

# A step in the right direction: Harmonizing measures for use in asthma patient registries



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Multiple asthma patient registries have been established globally to provide valuable information on current clinical management, including treatment patterns, adherence, and the long-term outcomes that are important to patients, providers, and other decision makers. These registries are established by different organizations (eg, research institutes, government agencies, and pharmaceutical companies) and therefore have different scientific, clinical, and policy purposes. Like other patient registries, asthma patient registries are effectively observational studies because they follow patients and collect data. Ideally, if set up well, these registries can investigate a range of prognostic factors for asthma, including clinical care, lifestyle, and environmental factors.

Although asthma registries are often used in isolation, their potential uses are expanded when similar registries are linked. Linking registries is challenging, with one of the major barriers being extensive variation in both types and definitions of outcome measures collected by these patient registries. This heterogeneity makes it difficult to link, compare, and aggregate data across registries, thus reducing the potential combined utility of these data. Therefore global consensus is needed not only on standardized measures of asthma outcomes to be used in asthma registries but also on other information needed to investigate factors associated with future risk of exacerbations and adverse events. Furthermore, investigating variations in asthma prognosis associated with potential risk factors and plausible effect modifiers, such as age, ethnicity, social class, and comorbidities, will facilitate the identification of high-risk groups that require closer clinical management. On the other hand, setting up ideal registries can be restricted by logistical issues, including funding constraints, and ethical concerns with pooling data from multiple institutions and countries.

The article published in the current issue of the *Journal* by Gliklich et al<sup>1</sup> presents findings of a project that aimed to develop a set of standardized measures of asthma outcomes for asthma registries in the United States. The project included 13 asthma patient

registries, including both severe and general asthma registries, and 46 currently used outcome measures were curated and harmonized. This process generated a minimum set of 21 standardized measures of asthma outcomes, which belong to 6 broad categories (survival, clinical response, events of interest, patient-reported outcomes, resource use, and experience of care) and can be used for both adult and pediatric patients. The project involved representatives from registries and a diverse stakeholder group (including clinicians, researchers, and representatives from medical specialty associations; health systems; community health centers; regulatory agencies; funding agencies; and patient advocacy organizations). Although 8 of the 21 invited registries declined involvement with this project, the registries that participated and those that declined participation had similar characteristics, and therefore the findings are likely to be generalizable. As the authors have suggested, this minimum set of outcome measures should be further tested in clinical settings for acceptance, feasibility, and utility.

Interestingly, another article published only 2 months ago by Bulathsinhala et al<sup>2</sup> used a modified Delphi process and 27 experts in the field of severe asthma research to identify 95 variables (from 747) covering a wide range of categories, including outcomes, for inclusion in the first international registry for severe asthma. The difference in the proposed number of variables between the 2 publications is related to one focusing on harmonization of the outcomes and the other focusing on generating a full list of all relevant characteristics, including confounding variables and potential effect modifiers. Nevertheless, these findings highlight that standardization of information collected in asthma registries has a long way to go to reach consensus on the type of information that should be collected.

The development and implementation of standardized measures to collect data across patient registries and clinical settings has multiple implications for both clinical management and research. Repeatedly collected standardized measures of asthma outcomes allow physicians/asthma specialists to more efficiently and accurately assess a patient's asthma phenotype and their response to treatment and in turn facilitate optimization of their asthma management. Implementation of standardized measures also enables evaluation of treatment patterns and outcomes for all asthmatic patients on a population health scale. Collecting data on the same outcomes consistently across health systems will create a national data infrastructure, an extremely valuable resource for asthma research.

