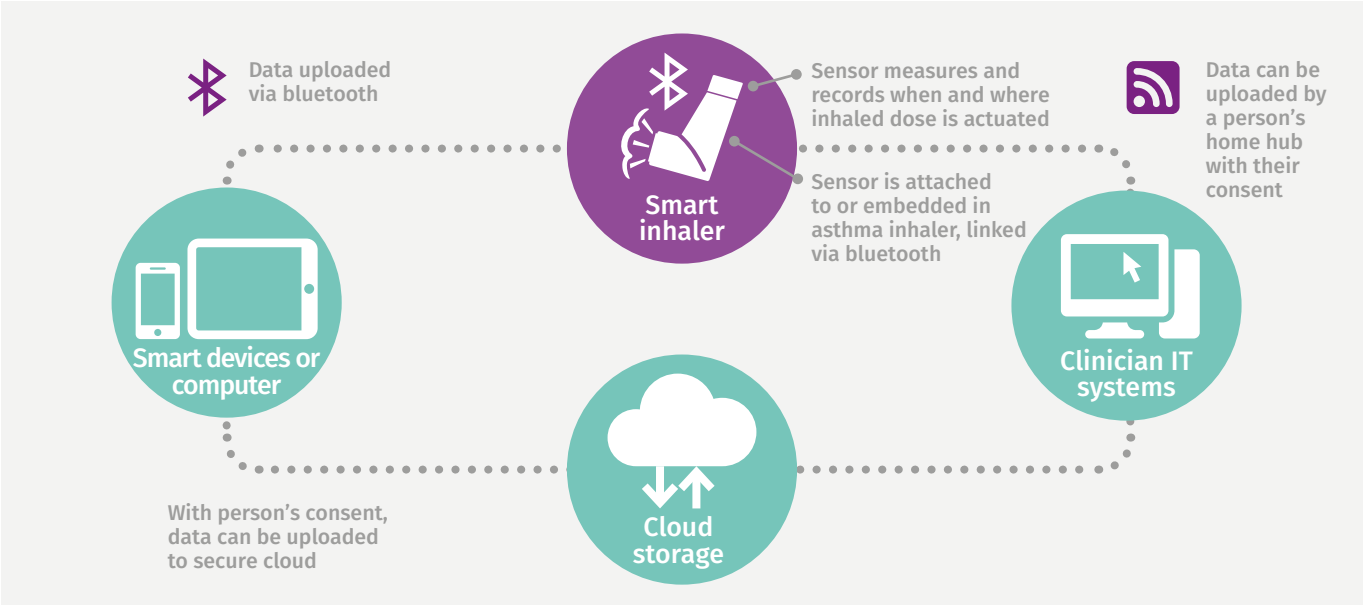


Figure 1: Smart inhalers and data flow

Technology-focused approaches to asthma care

The UK is facing an increasingly unmanageable demand on its healthcare resources.[17] There is an urgent need to reduce unplanned activity and medication budgets, and to support self-management of chronic diseases. A focus on new approaches in asthma offers an unparalleled opportunity to improve outcomes and reduce costs: asthma is very common, total medication costs are high, and adverse outcomes are largely preventable.

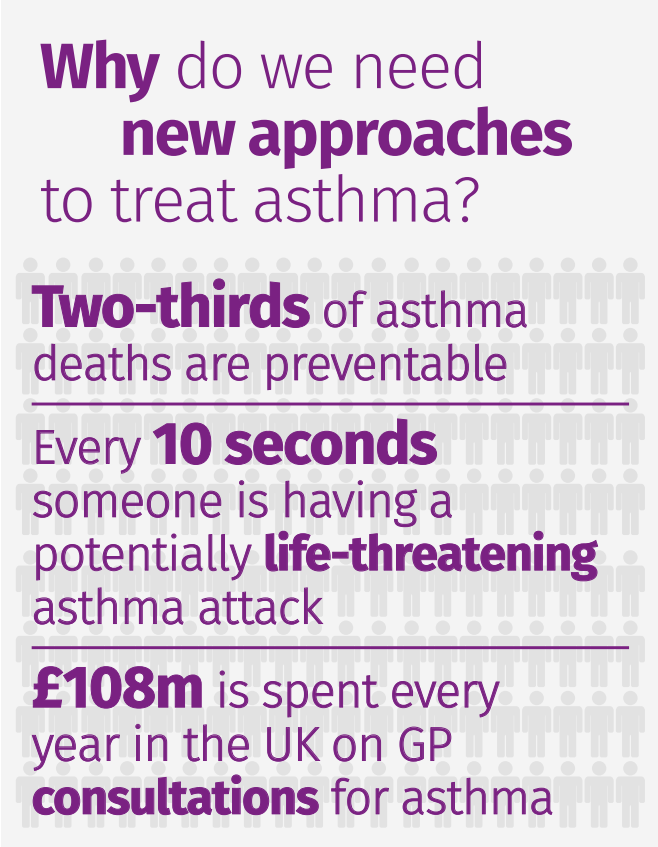


Figure 2: Asthma is common and costly and there are opportunities to prevent adverse outcomes[18,19]

It is important to emphasise that the burden of current suboptimal asthma management will largely be felt in the future. Asthma attacks in children and disengaged adults lead to cumulative lung damage,[20,21] and psychological ill-health.[22,23] Most individuals with asthma will not benefit from current initiatives directed at the multi-morbid elderly population until they have accrued largely preventable harm. There is clear evidence, however, supporting management strategies based on tailoring treatment to objectively measured aspects of an individual's asthma.[24] This requires significantly greater monitoring of this chronic and variable condition than is currently achieved through infrequent healthcare practitioner review. Digitally-driven encounters can be highly cost-effective,[25] but will require a coherent strategy to reach and equip all who may benefit. A greater emphasis on data-sharing between healthcare professionals is also required to ensure timely review of unstable patients and advice to non-specialists.

The UK has much to gain from deploying connected devices for asthma, but much to lose if this is done badly. Adopting inappropriate solutions wastes money in the short-term, and burdens the NHS with years of working around systems that are not fit for purpose. "Taking action" should not simply be about purchasing, but a rounded approach that builds the evidence base and facilitates the conditions for successful widespread adoption.

Challenge 2: *Asthma represents an ideal opportunity for the thoughtful widespread rollout of connected technologies.*

Seizing the UK advantage

The UK "market" is well-placed to lead on new management strategies involving connected technology, beyond its resource of people with asthma. These individuals are almost universally cared for within one system, with a single personal identifier permitting large-scale, relatively rapid rollout of systems and standards. The NHS structure also facilitates peer-review and assessment of clinical staff, improving the opportunities to ensure best practice is being followed.

