



Are outcome measures in allergic diseases relevant for the WHO's *International Classification of Diseases* in allergology?

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Purpose of review

To review and understand the impact of the outcome measures of allergic and hypersensitivity conditions for the WHO's *International Classification of Diseases* (ICD) and its impact in the management of anaphylaxis and identify potential strategies to improve patients' care and prevention.

Recent findings

The pioneer chapter addressed to allergic and hypersensitivity conditions in the 11th version of the WHO's ICD is the result of the evidence-based academic technical actions consistently following of collaborations of the allergy community and integrated international initiatives in order to reach quality outcomes measures of allergies worldwide.

Summary

Allergic and hypersensitivity conditions are increasing worldwide, however, they have never been well represented in the international classification systems, such as the ICD. The ALLERGY in ICD-11 initiative has been launched in 2012 in order to gather a better representation of these conditions in the ICD-11. As a result of the evidence-based academic technical actions acknowledged by the Joint Allergy Academies and the WHO, the pioneer chapter Allergy and hypersensitivity conditions has been constructed. This framework can be considered a milestone in the history of the allergy specialty. More reliable, accurate and comparable epidemiological data will be able to provide a big picture of these conditions and will support improvements in many levels of the health system. As knowledge derived from populations is key information for more realistic decision-making, the construction of the new section addressed to allergic and hypersensitivity conditions in the ICD-11 will allow the collection of more accurate epidemiological data to support quality management of patients, and better facilitate healthcare planning to implement public health measures to prevent and reduce the morbidity and mortality attributable to these conditions.

Keywords

anaphylaxis, classification, epidemiology, *International Classification of Diseases*, WHO

INTRODUCTION: EPIDEMIOLOGY IS A SCIENCE OF HIGH IMPORTANCE

Why epidemiological data are needed?

Epidemiology dates back to the Age of Pericles in fifth century B.C., but its standing as a 'true' science in 21st century is often questioned [1]. This is unexpected, given that epidemiology directly impacts lives and our reliance on it will only increase in a changing world. Currently, epidemiology is known as the study of the distribution and determinants of health-related states or events (including disease), and the application of this study to the control of diseases and other health problems. Various methods can be used to carry out

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KEY POINTS

- The weak identity of disorders in the WHO and the Family International of Classifications contributes to the lack of ascertainment and recognition of their importance for healthcare planning and resource allocation, and prevents clinical research from being performed.
- Outcome measures in allergic diseases: allergic and hypersensitivity conditions are increasing worldwide, however, they have never been well represented in the international classification systems, such as the *International Classification of Diseases* (ICD).
- The world needs better allergic and hypersensitivity health data.
- The ALLERGY in ICD-11 initiative: evidence-based academic technical actions consistently following globalization trends offering possibilities of collaborations of the allergy community and integrated international initiatives in order to reach quality care of allergic patients worldwide.
- The new 'Allergic and hypersensitivity conditions' chapter into the ICD-11 framework can be considered a milestone in the history of the allergy specialty. More reliable, accurate and comparable epidemiological data will be able to provide a big picture of these conditions and will support improvements in many levels of the health system.

epidemiological investigations: surveillance and descriptive studies can be used to analyze distribution; analytical studies are used to study determinants [2]. Professional involved in preventive medicine and public health use epidemiological methods for disease surveillance, outbreak investigation and observational studies to identify risk factors of diseases in populations and to get to the root of health problems and outbreaks in the community. Knowledge of these parameters is used to direct interventions and to implement disease control and prevention [1,2].

There are tangible results from epidemiological research. It is unquestionable that epidemiology, as a discipline, has saved millions of lives, from both infectious and noncommunicable diseases, through interventions and preventive programs that have been implemented as a result of study findings. In fact, the Centers for Disease Control and Prevention (CDC) credits medical epidemiologists with adding 25 years to the average life expectancy of people living in the United States since 1947 [3].

Models of health and disease are constructed around medical coding languages and this has created a need for mechanisms to collect, analyze,

interpret clinical data, build up registries and implement epidemiological data. A standard registry of morbidity and mortality data provides health information that is used for statistics and epidemiology, healthcare management, allocation of resources, monitoring and evaluation of research, prevention and treatment. This need has given rise to a process of coding, whereby words describing medical concepts are translated into codes for later analysis. Important gaps exist in the information available to policy makers when attempting to determine the disease burden from allergic disorders [4].

