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AN EVALUATION OF DIGITAL INHALERS: A CLEVER METHOD FOR COPD AND ASTHMA

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ABSTRACT

An important development in the treatment of asthma and chronic obstructive pulmonary disease (COPD) is the creation of digital inhalers. Thus, by providing real-time feedback, dose tracking, and predictive analytics to support patient adherence and maximize treatment outcomes, digital inhalers have brought together digital technology and conventional inhaler devices to create a workable and future-proof solution. The literature on the use of digital inhalers in the treatment of asthma and COPD, as well as their therapeutic advantages, disadvantages, and future prospects, is critically examined in this review. Through AI-driven insights and smartphone connectivity, the goal is to integrate important results and data regarding their effectiveness in enhancing medication adherence, asthma control, tailored treatment plans, and patient outcomes. Nevertheless, despite its advantages, it also has drawbacks, including expense, patient and user acceptability, cost-effectiveness, and data privacy issues. Future innovations that will transform digital respiratory healthcare systems include telemedicine platforms and AI-powered inhalers. With a focus on long-term clinical effects and integration into digital respiratory healthcare systems, this review concludes by highlighting the growing role of pharmacists in utilizing digital inhaler data to enable targeted interventions and drug management with the promise of improving patient outcomes in asthma COPD care.

KEYWORDS: Digital inhaler, Medication adherence, Asthma, COPD, Inhaler technique, Connected health, Remote monitoring.

Abbreviations

Abbreviation	Full form
COPD	Chronic obstructive pulmonary disease.
EMDs	Electronic monitoring devices.
HCPs	Health care professionals.
AI	Artificial intelligence.
PROs	Patient reported outcomes.

1. INTRODUCTION

Long-term respiratory disorders like COPD and asthma can result in spells of increased symptoms, coughing, wheezing, and difficulty breathing. Both illnesses frequently need patients to utilize inhalation medications appropriately and consistently over time, despite the differences in their underlying causes and treatment approaches. For many medications, inhaled delivery can target the airways while limiting systemic exposure; nevertheless, the practical benefit depends on choosing an appropriate device, comprehending the recommended regimen, and using the inhaler correctly.

Nearly 15% of people worldwide suffer from obstructive lung illnesses, for which aerosol therapies are crucial.[1]

Among the most difficult therapeutic approaches for individuals with chronic illnesses to self-administer are inhaled treatments. Certain breathing techniques that are synchronized with the inhaler's aerosol discharge are necessary for the best inhaled therapy. Furthermore, treatment regimen adherence is frequently less than ideal.[2,3,4]

In both asthma and chronic obstructive pulmonary disease (COPD), noncompliance with inhaled treatments is associated with worse outcomes and health status, more hospitalizations and exacerbations, and even death.[5,6,7,8]

Digital inhalers, also referred to as electronic adherence monitors, electronic monitoring devices, electronic medication sensors, or digital inhalers, have been around for the past 20 years, but they are only now becoming a significant part of e-health for the treatment of patients with COPD and asthma.[9]

There are several factors that contribute to medication non-adherence. A person may unintentionally miss doses due to forgetfulness, intricate regimens, cost, or trouble using the device, or they may purposefully miss treatment due to worries about side effects or questions about its benefits. Even when a patient claims frequent use, incorrect technique

may still occur. While standard methods, like interviewing the patient, verifying medication refills, or watching technique during sessions, can yield valuable information, they might not fully capture daily trends.

In order to make certain features of inhaler use visible between clinic appointments, digital inhalers were developed.

Sensors can monitor various aspects of device use or record when an inhaler is activated. While connected dashboards may assist therapists in seeing patterns that call for discussion, linked applications can display reminders, trends, and feedback. The main concern is not just if a gadget captures more data, but also whether the data is precise, intelligible, useful, and linked to significant patient outcomes.