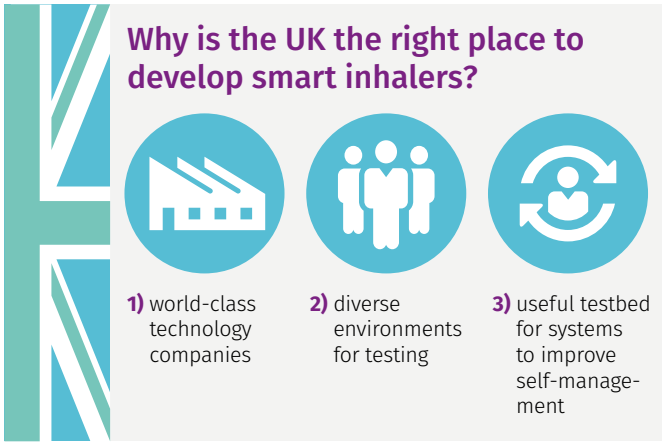
The almost universal use of electronic health records in UK primary care provides a platform for the collection of new data streams, as well as producing very large and representative primary care anonymised data sets for research, such as the Clinical Practice Research Datalink.[26] Secondary care has lagged, but the NHS is committed to being fully digitised by 2020.[27] The recent Wachter Review outlines the pathway to achieve this in secondary care,[28] and the formation of NHS Digital aims to leverage these data for healthcare improvement.

The NHS is committed to being fully digitised by 2020

Many developers and clinician entrepreneurs report frustration at the time and cost of gaining regulatory approval for medical devices, and the overall process for health technology assessment for digital innovations. This is understandable as frameworks were devised predominantly for approval of new medicines. However, it appears to have led to apps and devices being brought to market with caveats and disclaimers rather than regulatory scrutiny. The community of asthma-interested healthcare professionals has demonstrated a willingness to collaborate in terms of both service delivery (e.g. networked severe asthma

care delivery) and research (e.g. RASP-UK[29]). Co-ordinated discussions with the Medicines and Healthcare Products Regulatory Agency (MHRA) and National Institute for Health and Care Excellence (NICE) facilitated by patient groups such as Asthma UK have the potential to agree simple and affordable frameworks for development standards and the approval of connected devices and related software.

Given the size of the potential smart inhaler market, the key players are increasingly global technology and pharmaceutical companies. The United States has been the first major market targeted, and there is a risk that developers may spend relatively little effort tailoring their offerings or business models to publicly delivered healthcare systems and the unique UK healthcare landscape. This risks the piecemeal deployment of inappropriate or rigid systems that have been designed for specific sub-populations of patients or providers. UK technology companies produce world-class connected products in medical and other fields, and have great expertise in sensor technology, data processing, synthesis, visualisation, user centred design and security. There is also a diversity of cultural background and current environment that commends the UK as an excellent initial location for testing and development. The forthcoming increase in connected device use is therefore a major opportunity for UK companies to develop or tailor products for the NHS, and to export to emerging markets and low- and middle-income countries (LMIC) where there is a greater reliance on self-management due to the relative lack of specialist healthcare professionals.[30] Realising the potential of UK organisations in this area and taking advantage of this opening to ensure a large and successful rollout will require engagement from government, the NHS, and co-ordinated activity from existing facilitative structures such as Academic Health Science Networks.



Challenge 3: *The UK is ideally placed to lead on the development and strategic implementation of connected technologies for asthma.*

Time for connected technologies

The persistent and successful use of connected devices will rely on a significant change in clinical and administrative practice. Initial attempts at remote monitoring through stand-alone "telehealth" initiatives and dedicated software have largely been unproductive, though the technology was less advanced.[31] The major barrier to adoption to all new technologies lies in requiring users to change behaviour . They must learn to navigate new systems and interfaces, and to input data or change usual practice.[32] Devices that generated initial interest have proved to have a short engagement lifespan and are soon outdated.[33] Some software incorporating gamification has been used more persistently in other fields,[34] but this approach usually appeals to a relatively narrow demographic.

A key step is to design devices that are intuitive and discreet, and do not require any additional steps for users. Newer connected technologies are increasingly embedded in objects, reducing the requirement for dedicated user interaction (the Internet of Things or IoT). For example, cars are awash with sensors and processors that optimise function, increase safety and reliability (often ameliorating erratic human input) and improve functionality, through systems such as automated accident reporting. Similar principles can increasingly be applied in healthcare with facilitative software such as Apple Health. This program tracks the individual's step count without the need to download additional software or interact with a specific standalone device, but can also collate information from remote sensors.

In the next few years we will see a change from distinct "smart" devices to related technologies becoming embedded in inhalers and monitors, and the data they collect being contextualised by information from other sources, such as activity monitoring, local weather, air quality, and prescription record. The step change in the volume of use will require clinicians to start using IoT data as a central component of clinical assessment and monitoring, to support daily management and inform the nature and frequency of face-to-face interactions.

This data-rich environment produces new problems. The issues of making sense of the wealth of incoming information, keeping the data secure, and maintaining privacy are discussed later.

UK technology companies produce world-class connected products in medical and other fields

Figure 3: The Internet of Things: clinically useful information can be gathered from the multiple systems people routinely interact with each day

The changes in clinical practice will occur in the context of a NHS increasingly reliant on digital systems including electronic health records, computer-based prescribing, smartphone-based task management, and eObservations.[35]

Toward widespread adoption

The NHS has ambitious targets for the national implementation of new IT initiatives, and an enthusiasm to provide apps and connected devices at scale – with explicit national reimbursement for the first set of approved innovations from 2017.[36] These timescales are compatible with the rapid rate of progression of the technologies, both in terms of the connected devices and the ability to process and visualise the resultant large volume of complex data. The recent Asthma UK report, ***Connected Asthma***, discusses examples of innovative strategies and disruptive technologies. However, it is apparent from this and other recent review publications that there is currently no clear national strategy for the adoption of connected devices, and that the evidence base underpinning best practice lags significantly behind technical capability.

The lack of evidence raises the possibility that costly or time-consuming interventions may not result in meaningful clinical improvements, and could result in harm if inaccurate sensing triggers erroneous advice or inappropriate actions. In addition, the current lack of data standards for smart devices risks a situation where data are locked within one system and cannot be readily accessed. This will become a particular issue if more individuals begin to purchase their own devices and software, expecting a level of interoperability and future-proofing that currently does not exist. Of people with asthma surveyed as part of the ***myAirCoach project***, 44% were willing to pay £5 to £20 on an mHealth system to manage their asthma, and 17% willing to pay £20-£100.[37] Unlike traditional treatments, a large private market may be generated, setting norms and expectations which have an uncontrolled impact on healthcare services utilisation.

