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REVIEW ARTICLE

A REVIEW ON INTEGRATING SMART INHALERS FOR ASTHMA MANAGEMENT: A STEP TOWARD DIGITAL RESPIRATORY HEALTHCARE

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Abstract

Asthma remains one of the chronic respiratory disease that affects millions of individuals globally, over time, conventional inhalers have remained greatly useful in asthma control Nevertheless, there still exists a great deal of challenges in control of asthma including; lack of compliance, inappropriate inhalation methods, and lack of monitoring. Therefore, smart inhalers have introduced the union of digital technology and traditional inhaler devices, creating a viable solution and a future-proof solution through offering real-time feedback, dose tracking, and predictive analytics to aid patient adherence and optimize treatment results. The current review critically examines the current literature relating to the use of smart inhalers in the management of asthma, and their clinical benefits, drawbacks, and future perspectives. The objective is to combine critical findings and data regarding their efficacy in improving medication adherence, asthma control, treatment plans individualized and patient outcomes via AI driven insights and smartphone connectivity. However, despite its merits it also has limitations such as cost, user acceptability differing patient acceptability, cost-effectiveness and data privacy concerns. Future technologies, such as AI-powered inhalers and telemedicine platforms are set to revolutionize the digital respiratory healthcare systems. Lastly this review highlights the emerging role of pharmacists in using smart inhaler data to enable targeted interventions and drug management, with attention to long-term clinical effect and integration into digital respiratory healthcare systems with the promise of improving patient outcomes in asthma care.

Keywords: Asthma, digital healthcare, medication adherence, respiratory medicine, smart inhalers.

INTRODUCTION

Asthma, a chronic inflammatory airway disease, affects hundreds of millions worldwide and is a significant public health burden[1]. Control is highly dependent on patient adherence to prescribed inhaled corticosteroids and bronchodilators, which unfortunately is not satisfactory for the majority, leading to suboptimal control of asthma, more exacerbations, and higher health care utilization[2,3]. Forgetfulness, inadequate inhaler technique, and ignorance of the necessity of the drug provide facile facilitation for non-adherence[4].

Emergence of smart inhalers as technological advancements

To combat such chronic problems, "smart inhalers" battery-driven electronic devices clipped onto or integrated with conventional inhalers have now been launched as a new technology with potential. These can automatically monitor inhaler use, remind the patient, monitor inhaler technique, and report to patients and clinicians[5]. By offering unbiased feedback regarding medication adherence and inhaler use, smart inhalers can revolutionize asthma self-management and facilitate more individualized therapeutic treatments.

Exploring integration, key benefits, challenges and future prospects

This systematic review critically evaluates the current evidence of integrating smart inhalers in asthma management. This review aims to synthesize evidence regarding their effectiveness in improving medication adherence, asthma control, and patient outcomes, and examine associated challenges as well as the evolving role of pharmacists. Last, this review emphasizes the requirements of further research into long-term clinical impact and easy incorporation within existing health-care systems to maximize the potential of this technology.

Smart inhalers: Technology and mechanism

Smart inhalers are a novel technology innovation in the management of chronic respiratory disease including

asthma and COPD. Moving beyond the mere inhaler device, smart inhalers utilize digital technology to provide objective real-time feedback regarding medication usage, technique, and patient behavior[6,7]. This new functionality is designed to meet the main deficit between prescribed therapy and actual patient adherence and thereby maximize therapeutic effect and patient self-management of their own disease[8].

A smart inhaler is an electronic inhaler, either an add-on to an existing metered-dose inhaler (MDI) or dry powder inhaler (DPI) or an integrated inhaler, equipped with sensors and connectivity options[9]. Its primary function is to track and transmit digitally information regarding inhaler use, providing an overall picture of take of medicine and inhaler technique[7]. Smart inhalers, unlike traditional inhalers that rely on unverifiable patient self-reporting or on-clinical observation, yield an objective and real-time monitoring solution[8]. Smart inhalers transform the inhaler from an inactive drug delivery device to an active data collection device, forging an essential connection in the digital health platform for respiratory therapy[10].

Key components and functionality

Smartness in smart inhalers relies on the synergistic operations of some key components: sensors, bluetooth connectivity, mobile applications[11].

Sensors

At the heart of all smart inhalers are sophisticated sensors that have been programmed to track the various parameters of inhaler use. The sensors are key to acquiring objective information that guides patients and physicians alike[12].