The WHO and its role in public health

The WHO is a specialized agency of the United Nations (UN) concerned with international public health. Established on 7 April 1948, the WHO is a member of the UN Development Group. Its predecessor was an agency of the League of Nations [5,6]. During the 1945 UN Conference on International Organization, delegates from China, Norway and Brazil converged on the creation of an international health organization under the auspices of the new United Nations. The constitution of the WHO was signed by all 51 countries of the UN, and by 10 other countries, on 22 July 1946 [7].

The WHO's initial priorities were communicable diseases, in addition to women and children's health, nutrition and sanitation. More recently, the WHO has defined its role in public health as: providing leadership on matters critical to health and engaging in partnerships where joint action is needed; sharing the research agenda and stimulating the generation, translation and dissemination of valuable knowledge; setting norms and standards and promoting and monitoring their implementation; articulating ethical and evidence-based policy options; providing technical support, catalyzing change and building sustainable institutional capacity and monitoring the health situation and assessing health trends; implementing civil registration and vital statistics to monitoring social and health events [8].

The WHO Family of International Classifications

The WHO Family of International Classifications (WHO-FIC) is constituted of classifications that have been endorsed by the WHO to describe various aspects of the health system in a consistent manner. The classifications may be the property of the WHO. The purpose of the WHO-FIC is to assist the development of reliable statistical system at local, national and international levels, with the aim of improving health status and healthcare.

The classifications in the WHO-FIC and the broader United Nations Family of Economic and Social Classifications are of the three major types: reference classifications, including the *International Classification of Diseases* (ICD), related classifications and derived classifications. These are the classifications that cover the main parameters of health and the health system, such as death, disease, functioning, disability and health interventions [9].

WHO reference classifications are products of international agreements. They have achieved broad acceptance and official agreement for use and are approved and recommended as guidelines for international reporting on health and health outcomes. They may be used as models for the development or revision of other classifications, with respect to both the structure and the character and definition of the categories [9,10].

Classification involves the categorization of relevant concepts for the purposes of systematic recording or analysis. The categorization is based on one or more logical rules. Coding rules must be incorporated in the classification. Terminologies and classifications are not simply different points on a continuum, classifications are a necessary adjunct to terminology for standardized coding of information for statistical purposes. Terminology and classification should be considered as complementary [10].

The WHO-FIC Network, a network of WHO Collaborating Centres (WHO CC), NGOs and selected experts, has been established since 1970 to support WHO's work in international classifications. The principal role of the WHO-FIC Network is to promote the implementation, use, maintenance and updating of the WHO reference health classifications. The WHO-FIC Network Collaborating Centres also assist WHO in the revision and development of the reference classifications. Currently, there are 25 WHO CCs, part of the WHO-FIC Network, representing all the WHO regions [11]. In June 2018, the WHO designated the Montpellier CC for Classification Scientific Support, headed by P.D. and L.K.T. This designation is the result of the recognition for all the efforts done by ALLERGY in ICD-11 initiative efforts and it is intended to provide academic, research and scientific support to the WHO in the implementation, refinement and maintenance of the WHO-FIC in the areas of our expertise.

The International Classification of Diseases

The first International List of Causes of Death was drafted by Jacques Bertillon and colleagues in 1885. It was prepared based on the principle of distinguishing between systemic diseases and those

localized to a particular organ or anatomical site, and officially adopted for use in mortality registries in 1893 [12]. This classification, which was accepted by many countries and has been periodically revised, constituted the basis of the ICD.

The ICD is a global standard diagnostic classification for mortality and morbidity statistics maintained by the WHO. The ICD is the broadest classification and coding system used to monitor the incidence and prevalence of diseases and other health problems, reflecting the general health situation in countries and populations. This codification system is in use in more than 100 countries, available in 43 different languages and is responsible for allocating about 70% of the world's health expenditures [13].

Currently, the majority of countries use the 10th revision of ICD (ICD-10) or adaptations thereof [4,10]. ICD-10 has inherited a structure from previous versions of ICD in which topographic distribution frequently takes precedence over underlying mechanisms, triggers or any of the concepts currently used for allergic and hypersensitivity conditions. The inadequacy of this classification for these conditions is a major reason for the under-notification or misclassification in morbidity and mortality statistics (MMS) [14]. As an example, only two terms in ICD-10 for anaphylaxis are hidden within section T78 of *Other and unspecified effects of external causes* under the unsatisfactory title *Adverse effects, not elsewhere classified* [15], resulting in under-notification of anaphylaxis deaths [16].