It is notable that the first smart inhalers are being sold in the United States as systems where the sensor is bundled with both the clinical decision support system and the end user mobile application. Given the heterogeneity of asthma, of those who have the condition, and of the scenarios in which care is delivered, payers, clinicians and users will likely want to be able to select different interoperable components rather than have a single condition system from one provider. Research needs to be done before one common system becomes the default market option. Currently the systems set up have been designed by the device manufacturers or distributors, and not necessarily for a UK market. Standard-setting is likely to greatly shape the market, and caution should therefore be exercised.

It is also crucial that a clear roadmap focussing on practical issues is in place for the stages leading up to and through deployment to avoid some users or providers experiencing a costly and frustrating failure.

Challenge 4: *Widespread use of connected technologies will happen very soon. We must have a clear plan to ensure they are safe, effective and good value for money for all.*

Section Two:

Smart inhalers & stakeholders

Figure 4: Creating technologies that are acceptable and productive for people with asthma, health care professionals and providers will result in both the greatest benefit and the widest use

Connected technologies for asthma should be developed with multiple audiences in mind. Solutions that are solely focussed on an attractive user interface, reporting clinical data, or reconfiguring service use are burdensome to other interested parties and will not be successful (figure 4).

Facilitating self-management

Educational interventions and the use of written asthma action plans are both associated with improved asthma control and fewer adverse events.[38] Although it can be argued that these benefits can diminish over time if they are not part of a broader support framework, the evidence supporting self-management interventions for asthma is very strong.[39] There is therefore a clear argument that asthma should be an early focus for the deployment of connected technologies: if smart devices can't be made to work for asthma, where the self-management is so well-understood and effective, there seems little hope the approach will be successful for other common chronic diseases.

The NIHR PRISMS review of self-management identifies 14 components of effective self-management, and these have direct relevance to connected devices and the information that can be leveraged from their use.[40]

A barrier to success in the rollout of digital devices to support self-management has been their acceptability.[41] Poor engagement may follow from the burden of, or difficulty with, setting up and interacting with the device,[42] perceived sharing of potentially sensitive information,[43] or lack of trust in the legitimacy or accuracy of the technology.[44] The level of interactivity

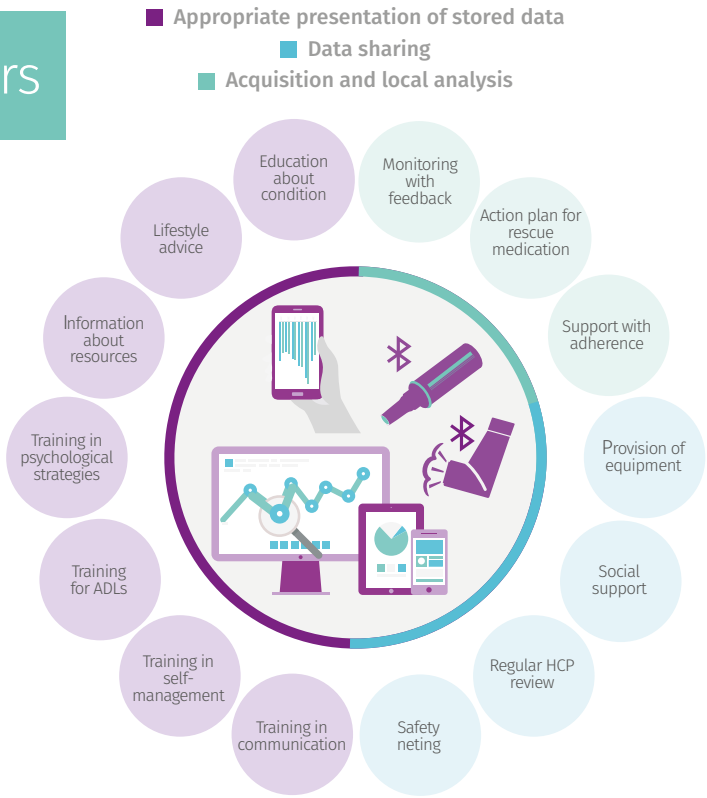


Figure 5: Enhancing and personalising self-management using connected devices

required with a given digital technology is a key determinant of acceptability, but the relationship is not straightforward. The requirement for more interaction can improve the quality of the experience for those who do engage and become longer-term users, but this increased demand may reduce the overall number of people who actually use the technology.[45]

People use their mobile devices in different ways, which creates further practical issues. For example, alerts generated by asthma-related software might be missed by someone who rarely looks at their phone, or has multiple alerts from entertainment, finance or social networking apps. The large and varied population of people with asthma will not be well served by a single style of approach, and any patient-facing digital intervention will benefit from scope to personalise interaction.

The time and cost commitments of involving a large, diverse group of people with asthma in the design of newer technologies may appear unattractive to developers, especially given the variety of opinion that is likely to result. However, the benefits are likely to outweigh initial expenditures: laboratory user testing can detect most issues that occur in the field,[46] so costs need not be high and successful design will

provide a competitive advantage. An example would be exposure to the issues end users have with multiple inhaler devices, and transferring information across multiple provider platforms. This could also include intuitive device design that removes the potential to disassemble the smart elements or to manipulate them to generate false data.

A better understanding of user perspective could also facilitate the incorporation of acceptable and useful data into online communities. Groups providing the potential for peer-to-peer support and motivation exist on dedicated platforms[47] and through social media, where users already share data from activity trackers.

This increased availability of information will create a more equal relationship between healthcare professionals and service users. The availability of large amounts of objective data on intermediate phenotypes (such as inactivity) and outcomes (such as asthma attacks) should also make it easier for service users and healthcare professionals to agree realistic targets for their care.

Gathering a more complete description of the context of disease activity involves the collection of detailed personal clinical and lifestyle information. Clear frameworks exist for the management of patient-identifiable data from existing data sources, though the 2013 Information Governance Review highlights the lack of standards both on gathering data using newer technologies and allowing patient access to this information.[48] That review recommended Clinical Commissioning Groups and Local Authorities should be responsible for ensuring the management of data from newer technologies conforms to best practice in the future, which would include the EU General Data Protection Regulation that comes into force in May 2018.[49] Anonymised clinical records and web search data are already sold on by the NHS,[50] and it is likely that directly collected granular data (such as peak flow or step count) will also become commercialised. These activities can be closely controlled, but it is of concern that connected devices can be remotely accessed and manipulated on an individual level.[51]

Users are likely to want to specify how closely they are monitored by connected devices and related software: part of this personalisation will relate to their needs around asthma, but part will be informed by their trust around the sharing of these data.

