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THE SMART INHALER REVOLUTION: ARE WE THERE YET?

Here, Mark Allen PhD, Consultant Mechanical Engineer, David Blakey, PhD, Former Senior Consultant Physicist, and Karla Sanchez, PhD, Senior Consultant Biomedical Engineer, all of Cambridge Design Partnership, discuss the benefits of smart inhalers and how they could influence the commercialisation of respiratory drugs in the future.

Asthma inhaler products have been employing electronic sensor technology with increasing sophistication and functionality since the 1980s, despite that, these devices have never achieved mainstream use – why? Several studies have shown the potential value of sensors in enhancing patient engagement and adherence – but the cost of these added features appears to outweigh their clinical utility. However, we may now be approaching a tipping point where smart inhalers can deliver new functionality that revolutionises respiratory therapy.

CLINICAL UTILITY OF A SMART INHALER

Smart inhalers employ sensors to monitor how people use their inhalers and employ feedback indicators to highlight errors and guide patients through onboarding and ongoing training. Sensor functions and electronic communications are typically integrated into an add-on device that is clipped onto the inhaler. The sensor data can be processed on a smartphone, which will usually have access to more comprehensive functions that help the patient with therapy support information, training, monitoring inhaler use, improving their technique and tracking adherence.[1]

The health benefits of a smart inhaler are measured by treatment outcomes, with better outcomes closely related to improved adherence to the dose regimen, leading to more stable symptom control and a reduced burden on secondary and emergency care.

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Patient engagement is critical for the success of smart inhalers, including improvements in adherence. A range of smart features has been tested to improve engagement, including repeat prescription automation, environmental trigger alerts, exacerbation prediction, lung health monitoring and patient support services. Patients and physicians can use these features to train, monitor and support the use of new inhaled therapies.

However, a demonstration of universal clinical improvement for patients remains elusive – partly because not enough studies have been performed and partly because individuals respond to engagement cues differently. The broad range of patients and different treatment pathways means that large numbers of patients are needed for sufficient data to draw conclusions. The personal engagement between patients and their inhalers can lead to further issues for clinicians when designing a suitable treatment plan.

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One recent study highlights different barriers to adherence in asthma and chronic obstructive pulmonary disease (COPD), as well as how patients need different interventions according to the underlying reason for their non-adherence.[2] However, clinicians often do not have enough time or data to identify these in a single consultation.[1,2]

Patients will respond differently to engagement cues depending on the reason behind their lack of engagement. A patient who has made a deliberate decision to stop using their inhaler because they do not want to be reminded of their condition needs different engagement cues to one who has forgotten a dose on holiday or misunderstood how to use their device correctly.

Could smart inhalers assist by providing data to help understand the cause of non-adherence and be designed for specific engagement needs? For example, an inhaler could be designed to identify inconsistent dosing with a simple timestamp to record use. Another, more complex, device could monitor airflow and activation co-ordination for training. If these smart inhalers can be shown to improve adherence in COPD patients, they would decrease the need for further medical interventions.[3,4]

Beyond clinical utility, smart inhalers could also help decrease net healthcare costs. Every visit to a clinician or instance of hospitalisation is costly both financially and environmentally (because of the carbon dioxide release associated with treatment and infrastructure).[5]

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SMART TECHNOLOGY BEYOND SENSORS

Clipped-on smart inhaler modules can be designed with a range of sophisticated sensor fusion controls and analyses, enabling additional benefits for users and healthcare professionals alike, such as the ability to review the actual delivery event against the expected clinical dose. This technology can also be integrated into the inhaler itself, for example, Digihaler[6] (Teva, Tel Aviv-Yafo, Israel) logs the time and date of actuations and provides instant feedback on the inhalations in its associated app, including training prompts if needed.

But beyond integration, how will smart inhalers develop? With recent advances in technology, it may be possible to grasp an opportunity that has remained out of reach until now. Smart sensors could be used to control the drug delivery process itself – or even control the aerosol particle size to suit each patient by age, breathing pattern or disease state. However, such dose control would require clinical trials to demonstrate safety and any claimed efficacy advantage. This method of digitally personalised dose control has recently been demonstrated in the Personalised Aerosol Loading and Management (PALM) device (Monash University, Melbourne, Australia),[7] but could this use of technology be applied to other inhaler types? This could, in theory, improve patient outcomes and provide a new pathway for commercialising respiratory drugs that require either a tighter control or higher efficiency of the dose delivery process.

Inhalers typically use energy stored in a compressed propellent or the airflow energy from the patient's inhalation. Electronic triggering systems for these mechanisms are challenging to develop but innovations, such as those found in vibrating mesh nebulisers,[8] may provide convenient aerosol delivery technologies that are automatically triggered by inhalation.

The concept of a closed-loop smart inhaler may not be new, but with recent advances in digital and sensor technologies and delivery systems, now may be the time to revisit closed-loop dose delivery control and explore its benefits for clinical utility. With new inhaled therapies on the horizon, innovative smart inhaler solutions will need to step up their game to facilitate this revolution in respiratory care.

ABOUT THE COMPANY

Cambridge Design Partnership is an end-to-end innovation partner, propelling global brands and ambitious start-ups to success. The company builds breakthrough products and services – from insight to ideas, prototypes to production – bringing innovation to life. Its teams are multi-disciplinary, uniting scientific rigour, design ingenuity and engineering excellence for consumer, healthcare and industrial clients.

People-centred, deeply collaborative and, above all, expert, Cambridge Design Partnership is uniquely positioned to shape the future for consumers, patients and industry. Even the company's ownership model is innovative – the company is 100% owned by employees, ensuring an open culture and a total commitment to each project's success.

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ABOUT THE AUTHORS

Mark Allen, PhD, is a Consultant Mechanical Engineer at Cambridge Design Partnership. He has a PhD and MEng in Mechanical Engineering from Loughborough University (UK), where he specialised in the prediction and measurement of liquid and gas flows and sprays, working on internal flow imaging and analysis of internal combustion engine technologies to reduce harmful emissions and improve performance. After leaving academia, Dr Allen moved to the medical device sector, working on the design and development of a range of devices from early to late stage, including the design and development of multiple autoinjectors for highly viscous formulations and a novel nasal spray device. His specialisms include simulation, mathematical modelling and data analysis.

David Blakey, PhD, is a Former Senior Consultant Physicist at Cambridge Design Partnership and has spent over 25 years creating new medical device technologies, products and processes, including mesh nebulisers, dry powder inhalers and autoinjectors. Before joining CDP, he worked in pharmaceutical R&D, leading device design teams and supporting process engineering and manufacturing at GSK. Dr Blakey's interests include aerosol science and micro-engineering of mechanical and fluidic systems.

Karla Sanchez, PhD, is a Consultant Biomedical Engineer at Cambridge Design Partnership, working as a mathematical modeller, researcher and bioengineer with over 10 years of experience in medical product development. She obtained her PhD from Imperial College London (UK) at the Physiological Fluids Group, where she focused on blood flow of the cerebral vasculature and distribution of cerebrospinal fluid. She has also worked alongside clinicians and academics to study blood flow in the kidney and complications of chronic kidney disease. Dr Sanchez has managed several successful commercial projects, launching a large range of infusion sets, orthopaedic and surgical devices. She is an enthusiastic STEM ambassador and holds an honorary visiting researcher position at Imperial College London.