Actuation Sensors: These are simple and detect when a dose is actuated from the inhaler. In the case of MDIs, it would typically be pressure sensors on force imparted on the canister. In this case, for DPIs, it might include devices to detect movement of a lever or opening of a dose counter. This information allows for precise monitoring of doses taken[14].

Inhaled flow sensors: For DPIs alone, they measure the inspiratory flow rate of the patient during inspiration. Optimal DPI drug delivery is heavily dependent upon a firm, consistent inspiratory effort. Such sensors can pick up on whether a patient's inspiratory effort is too feeble or too short and is therefore predictive of less than optimal technique that will lead to less than optimal medication into the lungs.

Accelerometer/gyroscope (orientation sensors): A few smart inhalers utilize accelerometers or gyroscopes to identify the orientation of a device. This might be utilized to ascertain whether the inhaler was oriented vertically during use (critical for MDI proper use) or whether the patient shook the MDI before use[6].

Time stamp sensors: Each data point that is being recorded is also time stamped, providing an accurate record of when each dose was taken. It would be possible to look at dosing rate, frequency of the dose, and if medication is being taken as directed (twice a day, as needed, etc.)[14].

Bluetooth Connectivity

Bluetooth Low Energy (BLE) is the data transmission technology behind smart inhaler devices. In recording usage history through sensors, data is transferred wirelessly from the inhaler to a compatible device, typically the patient's smartphone or tablet.

Smooth transfer of data: BLE allows for low-power efficient transfer of data to avoid depletion of the inhaler's battery life. Pairing is also nearly automatic so that patient uploading of data is not required[15].

Data Hub: The smartphone of the patient may be employed as an intermediary data hub where it receives the usage logs of the smart inhaler. This allows local storage of the data and subsequent synchronization with cloud platforms for storage and long-term analysis. In recording usage history through sensors, data is transferred wirelessly from the inhaler to a compatible device, typically the patient's smartphone or tablet.

Security: Encryption protocols for data are required to ensure security and privacy for patient confidential health data in transit and at storage[17]. Integrity and confidentiality of the data gathered through smart inhalers need to be ensured. Threats involved are bulk data leaks, illegal data transmission, and even data tampering stored, which might result in inaccurate treatment choice or even patient harm[18].

Mobile Applications (Apps)

The smartphone application is the primary interface through which patients, and at times clinicians, interact with the smart inhaler system[18]. It processes raw sensor data and convert it into actionable information

Tracking of adherence and visualization: The application provides a transparent, easy-to-read record of drug intake, e.g., dates, time, and potentially number of doses taken. Visual signals such graphs and charts can be used to educate patients regarding trends in adherence over time and good or bad times of adherence[19].

Reminders and alerts: Applications can be programmed to remind users of the missed doses for overcoming forgetfulness. They may even give notifications for missed doses or lack of use of the inhaler within a certain time frame[13].

Technique feedback: In case the smart inhaler has inhalation flow or orientation sensors, the app can provide instant feedback about inhaler technique. This can be in the form of visual prompts or reminders to the patient to breathe better, to hold the device appropriately, or to shake before an MDI dose properly[12].

Asthma control assessment: Some apps include evidence-based asthma control questionnaires (e.g., Asthma Control Test - ACT) or symptom trackers. Patients may be requested to report their symptoms at periodic intervals, and the app can correlate this with drug use, presenting an overall picture of asthma control[20].

Data sharing and communication: A natural part of healthcare integration, applications allow patients to share use data confidentially with their doctors, pharmacists, or other caregivers. This allows healthcare providers to see objective technique and adherence information, guide decision-making, and tailor counseling sessions[21].

Learning resources: Applications are typically complemented with learning resources on asthma, facts about medicine, triggers, and proper inhaler use, educating patients with the information they need to better control their disease[20].

Mechanism of smart inhalers

Smart inhalers operate through a continuous loop of data gathering, transmission, analysis, and feedback with the aim of enabling patients as well as healthcare professionals to gain greater control over respiratory disease.

Dose tracking

The elementary mechanism is dependent on precise tracking of the doses. When the patient initiates actuation of their inhaler, actuation sensors of the smart inhaler (or add-on device) log this event. These sensors are configured to record the physical movement of actuating the canister on an MDI or individual actions involving dose preparation and inhalation with a DPI[14]. Concurrently, a timestamp sensor records the exact date and time of actuation. This raw data—timestamp and dose count are held momentarily on the internal memory of the device. This objective notation is much superior to the recall-biased and inaccurate patient self-reporting, and hence provides a valid and verifiable account of drug-taking behavior[22]. The system can then analyze these timestamps to examine whether doses are being taken at prescribed time intervals, whether doses are being skipped, or whether there's excessive use of rescue drugs.

