THE POTENTIAL OF CONNECTIVITY AND MONITORING IN MESH NEBULISERS

In this article, Carolina Dantas, MD, Manager of Medical and Scientific Affairs, and Ulf Krueger, Chief Executive Officer and Founder, both at Pulmotree Medical, review the current connectivity and remote monitoring capabilities in mesh nebulisers – and their potential to impact patients' healthcare journeys and the clinical development of inhaled therapies.

Worldwide, respiratory diseases affect millions of individuals and remain a leading cause of death and disability, imposing a significant burden on both patients and healthcare systems.[1] The morbidity associated with respiratory conditions is related to symptoms such as breathlessness or coughing, and consequently to a reduction of quality of life. Moreover, the burden of disease extends beyond the patients themselves, with healthcare systems facing increased costs, more hospital admissions and productivity losses. It highlights the importance of developing effective and innovative disease control strategies, which is where novel inhaled therapies and devices assume a promising role.

In the rapidly evolving area of respiratory drug delivery, technologies addressing adherence and inhalation technique offer the opportunity to enhance personalised care for patients.[2] With current nebulisation devices allowing enhanced transpulmonary drug delivery, the potential indications and benefits of the inhaled route go beyond respiratory conditions to broader areas such as cardiovascular or immune diseases.

Digital technologies in healthcare are an active area of research and development, but their long-term success will depend on identifying real needs and integrating the interests of the different parties involved.[3] In the context of mesh nebulisers, despite remarkable evolution of the devices, relevant unmet needs persist and have a distinct impact on clinicians, patients and the industry. While tackling those challenges, connectivity and remote monitoring technologies have emerged as promising tools to help improve patient care, reduce risks in clinical development and push progress in respiratory medicine.

This article reviews, from the perspective of a clinician who transitioned to the healthtech and medical devices industry, the current connectivity and remote monitoring capabilities in mesh nebulisers and their potential to impact patients' healthcare journeys and the clinical development of inhaled therapies.

UNMET NEEDS IN NEBULISED THERAPIES

While progress in nebuliser technology is notorious, there are still relevant challenges to address, particularly when considering the following three important perceptions.

For clinicians, the uncertainties surrounding lung deposition can lead to questioning the treatment efficiency and raise concerns about risks for patients. In clinical practice, there is often doubt about the actual fraction of the administered dose that each patient truly receives and its precise deposition site. It is crucial to understand whether treatment outcomes can be attributed, for example, to disease evolution, the nebulisation process or drug effectiveness. Also, considering that the breathing manoeuvre plays a considerable influence in lung deposition, focus should be put on achieving optimal inhalation during nebulised therapy. Despite efforts from healthcare professionals to train patients, real-life variability in breathing patterns during nebulisation still poses a challenge that needs to be addressed.

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For patients, there is a pressing need for nebulisers that are smaller, user friendly and easy to clean but, at the same time, "smarter", with the ability to guide and provide feedback about the therapy. It is essential to alleviate the burden of disease for patients, by simplifying their interaction with the devices and facilitating therapy adherence, while simultaneously finding a balance between treatment effectiveness and patient engagement.

For the industry, the main challenge still lies in the high risks associated with clinical development of inhaled drugs. The inability to monitor highly influential parameters in drug deposition during inhaled therapies adds difficulty and complexity to clinical trials. The considerable variability in results often leads to costly study repetitions for dose finding and safety evaluation, thereby increasing overall expenses.

Altogether, tackling these unmet needs would help optimise nebulised therapies, ensuring better treatment outcomes, an enhanced patient experience and safer clinical development. Solutions to these problems are offered by the synergy between emerging effective nebuliser technology, innovative connectivity and remote monitoring tools, and the ever-expanding scientific knowledge.

THE RISE OF CONNECTIVITY AND REMOTE MONITORING TECHNOLOGY IN MESH NEBULISERS

Connectivity and remote monitoring technology have gained exponential relevance in recent years, transforming the landscape of medical devices and global healthcare. The progress witnessed so far in the nebuliser industry and, in particular, with mesh nebulisers, is truly remarkable, while the most prominent innovations are still to come to clinical practice. There is transformative potential in integrating mesh nebulisers in digital platforms with connectivity features that enable real-time data capture, remote monitoring and adherence tracking.

Mesh Nebulisers as Part of a Connected Platform

Mesh nebulisers have evolved far beyond their traditional function as standalone devices for respiratory drug delivery. The addition of connectivity capabilities has integrated nebulisers into a connected system or platform. These connectivity features enable automated real-time data transfer by wireless networks to digital platforms such as cloud storage or mobile apps. Detailed data about the inhalation process, flow rate, volume, time of nebulisation and adherence, as well as device status, are collected by the nebuliser and integrated into a connected platform.

As a result, nebulisers have become essential elements within a networked ecosystem that integrates relevant information regarding the therapy and the patient, while also offering the option to combine it with other valuable monitoring tools.