Challenge 5: *Involving people with asthma in the development of connected technologies and related systems will result in greater use and longevity of products*

Supporting healthcare professionals

Regular reviews are part of the recommended guidelines for clinicians to manage patients with chronic conditions. However, these are not always of use to patients, and the volume of reviews required contributes substantially to the high workload of healthcare professionals. This can compromise the quality of reviews, and mean practitioners struggle to keep abreast of the increasingly complex investigation and management strategies that are required.
The integration of data from connected devices into practice has the potential to make healthcare appointments faster, more targeted and more objective, and will increase the scope for monitoring and audit of practice to ensure standards are high across the traditional NHS and newer third-party providers. There is increasing consensus around which domains of modifiable traits should comprise an asthma review and risk assessment,[52,53] and new data streams from connected technologies could contribute to this process and vary the frequency of asthma reviews, relieving pressure on primary care.

The integration of data from connected devices into practice has the potential to make healthcare appointments faster, more targeted and more objective

The use of data from connected devices will also challenge the current approach of providing routine reviews at a set interval and could permit greater personalisation of care according to need, with benefits for the care of a variety of segments of the asthma population (see figure 6). Strategies for incorporating these data into decisions relating to the nature of review, or as a simple trigger for early review (recognise and rescue) is currently a neglected area of research. It is, however, a priority as there is a significant risk that clinicians could simply be exchanging some face-to-face consultations for an overwhelming amount of real-time information. Without appropriate validated risk algorithms, data visualisations and specific training for healthcare professionals, smart devices could be detrimental to efficient and safe working.

Although interested clinicians have been involved in the design of some apps and devices, designers have tended to take a “solution first” approach, designing a product and then bringing it to clinicians. The engagement of clinicians is crucial in focussing innovation in areas of need, in ensuring appropriate parameters are measured and reported in a standard fashion, and that any interpretation a system makes

is accurate and robust. The broader community of healthcare professionals must be able to readily visualise summary data from smart devices to inform their decision-making regarding treatment and follow-up. This community is likely to include "Healthcare Navigators" and people in similar new roles who will use an individual's data to direct them through the increasingly complex range of services available.

Challenge 6: *Developing technologies with clinicians will result in more useful and efficacious products, and potentially better use of clinician time.*

Lyndsey is single and on a low income, but likes to keep up with technology and owns a smartphone. Her general health is affected by damp in her house and she has been back and forth to her GP with poor asthma symptoms, but finds it hard to stick to her treatment regime.

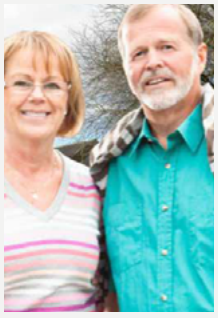
After another emergency admission, Lyndsey has been given a smart inhaler by her GP to record her inhaler use and explore what worsens her asthma. Her GP reviews the data collected and learns that despite her adherence to her preventer improving, she is still having regular asthma attacks.

Lyndsey is referred to the nearest specialist centre for severe asthma, where she is diagnosed with severe allergic asthma and responds well to Xolair.

Jaswinder has a young family, and will go online to look for health advice. She owns a smartphone and uses a PC and a tablet.

One of her three daughters was diagnosed with asthma at an early age and has been on the same treatment regime for a long time. Jaswinder has had to take her to hospital twice in the past year following an asthma attack, and her GP has given her daughter a smart inhaler and connected peak flow to record her control and explore what worsens her asthma.

The GP reviews the data collected and is able to show that her asthma repeatedly worsens when she stops taking her preventer medication.



Adrian isn't a big technology user, but does use a tablet device bought for him by his children.

He's been using a smart inhaler and connected peak flow, and tells the practice nurse that he's "doing ok" at his annual asthma review. His symptom scores suggest reasonably good control. The practice nurse reviews the objective data Adrian collected and notes frequent low peak flow scores, and he uses his reliever inhaler more than often despite being sedentary.

She uses these data to inform the decision to step up his therapy, and monitors the effect when he attends future check-ups.

Matthew has moderate asthma that has improved over time, has a young family, and tends to get the very latest tech gadget in the first six months after it's launched. He still worries that his asthma may worsen and sees his GP a couple of times a year.

He's happy to use a smart inhaler and connected peak flow, views his data over time, and uploads his data to his GP record online.

Using the objective data to demonstrate his consistent asthma control to his GP at Matthew's annual asthma review, both of them agree that Matthew does not need to see his GP face-to-face as regularly.

Figure 6: Examples of how connected devices might be used routinely in the near future

Benefits for healthcare providers

There is strong potential for providers to save money by reducing the need for face-to-face contact with healthcare professionals and by supporting self-management. The Chief Executive of the NHS, Simon Stevens, has said that NHS has been "penny-wise but pound foolish" in not supporting newer technologies for people with chronic diseases for just these aims.[54] He urged healthcare providers to "grab with both hands these practical new treatments and technologies."

In most areas of medicine, it is currently uncertain which digital interventions will prove efficacious in terms of acute outcomes, and crucially when initial promise will translate into effectiveness when deployed in the real world. In this regard asthma is at an advantage due to the initial research on smart inhalers. However, it is unrealistic to expect a step-change in practice to be rolled out very rapidly or reap immediate cost benefits as processes, algorithms, tools, business models and skills can only be refined through real-world feedback.

Little work has been done to determine how apps and devices will link to NHS systems in a standard manner. This is a crucial issue if data are to be used to make clinical decisions or to automate management steps. A protracted phase of the UK hosting multiple competing bespoke platforms will greatly reduce the potential benefit of connected technologies. Being unable to readily transfer between medicines in competing devices could also compromise the treatment options available. People with asthma will be sufficiently attached to a particular operating system to remain with the associated medication, even if a more suitable drug is recommended.

It is also important that organisations understand how best to secure data that are stored and in transit. Detailed information on medical issues and individuals' lifestyles will be contained in these datasets and is at risk given healthcare providers' relative lack of robustness against cyber-threats.[55]

Cost and time benefits will be much greater if remote monitoring promotes user and clinician confidence in flexible face-to-face care provision as well as reducing acute episodes. Having data in a standard form also permits large-scale anonymous data collection from connected devices. This allows providers to plan local services, and facilitates the benchmarking and comparison of providers against one another, against standards, and across time periods. It will also provide a valuable addition to research databases.

Challenge 7: *Accounting for the needs of healthcare providers and current systems when developing new technologies will increase their volume and breadth of use.*

Activated smart device user

- Improved self-management
- More appropriate use of healthcare resources
- Facilitated peer support
- New relationship with clinicians

Engaged clinician

- Better informed decision making
- More appropriate use of healthcare resources
- Able to advise more people
- New relationship with patients

Engaged provider

- Reduce burden on care facilites
- More appropriate use of healthcare resources
- New benchmarking opportunities
- Better informed planning of future services

Figure 7: Opportunities for clinical benefit

Section Three:

Opportunities and challenges

Current knowledge and activity

An exhaustive review of the literature is outside the scope of this report, but the following research conclusions are worthy of note.