Monitoring of inhalation and technique feedback

In addition to simple dosing counting, most of the smart inhalers have advanced sensors to measure the patient's inhalation style required for effective drug delivery.

Flow rate assessment: In DPIs, the speed of the patient's inhalation and amount of air intake are observed with the help of inhalation flow sensors. Proper use of DPI is a deep and rapid inhalation in such a way that the drug in powdered form is properly dispersed and distributed to the lungs. Should the inspiratory flow rate of the patient fall short of the optimal rate for the specific device, the smart inhaler system can sense this as an ineffective method[14].

Device shaking and orientation: Accelerometers and gyroscopes detect the orientation and movement of the inhaler. For MDIs, shaking the device before each use and keeping the device in an upright position during actuation are necessary to ensure adequate suspension of drug and are actions that sensors can verify are performed correctly. Inadequate technique, such as not shaking an MDI or breathing in too lightly when using a DPI, can lead too much of the medication settling in the mouth and throat rather than in the lungs, and this reduces therapeutic effect[12]. Upon detection of a technique error, the companion mobile app of the system can then provide immediate, real-time feedback to the patient. This is typically in the form of visual cues (e.g., a “red light” alert on the device or a graphic on the app), sound signals, or even short instructional videos that depict correct technique. Such immediate correction allows patients to correct their errors for subsequent doses, leading to better long-term technique and improved drug delivery[18].

Integration of environmental contextual data and alerts

Some of the most advanced smart inhaler platforms draw on external data sources in order to provide contextual data and proactive alerts towards a more preventive and personalized asthma care approach.

Environmental data integration: The two-way mobile app enables smart inhalers to integrate in external data streams such as local weather forecasts in the neighborhood, real-time pollen counts, and air quality indices (AQI) tracking concentrations of pollutants such as particulate matter (PM2.5), ozone, and nitrogen dioxide. Such integration most often makes use of the smartphone's location services to tap into local environmental data.

Trigger detection and preemptive alerts: By correlating the patient's inhaler usage patterns (specifically rescue inhaler usage) and self-reported symptoms with such environmental variables, the system can help detect certain asthma triggers for the patient. For example, if a patient had been using their rescue inhaler regularly on high-pollen or poor air days, the app can alert the patient to the association so that they realize what aggravates them exactly. Apart from this, some systems can provide proactive notifications to patients when they are or will be in an area that has high trigger levels. These alerts can command them to take preventive medication, don their rescue inhaler, or avoid certain activities outdoors, hence limiting anticipated exacerbations in advance[20]. Such a role revolutionizes asthma treatment from a purely reactive regime to a predictive and preventive one[25]. The entire data collected dose monitoring, inhalation technique, and environmental environment is typically transmitted via Bluetooth Low Energy (BLE) to an associated smartphone or tablet. It is then typically synced with a secure cloud-based system, wherein both the patient (via mobile app) and authorized healthcare professionals (via clinician dashboard) can access it. This robust data stream enables informed clinical decision making, patient individualization, and remote patient monitoring, ultimately resulting in improved overall asthma care[15,17,25].

Types of smart inhalers

Smart inhalers, by virtue of their capacity to track digitally the inhaler usage, can be divided into two main categories in terms of their level of interaction and response: passive monitoring devices and active monitoring devices. It is worth appreciating the difference between the two in an attempt to appreciate the different functionalities and clinical effects of various smart inhaler systems on asthma and COPD management.

Clip-on sensor devices or passive smart inhalers

Passive smart inhalers or electronic monitoring devices (EMDs) are smart inhalers that contain sensors that attach to existing inhalers and automatically track usage without requiring patient input. They are concerned with collecting objective data without concurrent intervention or interactive guidance of the

patient. Examples are; propeller health's sensors and adherium's smart inhaler sensors.

Process of operation

Dose tracking: The meters contain sensors (e.g., DPI mechanical sensors, pressure sensors for MDIs) that record every actuation of the inhaler. Every dose consumed has a timestamp assigned to it. The information is kept within the device for some period of time[27].

Data transmission: Periodically, this data that is stored is transmitted, typically through Bluetooth Low Energy (BLE), to a connected smartphone or a dedicated home hub. Subsequently, it is typically uploaded to a secure cloud-based location where it is made accessible to healthcare providers[28].

