

## The importance of patient choice in inhaled medication decision making

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### Key Points

- Inhaled medications are the cornerstone of therapy for both asthma and COPD. Therapeutic guidelines help in the selection of safe and effective drugs; the selection of the device must also be patient-centered.
- There is abundant evidence that optimized patient outcomes, minimized exacerbations and maximized adherence are obtained only with careful patient-device alignment; this entails consideration of patient device preferences, physical constraints on device use, and regular inhaler technique education.
- Patients strongly prefer to have trusted health care practitioners who understand and incorporate their preferences when managing their care.
- Medication and device choices/switches should only be conducted by prescribers, with patient knowledge, consent and training, to support adherence and optimize outcomes.
- Drug or device restrictions or switches implemented for cost reasons should never compromise disease control or patient well-being.
- While budget and sustainability concerns are important to all parties, enforced or encouraged switches among non-equivalent respiratory devices are neither health-based nor patient-focused.

### Background

Asthma is characterized by coughing, shortness of breath, chest tightness and wheezing. Asthma symptoms and attacks (episodes of more severe shortness of breath) usually occur after exercise or exposure to allergens, viral respiratory infections, irritant fumes or gases. While symptoms can be episodic, the disease is not. (1) Asthma is disproportionately distributed among children and young adults. In 2011–2012, about 3.8 million Canadians age one and older were living with asthma, of whom only one-third were well-controlled. (2) Consequences of poor control include emergency department visits – of which there were over 57,000 related to asthma in 2017/18. (3)

Chronic obstructive pulmonary disease (COPD) is a chronic, progressive lung disease which causes shortness of breath, cough and sputum production. COPD primarily affects the population 40 years and older. The primary cause of COPD is

tobacco smoking, including second hand or passive exposure. In 2011–2012, about 2.0 million Canadians were living with COPD. (2) Collectively, asthma and COPD incurred over \$2 billion in direct health care costs alone in Canada 2010. (4)

Inhaled medications are the cornerstone of therapy for both asthma and COPD. (5,6) These products have two constituent components: the drug and the device that delivers the drug. Optimal patient management must consider the advantages and constraints of both the drug and the device; device selection must be done as thoughtfully as with medications.

There is abundant evidence that optimized patient outcomes, minimized exacerbations and maximized adherence are obtained only with consideration of patient device preferences, physical abilities related to device use, and inhaler technique education. (7, 8, 9, 10) Failure to use devices correctly can lead to exacerbations (escalation of symptoms) and loss of disease control (11, 12) as well as unnecessary addition of therapy. (13) Switching among devices, or using more than one type of inhalation device, can also lead to sub-optimal outcomes. (14, 15, 16)

Concerns have arisen recently, inspired by new generic and 'analogue' formulations of drugs originally marketed in difficult-to-replicate devices: the dry powder inhaler (DPI). 'Inhaler analogue' refers to generic formulations of drugs delivered through different devices than the originator; notably, these analogues are reviewed at Health Canada as new products, not as generics. While generic pressurized metered-dose inhalers (pMDI) have been available for decades, there has been a struggle to replicate the DPI, with multiple regulatory failures and the compromise development of an inhaler analogue. There is strong concern about the equivalency of these products in health care practitioner (HCP) and patient communities, with the potential for undisclosed switching at the pharmacy level.

Observations of inhaler drug claims amongst different European countries have demonstrated major variability in product utilization across borders. It is believed that the unique EU policies, health systems and cost considerations in each country are partly responsible for differences in prescribing and medication use. (16) This is relevant to the Canadian context, where drug plan policies also impact product utilization. With Canada currently considering the implementation of national pharmacare, the influence of any additional cost containment requirements may exacerbate existing issues with patient access. These concerns are not unique to the inhaler analogue issue. Drug or device restrictions or switches implemented for cost savings alone should never compromise disease control or patient well-being.

The objective of this paper is to provide an overview of issues and concerns related to the intersection of patient choice and devices in asthma and COPD. Beyond the literature, a survey was administered to a convenience sample of patients (4), HCPs (3) and Canadian payers (2) to further explore the themes that have concerned the patient, HCP and payer communities.