2. Chronic Airways Disease and Inhalation Therapy

2.1 Asthma

Asthma is a common respiratory disease marked by chronic airway inflammation and sporadic symptoms such wheezing, coughing, shortness of breath, tightness in the chest, and physical limitations, Over 260 million people worldwide suffer with asthma.[10] Uncontrolled asthma is linked to a higher risk of severe flare-ups, which necessitate the administration of oral corticosteroids and urgent medical attention.[11,12]

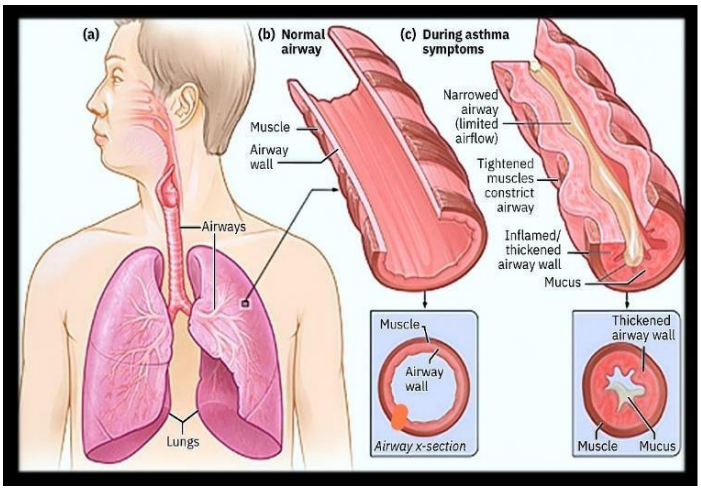


Figure: 1. Structural changes in normal and asthmatic airways.

2.2 Factors Responsible for Asthma

A key element of keeping asthma under control is adherence to inhaled asthma treatments but 43% of patients worldwide do not take their inhaled treatments as directed.[13] Patients, families, and health systems are severely burdened by poor adherence, which raises the risk

of uncontrolled asthma.[11,12] poor adherence can be inadvertent, such as in people with poor inhaler technique, or intentional, such as in people who do not use their inhaler or who have well-controlled symptoms and rightly determine that continued inhaler medicine use is not desirable. Despite initial training and teaching,[14] inhaler technique can degrade over time. Observational studies have indicated a link between poor inhaler technique and a higher risk of hospitalization or emergency department visits.[15,16]

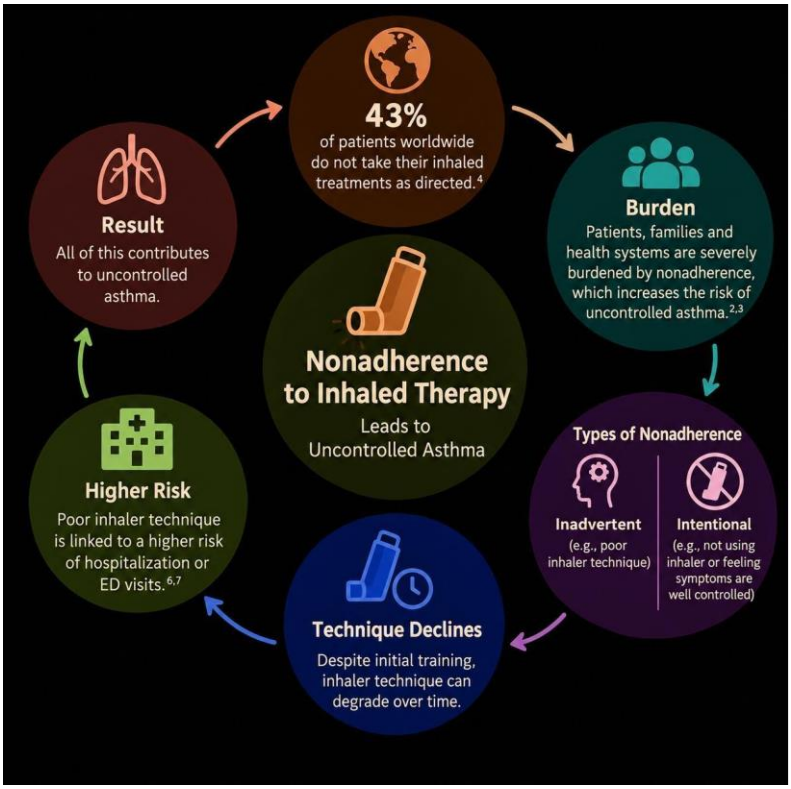


Figure: 2. Cycle of inhaler poor adherence and uncontrolled asthma.