Immediate feedback missing: The definitive feature of passive systems is that they never offer immediate audio, visual, or tactile feedback to the patient during or shortly after an inhalation event in terms of their technique or compliance. In certain designs, the patient does not even realize that their use is being tracked[27].

Primary purpose

To enable objective adherence data to be given to healthcare professionals so they can look for underuse, overuse, or inconsistent dosing patterns at follow-up consultations. Clinical consultation may be informed by this data, and treatment plans retrospectively corrected[18]. To enable research by giving real-world accurate adherence data for clinical trials and observational studies[29].

Advantages

- Convenience for the patient as it involves minimal active effort beyond usual inhaler use[27].
- It has a foundation layer of objective adherence data, better than self-reported adherence[14].

Disadvantages

- This type of inhalers does not fix real-time technique errors or missed doses[18].
- It is dependent on a healthcare provider to view data and offer feedback, thereby interventions are delayed.
- It is dependent on a healthcare provider to view data and offer feedback, thereby interventions are delayed[14].
- It will not contribute to a direct effect in enhancing adherence or technique independently without an official intervention program[18].

Integrated smart inhalers or Active Monitoring Devices

Active smart inhalers extend beyond passive data logging since they possess features that serve to give immediate feedback and interactive interaction with the patient. They require patient to actively engage with the device. They are specifically intended to actively aid and support enhanced adherence and technique. They mostly involve manual data entry or confirmation of inhaler use which help patient to stay engaged with their treatment plan (e.g teva's pro air digihaler)

Process of operation

High-end sensors: Besides timestamp and actuation sensors, active devices provide advanced sensors like inhalation flow sensors (more precisely for DPIs), accelerometers, and gyroscopes. These sensors record accurate inhalation maneuver parameters such as inspiratory flow rate, time, and device orientation[29].

Real-time feedback: It is the characteristic of active monitoring. Instantly after an inhalation, the device or its peer mobile app compares the sensor data against saved best parameters. In the event of deviation (e.g., insufficient inspiratory flow, improper MDI shaking/holding), the system immediately gives feedback in the form of visual cues (e.g., lights on the device, on-screen alerts), audio cues, or even brief instructional videos in the app. This feedback loop in real-time enables the patients to adjust their technique on future doses[30].

Reminders and alerts: Personalized reminders for due doses, reminders for missed doses, or alerts in the event of forgetting the inhaler can be provided through mobile applications associated with active smart inhalers[31]. Active reminders are designed to directly influence adherence.

Contextual data integration: Sophisticated active systems combine external data, e.g., local air pollution, pollen counts, and weather. By correlating them with symptom data and use of inhalers, the system can assist patients in determining individual triggers and offer pre-emptive warnings[32,33]. That is predictive and preventive care.

Interactive patient engagement: Apps linked to active devices sometimes have dashboards to display adherence and technique trends, symptom tracking facilities, educational materials, and occasional gamification to foster frequent use[34]. Safe information sharing with healthcare professionals also supports personalized telehealth consultations[35].

Primary purpose

- To directly enhance medication adherence and address inhaler technique in real-time[7].
- To enable patients to receive real-time, actionable information in order to improve self-management[31].
- To supply detailed information to allow healthcare professionals to deliver highly personalized and timely interventions[31,35].

Advantages

- Resolves directly several of the barriers to effective use of inhalers (forgetfulness, technique).
- Encourages patient self-efficacy and active engagement with their own care[31].
- Delivers richer, more actionable information to clinicians, allowing for more accurate therapeutic manipulation.

Disadvantages

- More likely to be more expensive than passive monitors[31].
- More challenging to operate for patients, in need of smartphone literacy and repeated app use[27].
- It Concerns regarding data privacy and security, as the involved data are sensitive[34].
- Risk of "alert fatigue" in case reminders are not optimized or personalized[31].

Clinical benefits of smart inhalers

Smart inhalers constitute an important advancement in chronic respiratory disease management for chronic conditions such as asthma and chronic respiratory pulmonary disease. By combining digital technology with the traditional inhaler hardware, they provide features beyond mere medicine delivery, providing objective data, real-time intelligence, and information with meaningful patient outcome impact. Clinical advantages of such devices cut across some of the most important areas leading to better and personalized respiratory care[32].