## Patient Preferences

Asthma and COPD populations share the need for personalized inhaler-based treatment, but have different characteristics to consider. Unlike COPD, asthma includes patients who are children, with specific vulnerabilities. Multiple caregivers are responsible for administering their treatment (family, school, daycare, and babysitter) in settings which can be chaotic and rife with environmental triggers. Across all ages, asthma is a dynamic disease; variability in symptoms can result in poor adherence during low-symptom phases, which can lead to exacerbations and emergency care; consequently, morbidity and mortality can occur in both the 'average' patient with intermittent care and the severe patient. By contrast, COPD occurs largely in older patients with different vulnerabilities: they may have multiple co-morbidities, potentially small support networks, and suffer from ageism and blaming due to smoking histories. They may have limitations from vision, dexterity, or cognition, and their COPD may receive less attention due to concurrent health challenges, or a passive approach common with some older adults.

Medication regimens for the asthma/COPD patient can be static but are often dynamic, in response to health/environmental changes, loss of symptom control, adverse event management, and evolving treatment options. HCPs may suggest changing even effective regimens to take advantage of newer benefits (such as once daily dosing). Any medication change involves some kind of discussion between the HCP and the patient, and reflects the nature of that relationship. Patients strongly prefer to have trusted HCPs who understand and incorporate their preferences when presenting options. Interviewed patients expressed strong preferences relating to adverse events (about which they feel health care professionals routinely under inform), their desire to reduce the number of daily inhalation administration times, and their device experiences in addition to the obvious need for optimized symptom control.

Patients may struggle with access issues across multiple fronts: spirometry testing, accurate diagnosis, respiratory educators and quality care by informed specialists, as well as medication access. Some asthma/COPD medications are not routinely covered by government plans and require extensive paperwork for access, or patient out-of-pocket expense.

Switches from branded products to generics occur at the pharmacy and are disclosed at the time of dispensing. However, switches between generics can also occur, without specific disclosure, and these can result in problematic loss of control, adverse events or device handling problems. Device switches have historically involved a different product altogether, necessitating a prescription, and therefore have not occurred via a routine prescription refill at the pharmacy.

## Device Considerations

Interviewed HCPs stated that the delivery device itself was at the heart of the prescribing choice. Therapeutic guidelines help in the selection of safe and effective

drugs; the selection of the device must also be patient-centered. Device-specific guidance is also available, emphasizing the critical need to align the device with the patient. (17) No device is suitable for all patients, or can always be operated effectively under conditions of stress. The prescriber must align both drug and device with the patient needs and preferences. This entails consideration of device complexity, need for visual acuity, manual dexterity or grip strength, ability to breathe deeply and/or forcefully (for a DPI), technique competence required for all device administrators (children or frail older adults may have multiple administrators), and other issues. Prescribers must also consider aids such as spacers, masks, etc. depending on patient characteristics. Ultimately, therapeutic outcomes can only be optimized with careful patient-device alignment to achieve adherence and appropriate device use. Partnership with the patient is crucial to this process – for information, choice and decision-making.

Often, the decision to switch among drug molecules also includes a decision to switch among devices, as many molecules are available only in device-specific formats. This requires careful thought to align with patient needs and preferences for both drug molecule and device suitability. Changes in device, similar to changes in drug, require monitoring by objective measures (spirometry) to ensure equivalent outcomes, and a patient support program at both the clinic and the pharmacy. Importantly, inhaler analogues can involve alternate dosing from the originator, plus a limited understanding of bioequivalence at the level of lung deposition, further enhancing the need for outcome measurement. A substitution of device at the pharmacy would be complicated and confusing, and may lack objective outcome tracking and patient support.

Patients may be willing to manage whatever device was associated with the drug that they had been prescribed, and may feel confident in their use, even if they don't like the device. Patients consistently describe that they use a device correctly, but in fact are not, and this is only exacerbated when patients are not involved in device selection, repeated assessment and education. (17)

Simple things can improve device usability, such as an effective and easily visible counting mechanism to keep track of puffs per administration – although it seems simple, when patients have to take two puffs from two different inhalers, it can be easy to lose track of the total number of inhalations. Reducing inhaler burden was also identified as improving usability. Patients strongly prefer to reduce the number of puffs per administration, and the number of administration times per day, to the minimum level which still maintained good control.