2.3 Use of Digital Inhalers and Medication Adherence in Asthma Patients

Maintaining the best inhaler technique and increasing medication adherence in asthmatic patients may be essential to improving asthma outcomes for both individuals and health systems. Electronic monitoring devices (EMDs) have the potential to improve medication adherence and maintain good inhaler technique by objectively measuring the frequency and accuracy of inhaler use. Unlike standard inhalers, which give patients little to no feedback, digital inhalers give patients direct feedback about their medication adherence, whether they are at risk of becoming overly dependent on short-acting β-agonists, and, for certain digital inhalers, feedback regarding inhalation technique.[17,18] Health care professionals (HCPs) can monitor and remotely offer patients with extra feedback (such as tailored adherence conversations or changes to asthma management) by receiving feedback from the EMD via a

dashboard. Digital inhalers can be either a newly made embedded device or an add-on sensor attachment to a regular inhaler.

Several studies have shown that using digital inhalers reduces the need for rescue inhalers and improves medication adherence, which is defined as frequent daily use of controls.[19-27] Digital inhalers can monitor adherence in two ways: passively, in which the patient is either unaware of the monitoring or receives no feedback; or actively, in which the patient receives biofeedback (BF) and/or clinicians have access to the patient's adherence data, which they can discuss with the patient. When BF is given through reminder notifications and active adherence monitoring by physicians, adherence is better than with passive monitoring.[19,20,23,25,27] Reviewing inhaler use in real time or on a regular basis, like with every clinical visit, is known as active adherence monitoring. Adherence to fluticasone furoate/vilanterol dry powder inhaler (DPI) increased significantly in the group given BF using a smartphone application, according to an RCT involving 437 adults with uncontrolled asthma. Over a 24-week period, the mean (standard deviation [SD]) percentage adherence in the BF arm was 82 (17)%, as opposed to 71 (27)% in a control group using a digital inhaler that was passively monitored (study arm difference: 12%, 95% confidence interval [CI]: 5–19%; $p<0.001$).[27] There was an additional 10% improvement when the doctor actively supervised adherence by examining patients' inhaler use and giving real-time comments. The fact that adherence was significantly higher than usual in the control group should be taken into consideration when interpreting this slight gain. More gains in controller adherence with digital inhalers were found by other researchers.[19,21,23,28,29,30] Another investigation in 100 adults with uncontrolled asthma found that over a period of 14 weeks, adherence to inhaled corticosteroids (ICS) declined less with the use of digital inhalers (−2%; 95% CI −7 to 3%; $p = 0.40$) than in the control group (−17%; 95% CI −26 to −8; $p < 0.01$) which did not receive reminders or feedback on medication use, representing a 15% (95% CI 4–25%; $p < 0.01$) difference.[20] At the same time, the percentage of short-acting beta agonist (SABA)-free days increased significantly in the digital inhaler group (19%; 95% CI 12–26; $p < 0.01$) versus a nonsignificant increase in the control group (6%, 95% CI −3 to 16; $p = 0.18$).[20]

Since claims data do not verify actual medicine use, digital inhaler data not only validate pharmacy claims data but also offer higher granularity and accuracy. Adherence with controllers was optimal (>80%) in 20% of 1745 ambulatory children and adults with asthma, moderately optimal (>50 to ≤80%) in 28%, suboptimal (>20–50%) in 25%, and poor (≤20%)

in 27%, according to a study.[37] Even in patients who were initially optimally adherent, these researchers found that during a 20-week period, adherence with controllers decreased by more than 25%.[37] Due to the already low level of adherence, the moderately adherent group showed the biggest decline in adherence (−32%), while the poor adherence group showed the least (−6%). Additionally, compared to patients in the other adherence groups (63.7% vs. 55.6%), the poor adherence group had an 8.1% (95% CI 2.9–13.3%; $p<0.01$) greater proportion of patients prescribed ICS alone. This finding implies that, in comparison to ICS therapy alone, an ICS product incorporating a bronchodilator may enable improved adherence. Following their release from the emergency room (ED), children with asthma participated in a feasibility study. Adherence to controllers was found to be only 36% in an intervention group compared to 32% in the control group among those who depended on reminder alerts but did not use active digital monitoring.[38]