Improved medication adherence

The most important problem in chronic respiratory disease management is good and regular medication adherence. Non adherence is generally followed by poor disease control, more symptoms, and risk of more exacerbations. Smart inhalers actually fix this by providing objective monitoring and proactive reminders[33].

Objective data collection: Inhalers that are "smart" have the ability to automatically capture date, time, and even location of each actuation, providing a precise and objective measure of medication usage that is less likely to be subject to error than patient self-report or prescription fill rates. The high level of detail in such data enables healthcare providers to understand patient behavior and patterns of adherence[36,37].

Real-time reminders and alerts: Related mobile apps can provide customized reminders for drugs that were given, remind patients to be alerted for missed doses, or even remind them if they left their inhaler behind[36,38]. Active reminder prompts remind patients to follow maintenance medication as advised. Evidence suggests that audiovisual reminder features can greatly enhance the medication adherence of adult asthma patients[14,28]. Usage of real-time and heterogeneous reminders also aids in reducing the likelihood of "alert fatigue"[14].

Enhanced self-management: By providing patients with a physical record of their medication use, intelligent inhalers enable them to better understand their actual patterns of adherence and hence develop more self-management skills. Such awareness can encourage patients to use their inhalers correctly and regularly[18].

Better symptom control

In addition to enhancing adherence, smart inhalers also optimize symptom control by the data-driven insights into disease patterns and precipitants, allowing better management decisions.

Identification of patterns and triggers of worsening control: Longitudinal use information is gathered from smart inhalers, which, when supplemented with patient self-reported symptoms, may be used to identify patterns of worsening control or indeed likely triggers. This enables patients and caregivers to monitor exacerbating symptoms and act preventively[34,35]. Certain smart inhalers are able to detect environmental conditions, such as high levels of pollution or pollen zones, offering additional information regarding possible triggers[39].

Inhaler technique feedback: Smart inhalers that are equipped with sophisticated sensors are capable of evaluating inhalation parameters including inspiratory flow rate, time, and direction of the device[40]. These devices offer audio-visual real-time feedback on technique error (e.g., inappropriate shaking, coordination), which can be altered by the patient in real time[35,41]. Appropriate technique is necessary for effective drug delivery to the lungs and directly influences improved symptom control[14,35]. It has been demonstrated that there is a high patient correlation with incorrect inhaler technique, making this real-time feedback crucial[35].

Enhanced control asthma scores: Clinical trials have shown that patients treated with digital inhaler systems have enhanced asthma control in comparison to conventionally managed patients. As a case in point, one trial reported an 88.7% probability for better control of asthma in patients using a particular digital inhaler system[35]. This is generally associated with reduced reliever medication use, reflecting better underlying disease control[14,34].

Personalized treatment plans: The volume of data collected by intelligent inhalers carries the potential for strongly personalized treatment plans that go beyond the one-size-fits-all approach. Although AI-based recommendations are an emerging field, evidence supporting personalized plans is robust and underpinned by contemporary capabilities.

Clinician granular insights: The granular data regarding drug use, technique, and symptom relationship give clinician's granular and distinctive insights that cannot be reasoned with traditional inhalers. The objective data enable clinicians to make more specific and personalized medication modification, dosage change, or additional patient education decisions[14].

Identification of suboptimal behaviors: Smart inhaler data are able to identify some suboptimal behaviors, including variable use or inappropriate technique, so that healthcare providers can shape interventions to the individual needs of the patient[14]. Targeted treatment has the potential to result in more effective therapeutic alterations[29,37].

Integration with environmental data: Highly advanced smart inhaler systems can be integrated with external data streams such as local air quality, pollen counts, and meteorological data by correlating patient inhaler use and symptom data with environmental conditions, the system is able to identify individual triggers and deliver proactive, personalized warnings or recommendations (e.g., "High pollen today, take your preventive medication")[36,37,40]. This is also a step towards predictive and preventive management strategy, enabling more personalized management plans in terms of environmental triggers[39].

Base for predictive analytics and AI: The ongoing nature of real-time data from smart inhalers provides a strong data set that is poised to be augmented in the future by predictive analytics and artificial intelligence. Both of these technologies can be expected to further improve personalization and therapeutic effectiveness by predicting exacerbation risk or simplifying

treatment schedules based on patient-specific patterns and environmental conditions[36,37].