There is clear imperative to undertake a programme of research relating to newer connected technologies. The preceding sections outline this need, and the opportunity for co-ordinated intervention. The need has also been highlighted through the European Asthma Research and Innovation Programme (EARIP), a three-year EU-funded programme led by Asthma UK, that set out to identify the key gaps in asthma knowledge. Industry, clinical, research, and patient group partners were involved in an academically rigorous process that identified relevant topics in the top unmet need research priorities, namely:

- assess the effectiveness of patient-professional communication to develop patient-professional partnerships, for example to optimise self-management and adherence
- evaluate the implementation of supported self-management, the educational needs of patient and caregivers, and the challenges faced and training needs of professionals
- develop tools to assess asthma self-management and inhaler technique in primary care settings.

People with airways disease appear to generally accept and interact with connected devices. Initial studies appear to support the acceptance of the use of smart inhalers and connected devices. Surveys have shown that three in four people with asthma would already be willing to carry and use a connected device that would monitor their inhaler usage.[13] In addition, a team at the University of Nottingham found that adolescents felt positively about using data to demonstrate their health behaviours to parents and healthcare professionals.[56] However, this acceptance is not universal, as illustrated by a high rate of lost or damaged smart inhalers in a recent UK paediatric study.[57] It is also expected that interaction with new technologies may decline for some users after the initial novelty has expired, as has been seen in other areas of healthcare.[58,59] It is therefore vital to design devices that are extremely intuitive and create a user experience much like their current inhaler, with accompanying apps designed to be useful and engaging. Further evidence is required, and the field will be informed by results from the large EU-funded myAirCoach project with which Asthma UK is also involved. This ambitious project works toward a novel mobile health tool based on wireless sensors that will observe people with asthma and help predict future asthma attacks. The initial focus of UK-based myAirCoach research is on the needs of users and what device features are associated with successful use.

Data from smart inhalers can provide clinically relevant insights. UK and Irish researchers have also been at the forefront of demonstrating the potential utility of connected inhalers in a real-world setting. For example, it has been demonstrated that electronic monitoring of salbutamol use can be undertaken at scale,[60] that electronically measured reliever use was a strong predictor of subsequent severe asthma attacks, and that many people with asthma were using very large amounts of salbutamol without seeking medical assistance.[61,62]

The quality of inhalation can also be assessed using a smart inhaler,[63] and the UK severe asthma community has begun to use such devices as part of the characterisation of patients before consideration of biologic agents.[64]

The research gap

Inhalers able to record the timing of actuations and upload these to a computer have been approved in use for more than 25 years.[65] Initial studies highlighted the capability of such devices to capture dose-dumping,[66] and to provide a more accurate measure of adherence to treatment than self-report or canister weighing.[67] Various smart inhalers of increasing complexity have since been developed. However, there has not been a commensurate increase in peer-reviewed publications in this area. Strong claims are made for newer products but there are few studies describing basic information such as accuracy, robustness, user experience, and clinical outcomes. Studies so far have either not been designed to, or have not been adequately powered to, show whether improved adherence is associated with significantly improved outcomes.[68]

Five key issues appear to contribute to this research gap:

1. **Methodology:** Newer technologies are revised and improved on timescales that are not readily compatible with the long life-cycle of standard clinical trials. For example, a traditionally designed study that was sufficiently lengthy to detect an effect on the rate of asthma attacks may span several software updates (both product and operating system environments), hardware refinements, and changes in end user digital behaviour, meaning the results are out of date by the time of scientific publication. Consideration is also needed of the endpoints reported in studies of connected devices to ensure all facets of deployment are robustly captured.

2. **Commercial pressures:** The pressure to retain a competitive advantage can result in an unwillingness to undertake research on products until after they have been launched. Developers are also looking to protect their investment and are filing patents around specific devices in their product portfolio. This contrasts with our usual expectations of the medical literature, where evidence of benefit beyond standard care and of safety are required before patients are exposed. This issue may be compounded by end users being less likely to change their behaviour to incorporate a new technology that they feel will not be widely adopted.

3. **Cross-discipline working:** Generating good information around smart inhalers requires data from a variety of specialists, such as engineers, computer scientists, respiratory physicians, psychologists and human factors experts. In contrast to medicine, dissemination of academic information in these fields is based more around conferences than paper journals. It can therefore be difficult to search and collate information (and to assess its academic rigour), and to build an effective research team. Innovators in technology are often not from an academic background and are usually not used to the level of evidence required in medicine, preferring to emphasise positive case reports.

4. **Silo-working:** Developing connected devices is challenging and consumes time and resource. It is therefore natural that commercial developers have largely focussed on one inhaler device type during development, and are keen to protect their intellectual property. They have also tended to create stand-alone software (decision support and mobile device apps) that gather, store and process information from these devices which do not yet work on a common platform. It is therefore difficult to plan and deliver "real-world" clinical studies for people who use a variety of inhaler types and clinicians bound to specific, protected IT systems.

5. **Uncertainty in deployment:** There are currently no set models for the widespread implementation of connected devices, with all the medication, system and professional interdependencies associated with this. This creates difficulty framing specific research questions and hinders the development of robust, commonly accepted health economic models that also allow for evolution of the enabling technology and systems within the NHS.

In addition, there may be a nascent issue of sampling bias in the populations that are studied: both participants and researchers tend to be interested in newer technologies and be able to adopt them rapidly. However, the UK has a number of representative datasets (e.g. The Health Improvement Network database, Clinical Practice Research Datalink, Salford Lung Study) that could be used to judge the external validity of any study of connected devices.

Challenge 8: *Realising the potential of connected technologies will require investment in a significant programme of research – including basic information such as accuracy, robustness, user experience, and clinical outcomes.*

Assessing value

In the past, medical interventions were largely judged on whether they were safe and efficacious. More recently, the range of available tests, devices and treatments has increased whilst resources are falling ever shorter of projected spend. Decisions must therefore be made upon the value of the intervention: the balance between cost and health benefit. This health benefit is related to the effectiveness of the intervention - its performance in real-world situations rather than the controlled conditions of traditional clinical trials.

There are currently no set models for the widespread implementation of connected devices, with all the medication, system and professional interdependencies associated with this

To judge the potential utility of smart inhalers, it is therefore crucial to acquire information that describes components of effectiveness such as uptake, efficacy against clinical outcomes, persistence of use, healthcare costs and negative effects. The cost and value of such devices and their implementation must also be described in a similar fashion to an industry value chain, though this is complicated by the variety of potential business for the implementation of connected devices (see table), and the lack of publicly available costs for many systems.

