



IMPROVING INHALATION THERAPY ADHERENCE WITH CONNECTED DEVICES

In this article, Edgar Hernan Cuevas Brun, Marketing Manager at HCmed, discusses the role of connectivity in improving adherence to medication and introduces the company's mesh nebuliser smart cap, Pulmogine+.

PATIENT ADHERENCE ISSUES

Non-adherence has been reported as a major issue in the treatment of most chronic diseases, affecting approximately 50% of patients, a large proportion of which are elderly people. Research has also shown that the implications of non-adherence can lead to critical problems, such as a decrease in treatment efficacy and an increase in the cost of medical care.¹ In the past, clearly identifying groups of patients that presented non-adherence behaviour based on socio-economic or pathologic factors was difficult to achieve.² However, finding effective methods to improve these behaviours still remains an important issue.³

Throughout the past decades, several platforms to monitor adherence have been introduced. The main goal is to educate and encourage patients who suffer from chronic diseases to follow their treatment. Nonetheless, awareness

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NON-ADHERENCE IMPLICATIONS IN CHRONIC RESPIRATORY DISEASES

Chronic obstructive pulmonary disease (COPD), asthma and cystic fibrosis bronchiectasis are among the chronic respiratory diseases in which a significant number of patients have been reported as not complying with their treatment. When it comes to bronchiectasis, one study stated that only half of the total patient sample completed 80% of their prescribed inhaled antibiotic medication to treat their condition.⁴ Similarly, although there is currently a wide range of options to treat COPD patients, a significant number of patients remain symptomatic, with no improvement in their condition, due to non-adherence issues that could be traced to the patients' health-related experiences, behaviours and beliefs.^{5,6} In a different study, it was reported that both COPD and asthma patients prefer to reduce their inhalation treatment to a single daily dose.⁷ This is a factor that should be taken into consideration when looking to improve treatment adherence in this group.

Low adherence in the treatment of respiratory diseases is not only related to patients not taking their prescribed medication – the mishandling of inhalation devices is another major factor. This results



Edgar Hernan Cuevas Brun
Marketing Manager
T: +886 2 2732 6596 Ext 26
E: henry@hcmed-inno.com

HCmed Innovations
Rm B, 10F
No 319, Dunhua S Rd
Da-an District
Taipei City
Taiwan

www.hcmed-inno.com

in even lower adherence levels when using inhalation therapy for the treatment of chronic respiratory diseases than other types of treatment.⁸ Intending to mitigate this problem, a guideline to optimise adherence for inhaled medications has been proposed. It describes three adherence process phases: initiation, implementation and persistence, and proposes a list of specific solutions for some of the main groups of issues. For example, receiving proper training on the handling of inhalers or switching to another, easier-to-use inhaler are ways to mitigate the patients' lack of knowledge.⁹

INTRODUCING ADHERENCE DEVICES

With the aim of helping patients achieve better levels of adherence to their treatment, several non-digital and digital devices have been introduced in recent years.¹⁰⁻¹² Non-digital devices include inhalers that incorporate counters in their design so that patients can keep track of

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the number of treatments that have been taken or that remain. Digital or connected devices, on the other hand, offer a wider range of features that rely on connectivity functions to allow patients to set reminders for their daily treatment, receive feedback on their inhalation profiles, and even have access to educational sections.¹² In most cases, these connected devices, which are part of the smart device category, are able to collect and store data in a secure data cloud to record treatments. The information can be readily accessed and reviewed by patients, and monitored by medical professionals, thus improving treatment efficacy.

While some smart devices are attached to products for inhalation treatment as add-ons, others have embedded components to the inhalation devices that create the smart functions. When it comes to add-ons, there are several commercially available smart caps that can be used with pressurised metered dose inhalers (pMDIs), as well as a few others that are suitable for dry powder inhalers (DPIs) and soft mist inhalers. On the other hand, most smart devices with incorporated connectivity components are smart nebulisers because their mechanism requires the integration of several other functions to measure parameters and collect information from aerosol-generated performance.

MESH NEBULISER SMART CAP – PULMOGINE+

As awareness of improving adherence to treatment continues to grow, the need for new adherence devices has become crucial in the development of inhalation devices. With the aim of contributing in this field, in 2019, HCmed Innovations began to develop a connectivity accessory that could be suitable for the Pulmogine Vibrating

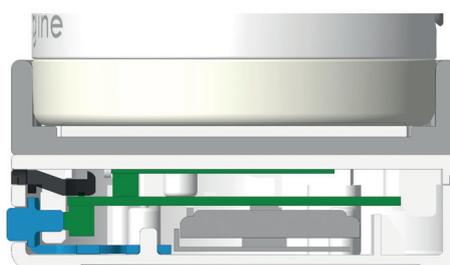


Figure 2: Outer and cross-section views of Pulmogine+.