Hospitalization Reduction

Early exacerbation detection: Although direct, large-data proof expressly showing decrease in hospitalization merely due to the use of smart inhalers is as yet a subject of ongoing investigation and necessitates robust studies, mechanisms and intermediate outcomes project immense potential for this benefit

Early worsening control detection: Through monitoring of drug adherence, technique, and symptoms in real-time, smart inhalers have the potential to detect early worsening asthma or COPD control. A sudden increase in the use of reliever inhalers, for instance, can forecast an imminent exacerbation so that appropriate action can be initiated prior to symptoms becoming so severe that they need to be treated urgently or during hospitalization[36,37,40]. Digital health technologies enable the development of "normal operating characteristics" for an individual and hence enable early detection of the first deviation from that condition[40].

Proactive clinical response: The constant flow of real-time data enables medical professionals to respond promptly to a change in patient signs or behavior, which may eliminate symptom worsening to critical exacerbations[36,37].

Clinical trial evidence: A number of studies have established that the use of smart inhalers can result in a reduction in emergency room use, hospitalization, and asthma exacerbations. Such an instance was a systematic review and meta-analysis that determined SMART, frequently supported by monitoring through the use of smart inhalers, lowered the risk of severe exacerbation and asthma hospital or emergency department visits[31,43]. The need for timely detection of exacerbations of conditions like COPD is also emphasized in order to avoid poor outcomes and hospitalizations[33].

Limitations and smart inhaler challenges

Smart inhalers offer huge clinical benefits in chronic respiratory disease management, their broad acceptance While and optimal integration into health systems are confronted by some main challenges and limitations. These challenges are of trans-economic, trans-technology, trans-user, and trans-regulatory nature that need to be addressed by smart inhaler multi-dimensional solutions for them to realize their full potential.

Cost and accessibility

The cost aspect of smart inhaler technology is the main hindrance to equal access, especially for disadvantaged groups.

Greater up-front costs: Smart inhalers, either as combined devices or as add-on sensors, have greater up-front costs than conventional inhalers[45]. The added expense might serve as a barrier for patients, particularly low-income ones or those who lack complete insurance coverage[14].

Reimbursement issues: The reimbursement environment for coverage and payment of smart inhalers and related digital health services is frequently unclear and extremely regionally divergent[46,47]. Unclear and unstable reimbursement policies may act as a discriminator against patient and clinician adoption, as clinicians will be less inclined to prescribe devices for which the patient has no coverage or for which they are responsible for paying high out-of-pocket amounts[46].

Socioeconomic inequities: The cost factor worsens already existing socioeconomic inequities in access to care. Low-income and rural communities, which will most benefit from increased adherence and monitoring, are most constrained by high cost and lack of insurance coverage[14]. This can further extend the digital health equity gap.

Infrastructure cost: Apart from the device, installation of smart inhaler schemes also involves added costs for supporting infrastructure like phones that are compatible with them, data plans, and dashboard development or integration for care providers' IT infrastructure, which put a strain on health budgets[46].

Data privacy and security

Risks associated with patient health data such as the storage, transmission, and collection of patients' sensitive PHI by smart inhalers are serious privacy and security concerns that should be given serious consideration.

Cyber attack vulnerability: Similar to other Internet of Things (IoT) medical devices, smart inhalers may be susceptible to cybersecurity flaws, which may compromise patient information to unauthorized use, tampering, or data breach[49-55]. Such flaws may be exploited to breach the confidentiality of sensitive respiratory health information[17,49-51].

Data confidentiality and integrity: Integrity and confidentiality of the data gathered through smart inhalers need to be ensured. Threats involved are bulk data leaks, illegal data transmission, and even data tampering stored, which might result in inaccurate treatment choice or even patient harm[49-52].

Interoperability and data sharing: Data sharing with healthcare professionals is a main advantage but a challenge too. Secured and efficient interoperability between heterogeneous smart inhaler platforms, mobile health apps, electronic health records (EHRs), and cloud platforms is complicated. Disjointed platforms can bring in more security threats and slow down overall data integration[51,54].

User acceptance and trust: Patient mistrust is overcome by issues of data privacy and undermine acceptance of smart inhaler technology and digital health solutions in general. Patients will resist accepting devices if they do not know how their own personal health data will be stored, used, or secured[17,46].

Regulatory compliance: Compliancy with very strict data protection laws (e.g., HIPAA in the US, GDPR in the EU) introduces complexity layers to manufacturers and healthcare organizations. Maintaining compliance throughout the entire data life cycle from data collection to storage and dissemination is an ever-changing challenge[50,52,53].