2.4 Chronic obstructive pulmonary disease (COPD)

Certain forms of permanent lung and airway damage that restrict patients' airways and make breathing difficult are referred to as "chronic obstructive pulmonary disease" (COPD). A patient may have COPD if they have been diagnosed with either chronic bronchitis or emphysema.

When a patient has COPD, their lungs and airways might change in the following ways:

- Patients' airways and lung sacs (alveoli) become less elastic.
- Airway constriction, fibrosis, and inflammation.
- Mucus that is thick in the airways.
- Destruction of the alveolar walls. They get bigger and retain air as a result.

Exacerbations, or worsening of symptoms, such as severe breathing difficulties, thicker mucus, wheezing, and coughing, are common in people with COPD. Severe exacerbations may require hospitalization.

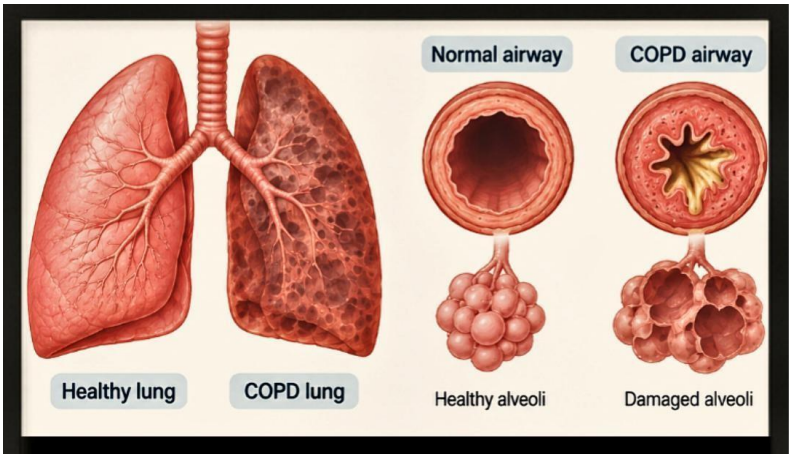


Figure: 3. Pathophysiology of Chronic Obstructive Pulmonary Disease (COPD).

2.5 Use of digital inhalers and medication compliance in COPD patients

An inventive advancement in the treatment of COPD is the use of digital inhalers, which integrate sensors and artificial intelligence (AI) algorithms. By monitoring usage trends, informing patients when their next dose is due, and offering feedback on inhaler technique, these devices can assist patients in better managing their respiratory problems. Compared to conventional inhalers, digital inhalers have a number of benefits, such as better symptom control and drug adherence. According to studies, digital inhalers can lower the risk of exacerbations, increase drug adherence by up to 59%, and enhance the quality of life for COPD patients.

Just around half of COPD patients regularly take maintenance inhalers, similar to those with asthma.[25,39] Using a digital ICS/long-acting beta agonist DPI given at discharge, adherence (when incorrectly taken events were eliminated) was only 30% over a month in a high-risk population of post-hospitalized patients with COPD, where daily use of controls is undoubtedly indicated. Less than 20% of patients routinely and correctly utilized their inhaler, indicating a considerable range in actual use.[25]

3 Digital inhalers

An inhaler that has been improved by technology is called a digital inhaler. One example of a advance medication is a digital inhaler. Technology is used by these medical gadgets to assist in gathering health data. An inventive advancement in the treatment of COPD is the use of digital inhalers, which integrate sensors and artificial intelligence (AI) algorithms. By monitoring usage trends, informing patients when their next dose is due, and offering feedback on inhaler technique, these devices can assist patients in better managing their respiratory

problems. Reminders can also be sent by a digital inhaler. If someone has problems remembering the dosages, this could be useful. Additionally, each app records the use of a maintenance inhaler and a rescue inhaler independently.