## **Training Needs**

Proper device use requires training and reinforcement, at all steps of the system, at all healthcare visits, by qualified personnel. Ideally this involves return demonstration, by the patient and/or their caregivers, with the patient's own inhalers and equipment. Even though patients may feel confident about their technique, the majority do not use their inhaler correctly. (18)

Device technique is routinely poor, across all settings, for multiple reasons. No device is universally successful (especially under stress), although a few devices are universally challenging. Product innovation can sometimes appear to be more focused on commercial needs than on patient-centered needs. The problem is compounded by a host of issues: inadequate and/or infrequent technique evaluation by HCPs, patient defensiveness, use of devices with different breathing techniques, confusion among caregivers, lack of financial support for health professional services, limited or variable access to HCPs, lack of alignment of patient characteristics to suitable device, etc.

Interviewed patients reported considerable diversity in device-training experiences, with some relying mostly on reading of package inserts and pharmacy handouts. Other patients had thorough training and follow up checks at every specialist visit, at the time of spirometry with the respiratory therapist.

Both patients and HCPs noted that accurate diagnosis and patient education about their disease was often lacking for patients: 'they show up with a cough and come home with an inhaler and a label' but lack an objective diagnostic test, an understanding of the disease, and the proper use of inhalers (including the differences between a reliever and a controller).

## Improving Outcomes

Optimizing outcomes in asthma and COPD is a multifaceted challenge. Patient engagement alongside positive patient-provider relationships are at the core of this task, as asserted by the Canadian asthma guidelines. (5) With asthma, as a disease of episodic symptoms, it can be challenging for patients to maintain disciplined adherence during periods of minimal symptoms. With COPD, patient aging with increased comorbidities and disability (physical or cognitive) pose evolving challenges.

Patient behaviours go a long way to management of external triggers for both diseases: medication adherence, but also monitoring their symptoms and respiratory outcomes, monitoring air quality, adjusting activities to external conditions, use of home air purifiers, minimizing exposure to allergens and other triggers, etc. Patient-provider interactions are central to facilitate disease education, device training, individualization of therapy, and the provision of tools to facilitate care (peak flow meters, etc.). Access issues – to specialists as needed, to routine spirometry-based diagnoses and monitoring, to respiratory educators, etc. – are concerning across several health care system domains. Interviewed HCPs added other needs: improvement in regulatory and payer review and evaluation of devices, competency and support of primary-care physicians and primary-care teams, and a multi-disciplinary team approach (including community pharmacies).

Among payer communities, there is a constant need to manage budget expenditures in the face of increasing health care costs. New drugs, new uses for

existing drugs and increasing numbers of patients conflict with government cash crises and other budgetary demands. Management of costs through restricted formularies, price negotiation, generic substitution and other measures are necessary and accepted tools. However, drug or device restrictions or switches implemented for cost reasons should never compromise disease control or patient well-being.

## Conclusions

Patients often have strong preferences about the type of device they use, as noted: 'people don't use what they don't like'. There is no one-size-fits-all approach to inhaled medications and care should not be prioritized on lowest-priced treatment options, as noted: 'with inhalers, device is everything'. A correct medicine with the wrong delivery device will not always be the best for each patient; patients are not interchangeable.

Patients with chronic diseases, like asthma and COPD, depend upon medication for day-to-day functioning and risk being most affected by treatment disruption. Unexpected changes in medications can lead to an increase of symptoms and exacerbations, additional healthcare costs, and an emotional burden that can affect work and school life productivity and commitments to family and home life. It is crucial that patients and their healthcare provider participate in the decision making regarding control of treatment options, rather than exclusively insurers, governments or other stakeholders.

For inhaled medications, devices are neither equivalent nor interchangeable. Treatment changes based on cost or convenience alone can affect patients' ability to manage their disease and introduce new healthcare expenses. Patient communities assert that informed patient consent is crucially important. Both medication and device choices/switches should only be conducted with patient knowledge, consent and training, with the primary prescriber. Patient preference and supporting maximum choice in inhaled therapies can support adherence and improved outcomes. While budget and sustainability concerns are important to all parties, enforced or encouraged switches among non-equivalent respiratory devices are neither health-based nor patient-focused.

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