User adaptation: technological literacy among elderly and non-tech-savvy patients

Success with the smart inhalers depends largely on patient activation of the devices, something which may be a major stumbling block for many.

Digital health literacy shortfalls: One of the biggest issues is differential digital health literacy between patients. Older people and technology non-users will find difficulty in synchronizing devices, opening mobile applications, reading information, or troubleshooting[56-60]. This will give rise to frustration, disengagement, and device abandonment[46,56,57].

Complexity of use: Although most of the smart inhalers are user-friendly, initial setup, synchro-nization, and repeated engagement with a smartphone program may still be regarded as overly complicated by certain users[46,61]. If the add-on is too difficult to install or to operate, then it may negatively influence adherence[41,62].

Alert fatention: An overdependence on reminders or poorly designed notification systems has the potential to lead to "alert fatigue", to the point that patients become used to the prompts and disregard them, nullifying the potential for compliance[14,63]. Improved design entails close attention to frequency of notification and tailoring.

Engagement and motivation: Encouragement of constant patient engagement with smart inhaler apps and data monitoring is required but difficult. Early patient interest can be lost over time, particularly if patients feel they do not derive continuous benefits or that the user interface is uninteresting[59,60].

Training and support requirements: Patients need to be well-trained and supported through ongoing training to be in a position to make efficient use of smart inhalers. This means adding to the workload of healthcare professionals, who will also need to train on incorporating smart inhaler data into practice and provide technical support[46,58,60]. The absence of protocols and staff for troubleshooting is an implementation barrier[61].

Regulatory and standardization issues

The fast pace of development of smart inhaler technology surpasses conventional regulatory structures, creating issues with approval, validation, and standardization.

Regulatory environment change: Smart inhalers are generally categorized as software as a medical device (SaMD) or software-enabled medical devices and thus have sophisticated and changing regulatory procedures in various nations (e.g., FDA in the US, CE marking in the EU)[64-68]. The absence of an internationally accepted definition of "smart inhalers" makes it even harder from a regulatory Perspective[69].

Evidence gaps and clinical validation: Although research holds promise for intelligent inhalers to enhance technique and adherence, evidence gaps remain, most notably their long-term effects on difficult clinical endpoints such as fewer exacerbations, hospitalization, and mortality, especially in settings other than controlled research[69,70]. Large, adequately powered clinical trials will be required to conclusively demonstrate effectiveness in real-world practice[14,34,63,71].

Standardization problems: Lack of adequate standardization of data formats, communication schemes, and interoperability among various smart inhaler vendors and health IT systems prevents effortless integration of data and complete patient management[59,69]. This fragmentation may reduce the usefulness of data gathered for population-level health intelligence.

Post-market surveillance: Smart inhalers' continuous safety, efficacy, and cyber security after they enter the market need strong surveillance systems. With the devices being updated with software on a regular basis, regulatory compliance and monitoring performance throughout the lifetime of the devices is a developing challenge[64-66].

Healthcare professional education: On a general note, there is no education of healthcare professionals on digital therapeutics such as smart inhalers. There is a lack of this type of information that can result in issues related to patient selection, incorporating the technology into clinical workflows, and properly interpreting the resulting data[64,66].

Future evolution and evolution of smart inhalers

The future of technology for smart inhalers is unfolding at a genuinely breathtaking pace in parallel with the progression of artificial intelligence, sensor technology, and digital infrastructure for health. Beyond their current role of optimizing technique and compliance, smart inhalers can be made increasingly pivotal to innovative and individualized respiratory management.

Artificial intelligence and machine learning in smart inhalers

The high amounts of data that smart inhalers monitor, from usage patterns, inspiratory flow, and environmental data, level the playing field for the application of artificial intelligence (AI) and machine learning (ML).

Predictive exacerbation analytics: It can unlock complex patient data patterns (e.g., increasing reliever use) and airway flow patterns, environmental triggers correlation with probability of an imminent asthma attack or COPD exacerbation days ahead. Pre-empt action, adjustment of medication, prevention of precipitants, or medical consultation could be enabled by advance warning, potentially prevent disaster episodes and admissions[72,73].

Personalized prevention: Personalized Risk Stratification: These algorithms can identify individual patient risk factors and individual patient exacerbation patterns in individual patients with the aim of providing highly individualized risk assessment. With this, prevention strategies can be made even more personalized.

Personalized treatment regimens: AI can personalize drug dosing and treatment regimens on regimen-outcome or compliance pattern association for the long term and deliver enriched and valuable therapeutic interventions[72].