Business model	Commercial income	Advantage	Disadvantage
Add-on device	Selling units to consumers or providers	Can be used for various drugs Gives choice to opt in to consumer and clinical team Users can construct data visualisation or incorporate into decision systems	For limited range of devices Users responsible for data collection, storage and analysis
Device and software	Selling units and charging regular fee for data visualisation and analysis	Can be used for various drugs Gives consumer choice to opt in May better assist self-managemnent	Potential for lock in to long, costly contracts Data presentation and use is limited by provider software Manufacturer holds personal data on individual
Drug in smart device	As per currently prescribed device/drug combinations	Removes potential for error in add-on devices Smart devices become part of routine care Could apply to all device types	Propriety drugs more expensive Smart capability for manufacturers' specific likely to be expensive Functionality of smart component fixed and may be limited
Drug/device/ software package	Medication sales +/- regular fees	Simple package requires less technical expertise Benefit from plug and play technology may be realised sooner	Restrictions to one manufacturer's drugs Potential for lock in to long, costly contracts Data presentation and use is limited by provider software Manufacturer holds personal data on individual

A research and facilitation framework

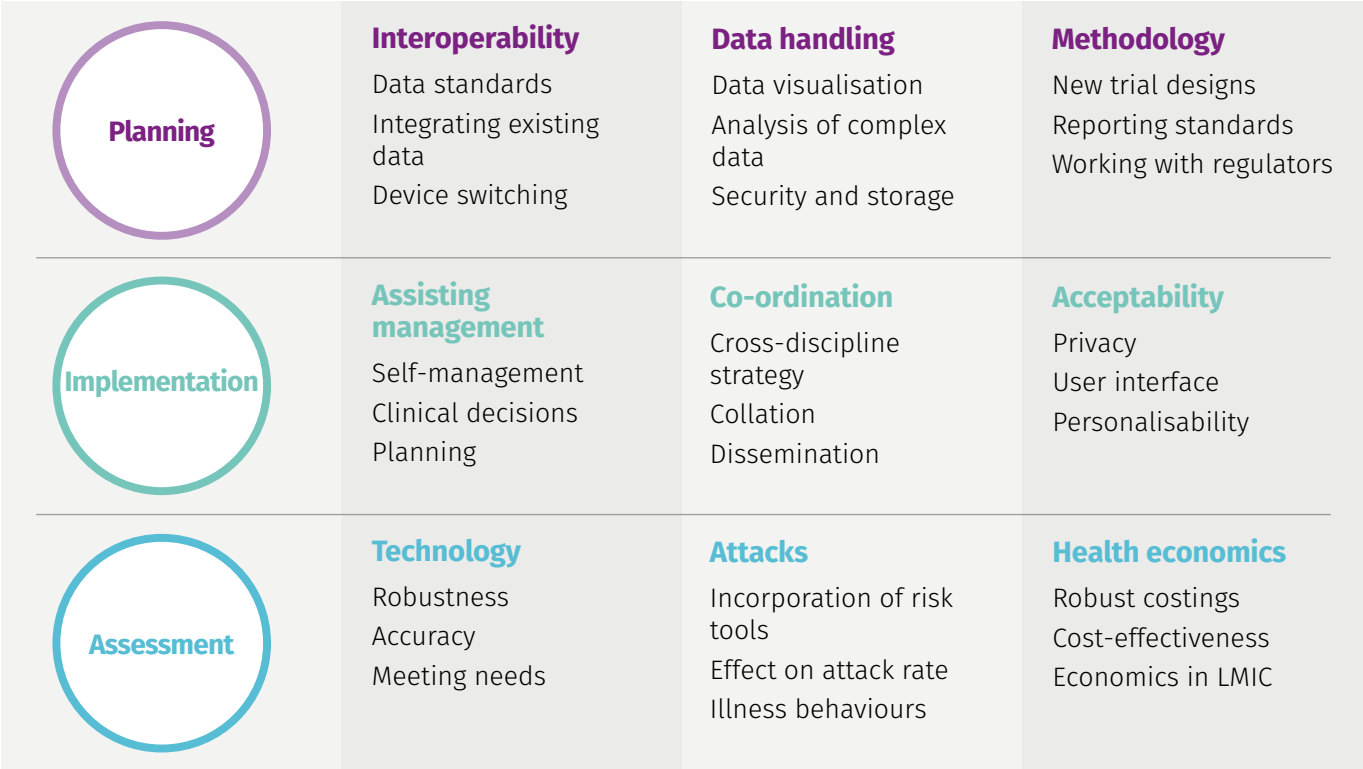


Figure 8: Building blocks of smart inhaler research and implementation

Planning for interoperability

It is encouraging to see the development of new connected devices for asthma. However, for these devices to have a long-term role in clinical practice, they must interact with existing systems and each other in a standard manner . This will allow information from different devices to be directly comparable, and mean there is no impediment to individuals changing their treatment. Indeed, it appears that reimbursement under the new NHS tariff for digital may be ***dependent on interoperability***.

As this ongoing and evolving area is in the best interest of the wider NHS, and is part of the remit of NHS Digital's Information Systems team, standards could be developed in conjunction with communities with specialist expertise such as the INTEROPen group and HL7 UK.

FACILITATING CONDITIONS: Detailed review of opportunities and challenges; interoperability and open access standards for devices and electronic health records.

POTENTIAL RESEARCH: Establishment of core data set and nature and accuracy of parameters included.

Planning for data management

Maintaining an individual's privacy and data security whilst they are exposed to continuous monitoring is an issue that affects many areas of healthcare.

The challenge for those interested in asthma will be to encourage computer science and engineering researchers to continue to engage with the disease area. That might include working with representatives from the UK's Digital Economy Research Centres, and the Farr and Turing Institutes, to build on initial asthma studies and research in non-healthcare areas.

A second key aspect of data handling will be to analyse and present complex data (e.g. location information) to people with asthma, their clinicians, and healthcare providers in a meaningful and efficient manner. Research in this area could establish principles that developers could follow. The Farr Institute represents a UK-wide collaboration of health informatics researchers supported by multiple funders. This existing structure would seem an ideal mechanism to explore and refine this complex big data problem, if responsibilities on how to respond to the data collected are made clear.

FACILITATING CONDITIONS: Agreement on standards for smart device data storage, transfer and sharing; anonymised and pseudonymised data available for research purposes.

POTENTIAL RESEARCH: Investigating the most productive way to display and leverage data for individuals, clinicians, and providers to plan and deliver high quality care; insights into the disease and health behaviours from new large datasets.