Figure 1: Pulmogine+ smart cap attached to Pulmogine vibrating mesh nebuliser.

Mesh Nebuliser. After analysing several factors needed for a nebuliser smart cap, such as ergonomics, connectivity, functionality and interface, the initial prototype of the smart cap Pulmogine+ has been completed and presents a number of components to become an important player in the field.

Pulmogine+ is a smart cap that is attached to the bottom part of the Pulmogine device (Figure 1). It is an easy-to-operate add-on that counts with a single on/off button and an LED light that indicates the status of the device (Figure 2). The technology used in Pulmogine+ comprises a Bluetooth system that is able to transmit data to a mobile app to collect information about the patient's nebulisation treatment. To use the smart cap, it should be first paired with a smartphone, through the mobile app. The smart cap is then able to transmit the collected information about the time, date and duration, which could be further translated by the mobile app by detecting the beginning of the treatment, and the end when the nebulisation treatment is complete. The recorded data makes it possible to keep track of a patient's treatment and compliance. This smart cap was designed to offer a simple but reliable mechanism, along with the mobile app, as a well-rounded connected platform.



Figure 3: Pulmogine+ mobile app interface.

The current mobile app demo has a wide range of options and functions. Starting with a slick interface, patients are required to register before the first treatment (Figure 3). Data about the patient is filled out in the patient information section. The next step involves the insertion of the treatment type (Figure 4). At this point, patients can programme the indication and medication for their nebulisation treatment, including the treatment period and the specific time at which the patient should nebulise their prescribed medication. The calendar option allows patients to add the complete length of the treatment that serves as a reminder.

Once all relevant information has been completed, the treatments are recorded and displayed on a simple interface that organises data about the type, time, date

and duration of treatment. The smart cap is also able to collect and retain up to 30 sets of treatment in an embedded memory. By doing this, records can be stored and later downloaded into the database of the mobile app the next time it is connected to the smartphone through Bluetooth connectivity. The inclusion of this function adds flexibility to patients to track their treatment data. Moreover, the mobile app has been designed to collect information in a subsequent connection, even if the Bluetooth is accidentally disconnected during the treatment.

Intending to further enhance patient compliance, a test evaluation page has also been included, which allows patients to track their condition throughout the

entire treatment course. Asthma Control Test (ACT) for adults, Childhood Asthma Control Test (C-ACT) for children, and Chronic Obstructive Pulmonary Disease Assessment Test (CAT) questionnaires are embedded into the mobile app to perform the tests when required by physicians, while keeping records of previous tests (Figure 5). Last but not least, a page comprising instructions for use has also been built in to ensure patients have access to all relevant information that could help them to achieve higher levels of adherence. The cloud system is currently under development and is expected to be ready in 2021 as collaborations with pharmaceutical companies and other partners are established.

IMPORTANCE OF DATA SECURITY AND OTHER ISSUES

Data security has become a big concern in the development of connected devices. As stored treatment and personal data of patients is intended to be shared between patients and medical practitioners, the assurance that all private data is securely stored has become one of the main pillars of connected medical devices. Regulatory

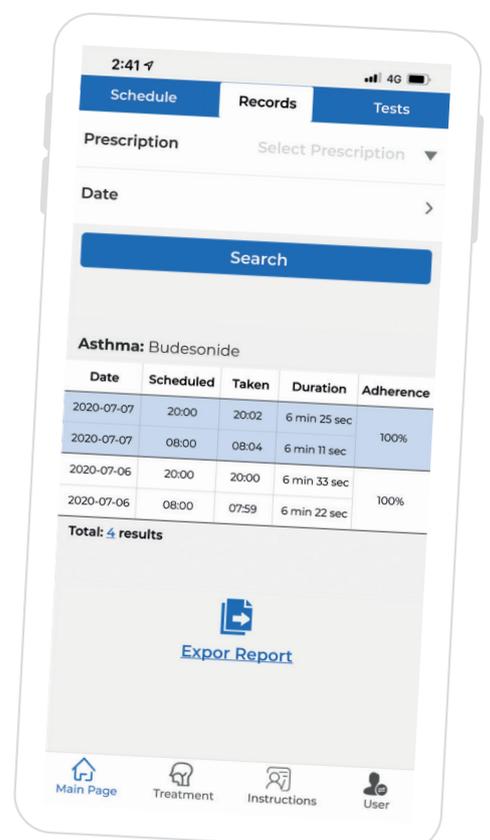


Figure 4: Treatment and indication page of mobile app.