Figure: 4. Different types of digital inhalers.

For the seamless transfer of death to a centralized platform or the system's healthcare providers, digital inhalers' networking features are crucial. These devices use Bluetooth or other wireless communication protocols to establish a connection between the patient and their care team. In addition to real-time data monitoring, this connection enables prompt interventions. When a patient forgets a dosage or uses an inhaler incorrectly, for instance, automated notifications can be sent out to give advice or serve as a reminder. By offering real-time feedback, individualized insights, and reminders, digital inhalers boost patient empowerment and accountability. Compared to conventional inhalers, it has a number of benefits, such as better symptom control and drug adherence. According to studies, digital inhalers can lower the risk of exacerbations, increase drug adherence by up to 59%, and enhance the quality of life for COPD patients. Inhalers are most frequently used by those with long-term lung conditions that impair breathing, such as asthma or chronic obstructive pulmonary disease (COPD).

Digital inhaler health platforms are made up of an inhaler that has been digitalized with one or more electromechanical sensors and related microelectronics to track the date and time of inhaler actuations. A connected smartphone, a specialized mobile application that collects data and communicates with the patient, a cloud server, and a portal for the physician to examine data sent to their dashboard are additional characteristics seen in some systems. Sensors for both rescue and controller inhalers can be employed with these single-user

devices. iOS and Android devices are compatible with all digital inhaler platforms, and their data is protected. The location of the "inhaler" is determined by the patient's smartphone and can be connected to environmental reporting for platforms that gather location data. The inhaler cannot currently be located using the Global Positioning System (GPS) because the data is derived from the smartphone rather than the inhaler's actual location.[40] This could limit the accuracy of connecting location data with inhaler use and/or tracking environmental exposure to triggers and association with asthma exacerbations.

The most popular commercial digital inhaler devices for tracking inhaler use (1) Propeller Health—global, (2) Teva Digihaler®—USA, (3) Amiko Respiro®—Italy, Germany, Portugal, Netherlands, and (4) Adherium Hailie®—global. Although the INCA gadget (available in Ireland and the UK) is not yet on the market, this evaluation includes published studies on the device that has greatly advanced our knowledge of this technology. The electronic sensors are either integrated within the inhaler (Teva Digihaler®, Respiro RSX01 dry powder inhaler) or attached (Propeller Health, Hailie®, Respiro®, INCA).[41] While inhalers with inbuilt sensors are recognized as drugs with digital capabilities and must go through separate regulatory processes for clearance, attachable sensors are considered devices. An electronic sensor time-stamps, logs usage, and retains data for a limited amount of time with each inhaler actuation. Some manufacturers' digital inhalers have extra sensors that measure air flow during inhalation or report sufficient shaking of pressurized metered-dose inhalers (pMDIs) before patient usage, in addition to recording patient inhaler use. For these readings, these sensors rely on variations in vibration, sound waves, or pressure. The inhaler's built-in batteries usually last up to 13 months. Depending on whether they are an inhaled medication with an integrated sensor or only a sensor device (510(k) approval), digital inhalers in the US must pass manufacturer testing and adhere to regulatory requirements.[42]

Patients can interact with their smartphone's digital inhaler application, which allows them to view current environmental conditions, record their health status using tools like the Asthma Control Test (ACT),[43] receive daily controller reminder alerts, and review their inhaler use on a daily, weekly, or monthly basis. Patients can activate and deactivate the devices' auditory and/or visual notifications to remind them to utilize their maintenance inhalers on a daily basis. Certain devices receive the signal directly from the digital inhaler, while others use alerts from smartphones.

Certain platforms offer smartphone alarm messages when rescue inhaler overuse occurs, recommending patients to get in touch with their physician and medical team. With each enrolled patient's permission, clinicians can view all data produced by the digital inhaler when it is synchronized with an internet-connected smartphone. Viewing the patient's controller adherence, evaluating some parts of inhaler technique, identifying medication overusers, reviewing whatever clinical data the patient has provided on their digital dashboard, and creating reports of these events are all possible remotely and in real time.