Developing research methodology

Clinical drug trial methodology is changing, with an increased use of newer adaptive and umbrella designs to improve efficiency and better reflect clinical practice. The application of such designs to connected devices has not been studied, but offers the opportunity to test iteratively improving devices, or a class of intervention. Research funders such as MRC and NIHR already support trials methodology research hubs and clinical trials units. This expert knowledge could be applied to the assessment of connected devices, perhaps through joint fellowship opportunities.

FACILITATING CONDITIONS: Recognition by regulators and funders of the need to improve approaches for assessing connected technologies.

POTENTIAL RESEARCH: Trial designs that adapt to iterative changes in the technology being assessed, capture the diversity in asthma and in device use patterns, and can read out data in stages to avoid delay in approval.

Implementing asthma management

Promoting effective self-management of asthma must be the cornerstone of any clinical strategy. Connected devices have the potential to significantly improve two aspects relating to self-management.

Promoting effective self-management of asthma must be the cornerstone of any clinical strategy

Firstly, providing objective feedback to the user and their healthcare professional may well increase concordance with intended treatment. The evidence base that this is the case over the long term remains weak. Major pharmaceutical companies have made substantial investments in smart inhaler technology, and more data in this regard are now being collected. However, a clearer understanding of which specific aspects of connected technology (e.g. types of reminders, type of feedback, data oversight by clinicians) are most useful is likely to require investigator-led studies. We hope pharmaceutical companies will continue to be open to supporting investigator-led studies in parallel with their planned research programs, as they are for medicinal products.

The second aspect of self-management that could be improved is the user's understanding of their disease. As noted, connected devices have the potential to educate about asthma, and synthesise personal insights (e.g. specific triggers). However, the low quality of information provided by many asthma apps raises concerns that this may be a wasted opportunity. Further research is needed into the specific content (and format) which is most productive for users, and how to personalise the interaction to allow for individuals' varied learning styles. The information produced by Asthma UK and learned institutions about the condition forms a sound starting point for collaborative research in this area.

FACILITATING CONDITIONS: An NHS standard self-management plan and core education and health activation messages.

POTENTIAL RESEARCH: Incorporation of new data streams into self-management; understanding which features of connected devices improve intermediate phenotypes such as concordance; behavioural insights into use patterns.

Co-ordinated research around implementation

The efficient progress of a robust evidence base around connected technologies in asthma will require co-ordination of effort across academic disciplines within and outside medicine. It will also require engagement with clinicians and providers in terms of product development, testing, care pathway redesign and dissemination of results.

We suggest there is a clear opportunity for dialogue between major funders in medicine and sciences to develop a co-ordinated research strategy alongside commercial entities entering this market in a significant way. A strong case could be made for seed funding the infrastructure of a national centre or programme grant, providing a focal point for interested academics and for those developing innovative products in need of testing.

FACILITATING CONDITIONS: Meetings and agreement between key stakeholders on research and deployment plan.

POTENTIAL RESEARCH: Research capability assessment; systematic reviews.

Assessing user acceptability

Innovative solutions fail if they are imposed on users without a clear understanding of what is acceptable to them. For connected devices, this starts with understanding and accepting the amount of personal information that is recorded and who will hold it. User interfaces should follow a similar format based on evidence around best practice - although it is not yet clear what that best practice is, how that varies for different user groups, or even how user groups should be defined. Both the information flow and interface

will also need to be readily adapted to the preference of the user: no one approach will be universally suitable across the population and the variety of care providers.

FACILITATING CONDITIONS: Increased co-ordination of user testing; point of access for developers.

POTENTIAL RESEARCH: Derivation of accepted definition of sub-user populations; user experiences and attitudes; description of how end users interact with smart devices.

Assessing the technology

As noted previously, technologies are developed and revised at a rapid pace. However, it is not clear that developments are aligned clearly with user needs and clinical outcomes. For example, most newer smart inhalers do not measure if MDIs are shaken, or if the product is actuated but not inhaled. It is also unclear how future developments in the sensors in mobile phones or smart devices might also be utilised. For example, it is technically feasible to add sensors to measure current local environmental conditions (e.g. temperature, pollutants), and vital signs such as heart rate or oxygen saturations – though adding sensors could increase cost and may reduce overall reliability.

The myAirCoach project will provide useful information on the greatest priorities in this area. However, there remains a need for developers to come together with learned respiratory institutions and patient groups to agree future technical goals, and standards for current devices (e.g. battery life, accuracy). This activity could be supported by the UK's Academic Health Sciences Networks, Innovate UK, and the NHS Innovation Accelerator.

FACILITATING CONDITIONS: Meetings and agreement between key stakeholders on technical standards and goals.

POTENTIAL RESEARCH: Accuracy and robustness of existing devices; extending device and software functionality to better meet clinical need.

Assessing the effect on attacks

By improving self-management and facilitating interaction with healthcare professionals, smart inhalers may reduce the risk of asthma attacks. The longer-term aim of research in this area will be to assess whether the use of smart inhalers reduces the rate of asthma attacks in a "real-world" randomised controlled trial. In the shorter term, progress can be made on incorporating appropriately derived and validated risk scores (such as evolutions of the Asthma UK Triple A test) into the interfaces of connected devices, highlighting opportunities for beneficial changes such as weight loss, smoking cessation, and treatment of comorbidities.

FACILITATING CONDITIONS: Co-ordination and adoption of one main risk assessment tool.

POTENTIAL RESEARCH: Impact of connected devices and semi-automated risk assessment on clinical outcomes; continued refinement of risk algorithm in real-world setting.

Assessing the health economics

Connected devices are increasingly being used for asthma, and will become cheaper and more commonplace as the costs of sensors and processors fall, from competition, and economies of scale. It is unclear, however, how effective they would need to be (and in which areas) for widespread deployment to be cost-effective. A suite of health economics work is required to undertake such simulations and incorporate data from studies as they become increasingly available. The most efficient portfolio of interventions (face-to-face, telehealth, connected devices and so on) may differ by geographical area and population served, and tools will need to be developed to assist healthcare commissioners in making such decisions. A system set up to cost-effectively support high-cost, frequently hospitalised asthma patients may be the wrong configuration to reap benefits amongst the majority – people with asthma who have fewer attacks requiring medical intervention.

FACILITATING CONDITIONS: Greater transparency around device costs; clarity around new tariffs that may apply to smart inhalers.

POTENTIAL RESEARCH: Cost-effectiveness of smart devices under various business models and levels of availability of face-to-face expert opinion.

Innovative solutions fail if they are imposed on users without a clear understanding of what is acceptable to them.