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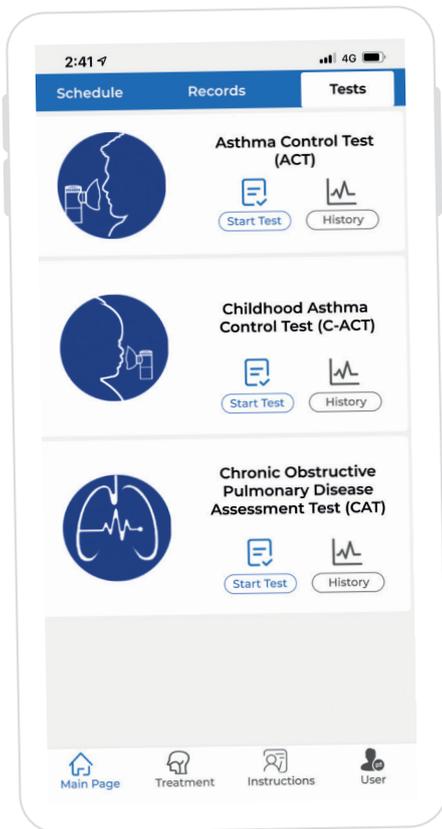


Figure 5: Test evaluation section of mobile app.

compliance for the hardware and software elements of connected devices, such as compliance with the Health Insurance Portability and Accountability Act (HIPAA) and ISO 13485, are fundamental for the development of smart devices.

As new technological advancements and the implementation of existing technologies are included in the development of connected devices for inhalation therapy,

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there are other issues that should also be addressed in order to keep up with the evolution of these devices for improved patient adherence. Among them, providing affordable products is indispensable to allow more patients to have access to these technologies, while properly instructing patients and physicians on the device operation is fundamental, and constitutes a major factor to be considered in the future.⁹ Moreover, sufficient levels of investment in the development process are also required to properly deliver products that fulfil hardware and software standards.

FUTURE DEVELOPMENTS IN CONNECTED INHALATION THERAPY

Existing smart caps for inhalation devices and smart nebulisers are already capable of storing valuable data regarding the treatment of patients, supporting patient adherence. HCmed’s next step is to expand collaborations with medical cloud partners and pharmaceutical companies for the future commercialisation of its connected products; ensuring a secure storage network is the next milestone in achieving commercialisation of connected devices.

Besides the smart cap Pulmogine+, HCmed is also working on a wider range of functionality for its smart breath-actuated nebuliser AdheResp. The AdheResp platform comprises a drug-device combination platform that will allow more data to be collected, such as breathing patterns, to provide insights into the condition of patients and improve adherence. Furthermore, it contains a lock-and-key function that activates the device with the use of a specific drug to reinforce compliance, while ensuring optimal drug delivery.

It is predicted that the next five years will be of great importance in the development of connected devices; therefore, companies should be prepared to play a bigger role in the development of connectivity functions for inhalation therapy. Only by building solid partnerships will it be possible to provide better solutions to patients and help solve current adherence issues.

ABOUT THE COMPANY

HCmed Innovations is focused on the development of drug-device combination products for inhalation therapy. It develops and manufactures portable vibrating

mesh nebulisers that offer a mature customisation platform. This technology enables efficient and reliable nebulisation of different types of medication, including small molecule synthetics and large molecule biologics, as either solutions, suspensions or even difficult-to-deliver high viscosity drugs. The newest products include the incorporation of breath actuation and connectivity features to enhance drug delivery and reinforce patient adherence.

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ABOUT THE AUTHOR

Edgar Hernan Cuevas Brun, Marketing Manager at HCmed Innovations, is responsible for the marketing analysis and research of new products as well as the branding of HCmed’s commercially available mesh nebulisers. He has more than five years of experience in the drug delivery field, holding a degree in biomedical engineering and an MBA. He is also in charge of co-ordinating HCmed’s participation and publications at major conferences, such as the European Respiratory Society International Congress and the American Thoracic Society Conference.

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