Monitoring Tools for Both Healthcare Professionals and Patients

By incorporating connectivity into mesh nebulisers, both healthcare professionals and patients gain access to information related to the therapy. The ability to monitor and analyse the patient's inhalation parameters, medication adherence and usage patterns can be valuable for clinical teams. When smoothly incorporated in the clinical routine of specialised multidisciplinary teams (nurses, physiotherapist or clinicians), patient monitoring can allow prompt interventions, thereby optimising patient outcomes and minimising risks.

Simultaneously, through these monitoring tools, patients can choose to easily track their treatment progress and receive personalised feedback and guidance using mobile apps or interfaces to cloud-based platforms. This way, connectivity empowers patients by providing them with the possibility to control their own treatment and improve self-management skills, ultimately enhancing patient engagement, adherence and satisfaction.

Reducing Risks in Clinical Studies

It is within the scope of clinical development that the addition of connectivity and remote monitoring capabilities in mesh nebulisers seems to create a greater impact. The ability to capture real-time data from mesh nebulisers to digital platforms allows researchers to collect reliable information about medication adherence, treatment response and patient-reported outcomes. Therefore, there is a minimisation of factors that influence the results of clinical studies and potentially an improvement in the outcomes. Early identification of non-compliant participants allows interventions and re-adjustments in trial design – granting more robustness and higher statistical power to studies. Particularly relevant in respiratory drug delivery, this proactive approach can reduce the need for study repetitions, resulting in accelerated development of novel therapies with lower costs.

Regarding patient safety, connectivity and remote monitoring enable real-time surveillance of study participants. This facilitates early intervention in the case of exacerbations or adverse events, mitigating risks and enhancing patient safety during the clinical development process. Digital platforms connected to mesh nebulisers also centralise data management in clinical trials by automatically capturing, securely storing, organising and analysing information in real time. Essentially, this allows a reduction of the burden for all parties involved in clinical development through optimisation of resources and timelines.

LIMITATIONS AND CHALLENGES

While mesh nebulisers with connectivity and remote monitoring features hold great promise, it is vital to address the challenges that come with their implementation. When it comes to accessing more information, it is reasonable to question the likelihood of usage in real-life clinical practice. Here is where accessibility and usability of digital tools are key to ensure easy access among diverse contexts and platforms in different health systems. Clinical

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development holds the greatest potential for connectivity and remote monitoring tools in mesh nebulisers, but concerns regarding patient data privacy and storage raise ethical and legal considerations. It is crucial to ensure robust security measures and compliance with data protection regulations. Overcoming these limitations and challenges will require collaborative efforts among stakeholders – including clinicians, researchers, technology developers and policymakers – to implement innovation while prioritising patient safety, data privacy and inclusive healthcare delivery.

FUTURE DIRECTIONS

Connectivity and remote monitoring capabilities can potentially revolutionise respiratory drug delivery by providing new patient-side parameters generated during nebulisation – unlocking new pathways for drug development. By capturing real-time data on patients' breathing patterns, such as flow rate and volume, nebulisers could offer important inputs for lung deposition models. This would enable the characterisation and display of each individual inhalation during drug delivery. Access to these previously unattainable parameters could mark a significant advancement in personalised respiratory medicine, fostering further knowledge and pushing evolution in inhaled therapies.

In conclusion, connectivity and remote monitoring features should be seen as a valuable improvement to an optimised mesh nebuliser device, rather than necessary requirements for the therapy. These tools come hand in hand with the technological advancements seen in the nebuliser industry, holding vast potential to help answer unmet needs and push progress in respiratory drug delivery.

ABOUT THE COMPANY

Pulmotree Medical specialises in the development of drug delivery systems with targeted deposition of drugs into specific areas of the lung. It supports pharma partners with comprehensive services around the product lifecycle of drug and device combinations.

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ABOUT THE AUTHORS

Carolina Dantas, MD, is a pulmonologist who adds to Pulmotree Medical the valuable insight of both physicians and patients. Specialising in respiratory infectious diseases and lung-related indications, such as cystic fibrosis and bronchiectasis, she has vast hands-on clinical experience with inhaled drug therapies. As Manager of Medical and Scientific Affairs, Ms Dantas's search for innovation in healthcare matches with Pulmotree Medical's forward-thinking approach to the evolution of respiratory therapies. Besides her knowledge in clinical research, Ms Dantas is an accomplished communicator in science, with published scientific papers, a book chapter and several original presentations at international conferences to her name. She holds a master's degree in Medicine and is a member of several international scientific societies.

Ulf Krueger has extensive experience in life sciences, which is the basis of Pulmotree Medical's business – particularly managing projects, programmes and portfolios in the field of inhaled drug delivery. Throughout his career, Mr Krueger has been particularly engaged in the development of pulmonary drug delivery devices and the targeted delivery of drugs to the lungs. In his former position as Director of Fox Nebuliser Programs at Vectura, he held responsibility for the entire sector of vibrating mesh nebulisers. Before that, he held various positions in the research and development department of PARI. He is a graduate biomedical engineer and a certified senior project manager (IPMA® Level B) and member of several scientific societies.