In development since 2007, ICD-11 is intended not only to rectify deficiencies in ICD-10 and to incorporate changes demanded by scientific advances, but also to take advantage of the revolution in electronic data handling since the publication of ICD-10 a quarter of a century ago. ICD-11 may be regarded as a suite of classifications, which is based on a detailed and comprehensive polyhierarchical web-like Foundation in which any single disease entity may be represented in more than one location. The ICD-11 beta draft is an online platform continuously reviewed by scientific peers and updated accordingly what permits additions, deletions and changes. The ICD-11 has been created based on a digital library including all ICD entities called *Foundation Component*, which is the basis of the construction of a user-defined list, called *Linearization*. The ICD conditions listed in the *Foundation Component* can be linked to the online beta draft linearization by index citation. This also permitted the construction of a range of specialist classifications in which the detail contained in the Foundation is retained but which can link to ICD-11 MMS.

ARE OUTCOME MEASURES IN ALLERGIC DISEASES RELEVANT FOR THE WHO'S INTERNATIONAL CLASSIFICATION OF DISEASES IN ALLERGOLOGY?

Outcomes measures in allergic diseases

Allergic and hypersensitivity conditions are multi-dimensional problems that can be expressed in many different organs and in all age groups, having a significant impact on the quality of life of patients and their families. The clinical picture of these conditions is complex, covering a myriad of entities, such as anaphylaxis, asthma, rhinitis, drug, food, and insect hypersensitivity, eczema, urticaria and angioedema. Therefore, every health professional can face both mild and severe allergic conditions and it is believed that the world is dealing with a real allergy epidemic, resulting in considerable consequences for patients around the world and in important costs for societies [17,18]. A steady increase in the prevalence of allergic diseases globally. It is estimated that more than 150 million Europeans [19] and over 30–40% of the world's population are affected by these conditions [20], and it accounts for more than 17 million outpatient office visits per year in the United States of America alone [21].

The world needs better health data related to allergic and hypersensitivity conditions

Although available data, specifically those collected during the past decades, show an increased frequency of allergic and hypersensitivity conditions, there are still challenges in interpreting this information [18,19,21,22] and its global applicability. The most widely discussed issues in the epidemiology of allergy and hypersensitivity over the last 10 years are: regional variations in concepts and definitions [21], whether prevalence or incidence is the best measure of the frequency in the general population and whether the increasing incidence published is real or reflects different methodologies and definitions used.

Over the last several years, an increasing number of clinical databases have been developed to capture reliable epidemiological data in the field at both national and regional levels. However, a substantial proportion of the current data on the epidemiology of allergy and hypersensitivity conditions has come from registries with limited scope and population source. Different methods have been applied in an attempt to reach reliable epidemiological data, but most of the studies have focused on specific triggers or at-risk populations. Lack of harmonized strategies to record cases hampers collection of comparability data and accurate epidemiological data. In general,

registries are representative sources of epidemiological data only if the reporting of the conditions is mandatory and the data are validated [21].

On the other hand, broad population-based studies allow descriptive and analytic epidemiological analysis covering the general population and identify all or a known fraction of the cases in a particular community. Generally speaking, population-based studies have adopted the WHO's ICD as the main tool to capture the proposed outcomes. These studies have been especially useful in detailing time-related trends, capturing clinical practice and principal discharge diagnosis coding statistics, and in providing broader morbidity and mortality statistics (MMS). However, allergic and hypersensitivity conditions have never been well classified under the ICD context, either for morbidity [14] or for mortality data [16]. This is exemplified by the under-reporting of anaphylaxis deaths under the ICD-10 classification using the Brazilian national mortality database, given that no anaphylaxis-specific ICD-10 codes that are considered valid for coding underlying cause-of-death [16]. The weak identity of disorders in the ICD contributes to the lack of ascertainment and recognition of their importance for healthcare planning and resource allocation, and prevents clinical research from being performed. Anaphylaxis resides in ICD-10 under the nonspecific 'Chapter XIX Injury, poisoning and certain other consequences of external causes' which the main references are 'Anaphylactic shock due to adverse food reaction' (T78.0) and 'Anaphylactic shock, unspecified' (T78.2). Moreover, the term 'shock,' which means the drop of blood pressure, is one of the anaphylaxis manifestations, however, should not be taken as synonymous or always together [15].