3.1 The ailments that can be treated by digital inhalers

Asthma and COPD are most frequently treated with inhaled medicines. They are occasionally prescribed by doctors to treat bronchitis and other respiratory illnesses.

Additionally, providers employ them to treat:

- Cystic fibrosis
- Diabetes
- Flu
- Parkinson's disease
- Schizophrenia.

3.2 DIGITAL INHALER: Working

Using a digital inhaler is easy.

Digital inhaler add-ons are medical gadgets that collect detailed information about each inhaler use. They use Bluetooth to transmit data to the phone's application, which in turn gives researchers or doctors information on COPD and asthma for more effective therapy.

1. ATTACH: Attach a smart gadget to your inhaler.
2. CONNECT: Connect the device to your phone's app
3. COLLECT: Utilize the inhaler as previously and get information
4. SHARE: Receive precise care based on accurate data.

3.3 The information gathered by a digital inhaler

Every time a drug is used, digital inhalers gather extensive data. It comprises, among other things:

- Uses of medications.
- Incidence of asthma attacks.
- The impact of weather on inhaler use.

- Medication compliance.
- Phases of aggravation.
- Long-term patterns and data.

4 Digital Inhalers' Advantages

Integration of telemedicine and remote monitoring: digital inhalers enable remote monitoring of patients' asthma treatment, which may be particularly helpful in situations when in-person visits are challenging. Healthcare professionals can examine patient inhaler usage data and symptom trends via a connected portal. By using this feature, physicians may monitor patients' progress, adjust treatment plans, and provide timely advise without having to meet in person. Depending on the time of the dose, digital inhalers remind patients to take their medications on time, easily, and automatically. They also notify patients of missed or repeated doses. The patient can receive these reminders from any location. When there are numerous medications to remember, these gadgets might reduce the stress associated with remembering to take them on time. Finally, they track symptoms for both patients and doctors to understand how, where, and when symptoms worsen and to monitor the usage of the rescue inhaler for immediate short-term relief. They can also help enhance inhalation technique and efficacy.

The therapy of conditions like diabetes mellitus, obstructive sleep apnea, and heart disease is being revolutionized by the expanding digital transformation of healthcare.[44] Although digital inhalers have been around for more than 20 years, their adoption into standard clinical practice has been sluggish and they have mostly been used in clinical trials. Payers are becoming more supportive of the use of digital inhalers in clinical practice as a result of their increased availability, capabilities, and the benefits of their usage in clinical studies.[45] Crucially, because of better adherence and related health outcomes in asthma and COPD, these devices are projected to result in significant cost savings.[46,47] We go over the significant significance that these devices could play in the treatment of COPD and asthma patients.

5 Increasing the use and adherence to inhalers

Patients with asthma and COPD have some of the lowest rates of medication adherence for common chronic diseases,[48] which has a substantial influence on health outcomes and expenses.[46,47] Poor adherence has been linked to a higher risk of exacerbations, worse symptom control, and mortality in both COPD and asthma.[46,49-52] Long-term

maintenance therapy adherence is typically 50%,[53] while adherence in asthma and COPD may be even lower because nonadherence frequently has no immediate repercussions for the patient.[54,55] According to pharmacy claims data, people with asthma[56] and COPD[57] frequently use daily maintenance drugs at a rate of less than 50%. It has been demonstrated that poor adherence and the ensuing poor clinical outcomes result in higher direct and indirect expenses; studies have revealed that suboptimal inhaler use costs the US economy between $7 and $17 billion annually.[58,59] However, health care usage is decreased, patient-reported outcomes (PRO) are improved, and mortality is decreased in patients with substantial disease who take their inhaled drugs as prescribed.[54,60,61] Clinicians encourage daily use of controllers because studies on asthma and COPD suggest the regular use of maintenance inhalers (also known as adherent and regulated). Based on patient self-reports of inhaler use, physicians tend to overestimate adherence, and digital adherence monitoring will probably show that more of their patients are poorly managed and do not follow their recommended regimen.