Summary

Challenge 1: *The technical capability to introduce connected devices to address key issues in asthma care (such as adherence) is already here, though this does not imply that ideal care pathways, processes and devices yet exist.*

Challenge 2: *Asthma represents an ideal opportunity for the thoughtful widespread rollout of connected technologies.*

Challenge 3: *The UK is ideally placed to lead on the development and strategic implementation of connected technologies for asthma.*

Challenge 4: *Widespread use of connected technologies will happen very soon. We must have a clear plan to ensure they are safe, effective and good value for money for all.*

Challenge 5: *Involving people with asthma in the development of connected technologies and related systems will result in greater use and longevity of products.*

Challenge 6: *Developing technologies with clinicians will result in more useful and efficacious products, and potentially better use of clinician time.*

Challenge 7: *Accounting for the needs of healthcare providers and current systems when developing new technologies will increase their volume and breadth of use.*

Challenge 8: *Realising the potential of connected technologies will require investment in a significant programme of research – including basic information such as accuracy, robustness, user experience, and clinical outcomes.*

Research insights

- There is clear imperative to undertake a programme of research relating to newer connected technologies.
- Data from smart inhalers can provide clinically relevant insights.
- People with airways disease appear to generally accept and interact with connected devices.

Planning

- Interoperability
- Data handling
- Methodology

Implementation

- Assisting management
- Co-ordination
- Acceptability

Assessment

- Technology
- Attacks
- Health economics

Main action points

For government and decision-making bodies

- There is an overall need to prioritise this area. Creating facilitative conditions for connected technologies has the potential to create wealth and employment in the UK.
- The promise of connected technologies will not be realised unless substantial work is done on data standards and interoperability with NHS systems. It is crucial this work starts as soon as possible.
- Clear technical standards for smart inhalers will ensure consumers receive devices that are robust and accurate, and collect clinically meaningful data. The creation of standards against which organisations like NICE can appraise new products is overdue.
- There is currently a lack of clarity over the funding structure for connected devices in the UK and limited understanding of how this will align with developers' business models. The elucidation of this by NHSE will facilitate innovation and allow healthcare providers to co-ordinate their plans for future services to maximise progress and minimise waste.
- The health technology appraisal system across the UK needs to be efficient to ensure that it is an attractive first market destination for smart inhaler companies looking to introduce their products.
- An industrial grand challenge for asthma management could seek to harness device and drug-based monitoring technologies, combined with patient data, aimed at automating asthma care where this could be appropriate.
- Researchers will need access to data-enabled populations at sufficient size and representation to enable cost-effectiveness testing and development of implementation models for smart inhalers.

For healthcare organisations

- Connected devices will form an essential component of systems in the UK that reduce the burden on care settings. Healthcare providers need to come to a consensus as to what data they require about and from new technologies to effectively deploy them.
- "Internet of Things" technologies generate very large amounts of data in a continuous stream. Healthcare providers need to plan how these data are to be stored and meaningfully integrated into electronic patient records, and settle questions about who owns the data.
- Deploying new technologies is likely to increase short-term costs. Providers will need to work with health economists to determine what models are likely to be sustainable and where initial priorities for asthma lie.

For healthcare professionals

- Developers often lack an understanding of the measurements useful to clinicians and how they are best presented. Therefore, healthcare professionals and their professional bodies should begin the process of agreeing the desirable attributes of clinically useful connected devices for asthma.
- Smart inhalers and other connected devices are available, and may soon be in widespread use in the UK. Clinicians should give thought now as to how these new data streams can be most usefully and safely integrated into their usual schedule and how resources may be redeployed to maximise their use.
- Clinicians should also consider how these new data streams can be included into existing clinical decision-making systems for asthma.

For industry

- The effectiveness and longevity of connected technologies depends on their co-creation with end-users, clinicians, and providers. Developers will need to demonstrate clear engagement with these groups before products are considered for use in the UK.
- People with asthma usually have more than one medicine, and drugs or devices are often changed because of asthma's variability. Stand-alone solutions that are not readily compatible with other systems will not be successful.
- The provision of connected devices and related devices is costly and potentially harmful. The standard of evidence required before their deployment in the UK is much higher than for lifestyle products such as activity monitors. Developers must consider building studies into their budgets and timelines.

For researchers and research funders

- The efficiency and effectiveness benefits of deploying connected technologies for asthma will not be realised in a safe and timely manner without co-ordinated, high-quality research. Research funders can provide leadership in this area and should consider directed calls.
- In a competitive UK marketplace, it is likely that specific products for asthma will be tested against standard care. Additional research is therefore required to investigate the underlying principles of what elements of connected technologies are beneficial for which measures in which populations.
- The healthcare value of incorporating data from connected devices into self-management, risk scoring, and clinical decision making is uncertain. Future research should include consideration both effectiveness and cost-effectiveness.

Acknowledgments

This report was written by Dr John Blakey from the Liverpool School of Tropical Medicine, and by Joseph Clift from Asthma UK. This was also informed with expertise provided by Kay Boycott, Daisy Ellis and Dr Samantha Walker from Asthma UK.

Asthma UK would like to thank AstraZeneca, GlaxoSmithKline, Novartis, Roche and Teva for their financial support in the production of this report.

We would also like to thank the following people for their comments on the report: Julia Chambers (Adherium Ltd), Charles Lowe (Digital Health and Care Alliance), Melissa Manice (Cofounder and CEO, Cohero Health), John Pritchard (Philips), Dr Dominick Shaw (University of Nottingham), Professor Aziz Sheikh (Asthma UK Centre for Applied Research, University of Edinburgh), Dr David Stables (Trustee, Endeavour Health).

We would also like to thank GlaxoSmithKline, Novartis and Teva for commenting on the report. The report was also informed by around 40 attendees of a roundtable event held in 2016 by Asthma UK at the ***European Respiratory Society International Congress.***

The views presented in this report are those of Asthma UK and do not necessarily represent the views of the individuals and organisations named above that offered feedback during its development.

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All hyperlinks in the references above, and elsewhere in the report as a whole, are accessible as of January 2017.

Every ten seconds someone in the UK has a potentially life-threatening asthma attack and three people die every day. Tragically two-thirds of these deaths could be prevented, whilst others still suffer with asthma so severe current treatments don't work.

This has to change. That's why Asthma UK exists.
We work to stop asthma attacks and, ultimately, cure asthma by funding world-leading research and scientists, campaigning for change and supporting people with asthma to reduce their risk of a potentially life threatening asthma attack.

We fight asthma in three ways:

- We fund world-class asthma research.
- We campaign to improve the quality of care received by people with asthma.
- We help hundreds of thousands of people a year with our expert advice and support.

To find out more about Asthma UK's work:

Asthma UK Helpline:
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