The ALLERGY in *International Classification of Diseases-11* initiative: process and achievements

With the aim of having a better representation of allergic and hypersensitivity conditions, including anaphylaxis, in international classification systems and taking the window of opportunity presented by the ICD-11 revision, the documented anaphylaxis deaths under-notification data [16] triggered a cascade of strategic international actions. The ALLERGY in ICD-11 initiative has been launched in 2012 in order to update the classifications of allergic and hypersensitivity conditions for the new ICD edition. The initiative is based in a strong academic technical evidence-based process acknowledged by a Joint Allergy Academies' consortium and the ICD

WHO governance [4,14,16,22²²,23²³,24²⁴,25²⁵,26–28,29²⁹,30³⁰,31³¹,32³²–35³⁵,36³⁶,37³⁷]. These efforts have resulted in the construction of the pioneer ‘Allergic and hypersensitivity conditions’ section under the ‘Disorders of the Immune system’ chapter of the online ICD-11 Beta draft [25²⁵,38]. For the first time, allergy and hypersensitivity are elected as individualized conditions into the ICD-11 frame, receiving a sub-section addressed to this condition.

Vignette: lessons from clinical practice

In the first visit to the allergy clinic after having been seen by other specialties, a 41-year-old man, with no known previous drug allergies presented the following clinical history. Twenty minutes after intaking Ibuprofen 400 mg for headache, he developed the first episode of facial angioedema. He received treatment and recovered after 18–20 h. The patient presented personal history of persistent asthma under continuous treatment for more than 15 years and chronic rhinosinusitis with nasal polyps, undertaking three ear, nose and throat (ENT) surgeries in the last 2 years, and was prescribed at least four cycles of systemic antibiotics per year. The search for other differential diagnoses resulted negative. He underwent allergological work-up, which confirmed the hypersensitivity because of nonsteroidal anti-inflammatory drug (NSAIDs). Final diagnostic hypothesis would be Widal (or Samter) syndrome; drug-induced angioedema was the clinical diagnosis, and NSAIDs for trigger. From the ICD-10 view [15], the case would be classified with a combination of disorders for the final hypothesis (*J45.0 Predominantly allergic asthma + J31.0 Chronic rhinitis + J32.0 Chronic sinusitis + J33 Nasal polyp + T78.3 Angioneurotic oedema + Y45 Analgesics, antipyretics and anti-inflammatory drugs*) as Widal/Samter syndrome is missing in the ICD-10. For the clinical diagnosis, it would receive the out-of-date nomenclature as angioneurotic oedema (T78.3) + Analgesics, antipyretics and anti-inflammatory drugs (Y45.0). Although the corresponding ICD-11 codes are not completely defined, applying the ICD-11 logic [38], the case would be classified as *CA09.0 Samter syndrome* and *EJ01.1 Drug-induced angioedema + XM409771066 Anti-inflammatory drug nonsteroidal* for the acute phase of the reaction. Making specific diagnosis visible in the ICD, such as Samter/Widal syndrome, will be able to support the allocation of resources to improve diagnosis, management and research in the field.

CONCLUSION

Perspectives of morbidity and mortality statistics for allergic and hypersensitivity disorders

Allergic and hypersensitivity disorders are managed not only by allergists but also by specialists from a range of different disciplines and it is believed that the world is dealing with a real allergy epidemic, resulting in considerable consequences for patients around the world and is an important cost for societies. Timely, the new *Allergic and hypersensitivity conditions* chapter in the ICD-11 framework can be considered a milestone in the history of the allergy specialty. More reliable, accurate and comparable epidemiological data will be able to provide a big picture of these conditions and will support improvements in many levels of the health system.

As knowledge derived from populations is key information for more realistic decision-making, the construction of the new section addressed to allergic and hypersensitivity conditions in the ICD-11 will allow the collection of more accurate epidemiological data to support quality management of patients and better facilitate healthcare planning to implement public health measures to prevent and reduce the morbidity and mortality attributable to these conditions.

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Conflicts of interest

There are no conflicts of interest.

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