Similar to the United States, a variety of asthma patient registries exist in other countries, and whether standardized measures should be country specific or could be applicable internationally is a question that needs consideration. Potential differences in asthma phenotypes and genetic/ethnic differences between countries must be taken into account when using country-specific data. The previously described study<sup>2</sup> that generated 95 core variables provides a platform for developing

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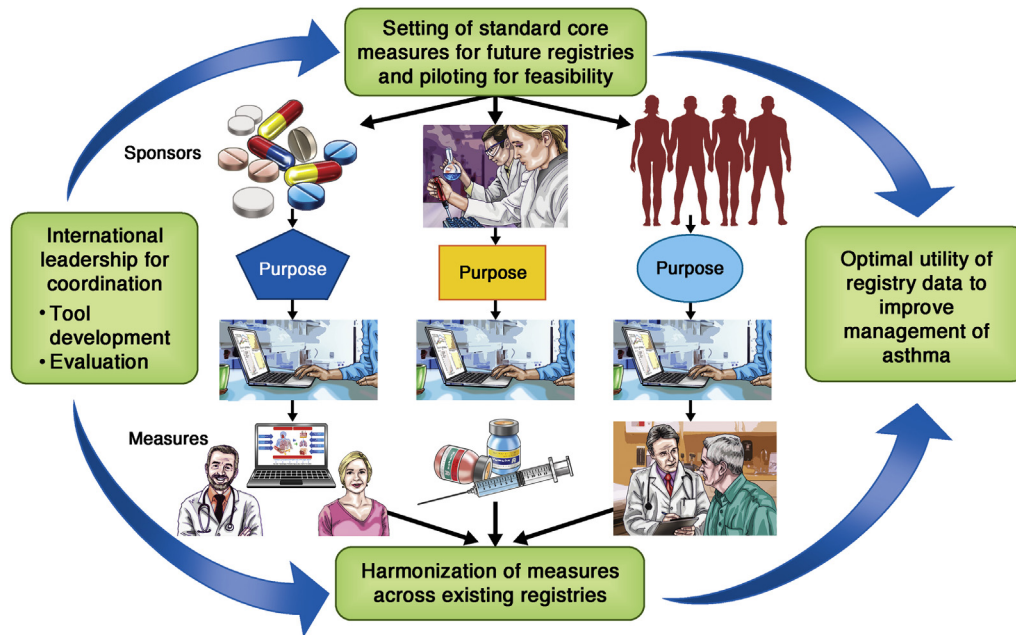
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**FIG 1.** Progressing the role of asthma registries: harmonization and optimization to enhance research and patient outcomes. Schema representing multiple registries with multiple purposes, patient populations, and care settings are shown. Harmonization of existing asthma measures and development of standard measures for new and existing registries can affect both asthma research and patient care.

international consensus on a minimum set of variables that can be included in all the asthma registries to compare and combine them. Furthermore, a clear ongoing coordinating and governance process is necessary to oversee such minimum standards, determine when updates and revisions are needed, and determine whether new measures should be adopted and harmonized. Regular review and updates are also necessary to reflect changing treatment paradigms and to address challenges encountered by registries that implement the specific measures determined.

Standardization of measures of asthma for various purposes has been successfully achieved previously. For example, internationally standardized guidelines for asthma diagnosis have been implemented widely in clinical settings, and standardized asthma outcome measures for use in clinical trials have been developed.<sup>3-5</sup>

To advance the approaches to standardizing asthma registries, it is essential to harmonize existing registry measures so that historical data can be used, as well as to determine measures to be collected prospectively so that all relevant data are collected the same way (Fig 1). Implementation of a minimum set of standardized measures among registries and clinical practice would foster collaboration across the asthma registries, which will lead to efficient investigations of new questions. Although the work of Gliklich et al<sup>1</sup> is a major step in the right direction, a broader plan and international leadership for extending this work globally and ongoing updating of measures are vital to the ultimate success

of standardization of registry measures. Given different phenotypes of asthma and the possible variation of the associations across different populations, standardized global registries with the minimum set of data alone are unlikely to substantially contribute to personalized management, but this will create a platform to facilitate/coordinate other measures toward better management and asthma treatment. Successful use of asthma registries for personalized management needs further advancement of the methodological work and global expert consensus to determine essential data to be collected.

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