6 Improving Patient-Reported Outcomes (PROs)

The effect of digital inhalers on PROs in pediatric asthma,[19,22,24,30] adult asthma,[20-22, 24,25,33,36] and COPD[27,33,36] has been documented in seven investigations. Whether using[19,24,25] or active clinician monitoring,[20,22,26,36] PROs generally improved in the majority of asthmatic patient studies. Improvements in PROs were not statistically significant in two asthmatic patient investigations.[21,30] It's interesting to note that PROs improved when digital inhalers with SABA alone were used (i.e., no controller treatment),[22,24,26] maybe as a result of the research/health care team's tighter monitoring and cooperation. In two studies of COPD patients, PROs improved with the use of digital inhalers,[26,36] but not in another study.[33] This could be because the latter study only included patients who had experienced an exacerbation in the prior year, potentially representing patients with more uncontrolled disease than in the other two studies.

7 Future Applications and Implementation Considerations

The adoption of digital technology in ordinary clinical practice is still hampered by a number of factors, including cost, patient and provider acceptability, data management, sustainability, and successful integration into the care pathway.[62] Improving uptake can be achieved, for instance, by outlining the function of digital inhalers in illness monitoring and diagnosis. The characteristics of patients who are most likely to benefit from the adoption of digital inhaler-

based therapies are now being studied.[63] Informed permission, autonomy, trust, privacy, secrecy, and remote patient monitoring are more ethical concerns that may need to be taken into account before being put into practice for patients, providers, and other stakeholders.[64] However, these concerns are not unique to digital inhalers; remote patient monitoring has long been used in other medical specialties, such as cardiovascular disease, diabetes, and tuberculosis, and these ethical and privacy concerns have been thoroughly examined and discussed,[65] taking into account the special advantages that electronic adherence monitoring offers. In particular, digital inhalers only gather device-specific data, namely the date and time of each dose; certain devices, like the Digihaler, also log PIF. The devices do not track or record any other data; location data is only gathered when paired with an app. The microphone is positioned to block out background noise and other irrelevant audio, and even audio-based systems capture data for less than a minute before "timing out." The Health Insurance Portability and Accountability Act (HIPAA) must be complied with for any data transferred on the cloud. As with other electronic medical records, people have the option to opt out of cloud data sharing and only share data via direct download between the device and computer.[66] When paired with artificial intelligence techniques, digital inhalers' ability to provide comprehensive information regarding medicine administration has the potential to completely transform the treatment of asthma and COPD. For instance, Inspirer Mundi uses a machine learning approach that can evaluate pharmaceutical self-administration to enable remote monitoring of inhaler use.[67] The "big data" collected by digital inhalers may be able to forecast and/or lessen future exacerbations if these artificial intelligence techniques can be applied to it. However, a significant quantity of data will be needed to accomplish this, and it will probably need to come from a variety of sources, including data from cellphones, digital spirometers, and/or other wearables like smartwatches, in addition to the data acquired by the inhaler device.[66]

8 CONCLUSION

By bridging the gap between prescribed treatment and actual medication use in patients with asthma and chronic obstructive pulmonary disease (COPD), digital inhalers represent a promising advancement in respiratory healthcare. These devices provide valuable insights into medication adherence and inhaler-use patterns through electronic sensors, digital feedback, personalized reminders, and real-time monitoring. Their integration with smartphone applications and healthcare professional dashboards can support timely interventions, improve inhaler technique, and facilitate more individualized disease

management. According to the evidence discussed in this review, active monitoring, combined with patient feedback and professional guidance, can improve medication adherence and may contribute to better disease control and patient-reported outcomes. However, patient acceptance, data privacy, affordability, and integration into routine clinical practice remain significant barriers to their widespread adoption. Future advancements in artificial intelligence, telemedicine, and predictive analytics could further enhance their clinical utility.

Ultimately, digital inhalers should be viewed not merely as medication-monitoring devices but also as tools for strengthening collaboration between patients and healthcare professionals. With appropriate clinical guidance and further long-term research, their effective implementation has the potential to promote patient-centred respiratory care and improve the overall management of asthma and COPD.

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