Real-time decision support: Future smart inhaler devices empowered by AI can facilitate real-time

decision support for both patients and healthcare professionals and provide decision-making data for early intervention through monitored and predictive monitoring[72].

Wearable device integration

Integration of the smart inhaler with other wearables in the healthcare sector can potentially provide long-term and overall respiratory monitoring[73].

Holistic health data: Information from smart inhalers and wearables (smart patches, activity wearables, smartwatches) can potentially provide an overall snapshot of the health of a patient. Wearables can monitor physiological data such as heart rate, sleep, physical activity, and even slight variation in respiratory rhythm or cough rate, which can be correlated with inhaler use and symptom severity.

Continuous passive monitoring: Through this integration, there is passive, continuous monitoring of a patient's respiratory status and receives updates regarding their status even if they are not necessarily on their inhaler[74,75].

Environmental setting: Global positioning system (GPS) and environmental wearables can provide precise environmental and locational data (e.g., air quality, pollen levels, humidity, temperature) to be correlated with inhaler use in the detection of particular environmental perpetrators of symptoms or exacerbations[39].

Early warning systems: The combined stream of information from wearables and smart inhalers can produce a robust early warning system that notifies patients and careers of impending issues before they begin, enabling timely response[74,75].

Telemedicine and Remote Patient Care

Enhanced remote monitoring: Smart inhalers provide objective, real-time measure of drug use and inhaler technique that can be safely uploaded to the healthcare professional's dashboard. Patient response can be tracked, non adherence can be detected, and therapeutic success can be gauged without requiring frequent visits to the clinic[34].

Data-driven teleconsults: High levels of smart inhaler data are visible to clinicians through teleconsults, which enable better informed, individualized discussion of treatment plan, adherence, and technique optimization[76]. Quality of care at a distance is underpinned by data more than would be with patient self-reporting.

Proactive interventions: Remote access patient access data offer the care team the chance to respond proactively to identifying concern trends, e.g., reliever inhaler overuse or nonadherence to maintenance drugs[59,75]. Exacerbation and emergency department use can be avoided.

Increased access to care: Among the mobility-disabled, rural, and full-scheduled patients, telemedicine smart inhaler significantly increases specialist breathing care accessibility by eliminating work disruption and travel time[76].

Future Smart Inhalers

Next-generation smart inhalers will be more advanced with increased security, ease of use, and patient autonomy.

Biometric authentication: Double-checking that the correct patient is using the device, next-generation smart inhalers can also include biometric authentication technology such as fingerprint or voice biometrics[17].

Voice-guided support: Voice-guided technology has the potential to revolutionize user accommodation for less familiar or older patients. Inhalers can provide immediate verbal feedback on technique (e.g., "breathe deeper", "breathe for ten seconds") and verbal reminders of appropriate use timing, facilitating more natural and intuitive correct use[29]. Voice control can also facilitate patients entering symptoms or requesting reminder messages without having to touch the screen of a smartphone.

Integrated sensors of lung function: Although inspiratory flow is already included in certain meters, next-generation intelligent inhalers may have more advanced sensors to provide instant and easy lung function tests (e.g., peak expiratory flow, forced expiratory volume) from the device directly with notification of lung health trends[69].

Individualized drug delivery: Intelligent high-tech next-generation inhalers will be able to finally take drug delivery from optimal drug delivery to optimal medicine deposition in the lung for maximum therapeutic effect to real-time physiological feedback[29].

CONCLUSIONS

Smart inhalers revolutionize respiratory therapy with the digital transformation of traditional devices, improving drug technique and compliance. They offer meaningful clinical benefits with objective assessments and personalized feedback. Despite adversity like cost, data protection, and patient accommodation, their outlook is favorable. With predictive analytics through AI, seamless integration with wearables for full monitoring, and use in telemedicine, more proactive, personalized, and accessible care will be in store. These innovations are bound to transform the management of chronic respiratory disease, leading to improved patient outcomes and quality of life globally.

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AUTHOR'S CONTRIBUTIONS

Yaltang SE: writing the original draft, methodology, investigation. **Said SS:** literature survey, data processing. **Noro PF:** literature survey, critical review. **Vaghela M:** editing, review. Final manuscript was checked and approved by all authors.

DATA AVAILABILITY

The datasets generated or analyzed during this study are available from the corresponding author upon reasonable request.

CONFLICTS OF INTEREST

None to declare.

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