

## Could an electronic tool to assess asthma control with a 1-day timeframe be useful for clinical management?



Asthma is a heterogeneous disease defined in part by a history of respiratory symptoms that vary over time and in intensity. Therefore, symptom assessment is at the core of asthma management,<sup>1</sup> and leveraging mobile health (mHealth) apps to remotely monitor it is a promising strategy in clinical practice and research, especially because most of the population owns a smartphone in the present day.<sup>2</sup> However, the wide variety of mobile apps available for asthma with different purposes, such as health education, symptom recording, or medication reminders,<sup>3</sup> could lead to fragmented information.

In *The Lancet Digital Health*, Bernardo Sousa-Pinto and colleagues<sup>4</sup> present the development and validation of a score for electronic daily asthma control (e-DASTHMA). They describe the analysis of 135 635 1-day observations from 1662 users of the MASK-air app who were treated for asthma. First, they developed a set of data-driven scores based on reported asthma symptoms (from a 0–100 visual analogue scale [VAS]) and medication administered, and assessed their construct validity, test–retest reliability, and responsiveness. Second, they performed an external validation using a cohort of patients with physician-diagnosed asthma who reported the daily effect of asthma symptoms on work or school activities through another app (InspirerMundi). This external validation also included a comparison of the developed scores with the Global Initiative for Asthma (GINA) patient classification rated by the physician, through area under the receiver operating characteristic curves. e-DASTHMA was referred to as a digital biomarker that can complement existing instruments that measure asthma control within longer time frames (1–4 weeks).

This study<sup>4</sup> uses a novel approach to measure asthma control by focusing on both symptoms and medication administered during a single day. Existing questionnaires either do not have a specific question about medication (the Asthma Control Test<sup>5</sup> and Asthma Control Questionnaire<sup>6</sup>) or have a single question that only addresses the need to increase medication (Control of Allergic Rhinitis and Asthma Test<sup>7</sup>). e-DASTMA, however, specifically asks

about the medication administered that day. For example, consider two people with asthma reporting the same amount of symptoms (VAS 30), but with different treatments. The patient who took an inhaled corticosteroid with formoterol that day would have a e-DASTHMA score of 25.6, and the patient who took an inhaled corticosteroid and a short-acting  $\beta$ -agonist would have a score of 32.8, which according to the cutoff point for e-DASTHMA ( $\geq 28.9$ ) indicates worse asthma control. Hence, the second patient would be a candidate for a treatment change according to the GINA stepwise approach<sup>1</sup> after assessing other aspects of asthma management, such as treatment adherence or inhaler technique.

We agree with the authors that e-DASTHMA would avoid recall biases and might allow for the better identification of exacerbations than other asthma control tools with longer time frames. However, a 1-day time frame does not imply reporting every day, which would be burdensome and could jeopardise feasibility. In fact, in this study,<sup>4</sup> 2955 patients were excluded because they did not provide data in 3 different months on the MASK-air app (only reporting 5 days on average), whereas the included participants reported 82 days on average (10% of the number of days of the study period). Is this a poor response rate for a tool with a 1-day timeframe? Would completing e-DASTHMA only when symptoms worsen be enough to generate valuable information for decision making? It should be considered that the users are patients with a chronic condition, which is already a burden per se.

The term digital biomarker has generated controversy and currently does not have a consensus.<sup>8</sup> Biomarker has been defined as a characteristic measured as an indicator of biological or pathogenic processes, or responses to an exposure or intervention (eg, molecular, histological, radiographical, or physiological characteristics), and it does not include an assessment of how an individual feels, functions, or survives.<sup>9</sup> Hence, a patient-reported outcome measure, such as reported symptoms and medication, does not fit the definition of a biomarker. Therefore, despite the value of using a daily asthma control score constructed from patient-reported

Published Online  
March 3, 2023  
[https://doi.org/10.1016/S2589-7500\(23\)00042-0](https://doi.org/10.1016/S2589-7500(23)00042-0)  
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variables collected through an mHealth app, it is questionable whether it can be considered a digital biomarker. To avoid confusion or creating false expectations about the methods used, we would recommend to use the term indirect digital biomarker, a concept previously proposed<sup>8</sup> to encompass digital footprints linked to symptoms that might act as latent variables indirectly linked to a biological variable.

In summary, this study shows the use of real-world data obtained via an mHealth app to create e-DASTHMA, a promising tool for the assessment of asthma control over a 1-day period. Further research is needed to support the content validity (based on expert panel judgements) and suitability for implementing e-DASTHMA in research and clinical practice.

Financial support for this comment was provided through grants by the Generalitat de Catalunya (AGAUR 2021 SGR 00624) and by the Universidad de Costa Rica (OAICE-85-2019).

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