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### ► To cite this version:

Luciana Kase Tanno, Nicolas Molinari, Sophie Bruel, Jean-Luc Bourrain, Moises A. Calderon, et al.. Field-testing the new anaphylaxis' classification for the who International Classification of Diseases (ICD)-11 revision. *Allergy*, 2017, 72 (5), pp.820-826. 10.1111/all.13093 . hal-01409034

**HAL Id: hal-01409034**

<https://hal.sorbonne-universite.fr/hal-01409034v1>

Submitted on 5 Dec 2016

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Received Date : 25-Sep-2016  
Revised Date : 29-Oct-2016  
Accepted Date : 20-Nov-2016  
Article type : Original Article: Anaphylaxis

## FIELD-TESTING THE NEW ANAPHYLAXIS' CLASSIFICATION FOR THE WHO INTERNATIONAL CLASSIFICATION OF DISEASES (ICD)-11 REVISION

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### ABSTRACT:

**Background:** In order to consolidate the new classification model addressed to the allergic and hypersensitivity conditions according to the International Classification of Diseases (ICD)-11 revision timeline, we here propose real-life application of quality assurance methodology to evaluate sensitivity and accuracy of the "Anaphylaxis" subsection.

**Methods:** We applied field-testing methodology by analyzing all the consecutive inpatients' files documented as allergies from the University Hospital of Montpellier electronic database for the period of one year. The files clinically validated as being anaphylaxis were manually blind-coded under ICD-10 and current ICD-11 beta draft.

This article has been accepted for publication and undergone full peer review but has not been through the copyediting, typesetting, pagination and proofreading process, which may lead to differences between this version and the Version of Record. Please cite this article as doi: 10.1111/all.13093

The correspondence of coding and the impressions regarding sensibility were evaluated.

**Results:** From all 2,318 files related to allergic or hypersensitivity conditions, 673 had some of the anaphylaxis ICD-10 codes; 309 files (46%) from 209 patients had anaphylaxis and allergic or hypersensitivity comorbidities description. The correspondence between the two coders was perfect for 162 codes from all 309 entities (52.4%) (Cohen-kappa value 0.63) with the ICD-10 and for 221 codes (71.5%) (Cohen-kappa value 0.77) with the ICD-11. There was a high agreement regarding sensibility of the ICD-11 usability (Cohen-kappa value 0.75).

**Conclusion:** We here propose the first attempt of real-life application to validate the new ICD-11 “Anaphylaxis” subsection. Clearer was the improvement of accuracy reaching 71.5% of agreement when ICD-11 was used. By allowing all the relevant diagnostic terms for anaphylaxis to be included into the ICD-11 framework, WHO has recognized their importance not only to clinicians but also to epidemiologists, statisticians, health care planners and other stakeholders.

KEY WORDS: anaphylaxis, classification, International Classification of Diseases, validation, World Health Organization

### **Background**

ANAPHYLAXIS' CLASSIFICATION IN THE WHO INTERNATIONAL CLASSIFICATION OF DISEASES (ICD)

The spectrum of clinical presentations of allergic and hypersensitivity conditions is wide and, therefore, these disorders are managed not only by allergists but also by specialists from a range of different disciplines. A simple example is anaphylaxis, which could be faced by different health professionals. Up until recently, although the allergy community has made efforts to work on the classification of specific clinical allergic or hypersensitivity disorders, the document produced (1-3) have never reached consensual universal language for use by many different health settings.

A key role of the World Health Organization (WHO) is to produce, maintain and implement international health information standards, to provide a consensual, meaningful and useful common language for use by governments, health care providers and consumers. Internationally agreed classifications facilitate the storage,

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access, retrieval, analysis, interpretation and comparison of morbidity, mortality and health-related data. For these reasons, the WHO issued and has maintained the International Classification of Diseases (ICD) so that, in most countries, morbidity and mortality statistics are routinely compiled according to regulations and recommendations adopted by the World Health Assembly (WHA) (4). They ultimately help to distribute health expenditures at each nation level.

Anaphylaxis is known as a serious allergic reaction that involves more than one organ system (e.g. skin, respiratory tract, and/or gastrointestinal tract). It can begin very rapidly, and symptoms may be severe or life-threatening (1). Although anaphylaxis has been pointed as a high priority public health issue in the allergy community and food allergy world, it has never been considered a priority by the Orphanet (5) nor well addressed by a single section in the WHO ICD frame (Figure 1), resulting in its misclassification and undernotification regarding both morbidity (6) and mortality data (7). From the ICD-10 perspective, anaphylaxis is classified under the “T78 Adverse effects, not elsewhere classified” chapter. Under this confusing chapter, only severe cases of anaphylaxis have been prioritized (T78.2 Anaphylactic shock). In fact, obstruction of the upper and/or lower respiratory tract leading to respiratory distress and potential fatality is more commonly observed in anaphylaxis than hypotension and shock *per se*. The misclassification implied in the ICD-10 is exemplified by scattering “T78.2 Anaphylactic shock” at the same level as the “T78.3 Angioneurotic oedema”, “T78.4 Allergy, unspecified” and “T78.9 Adverse effect, unspecified” under the same heading (Figure 1).

Taking the window of opportunity presented by the ongoing ICD-11 revision, the documented anaphylaxis deaths under-notification data (7) triggered a cascade of strategic international actions supported by a Joint Allergy Academies’ consortium and the ICD WHO governance (6-20) in order to update the classifications of allergic and hypersensitivity conditions for the new ICD edition. 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 (12,13,21), and “Anaphylaxis” is currently one of the six headings of the section recently compiled for the forthcoming 11<sup>th</sup> Revision of ICD (Figure 2).

The *Allergic and hypersensitivity diseases* section proposal was validated by crowdsourcing (9) and simplified according to ICD Revision Steering Group (RSG) guidance (13); the “Anaphylaxis” subsection was the most well accepted modification. The development of the now visible “Anaphylaxis” subsection involved strong academic input and extensive consultation and agreement from the relevant Topic Advisory Groups (TAGs) and Expert Working Groups (EWGs). The building process of the section, undertaken with WHO RSG guidance, started in February 2014. As a result of all the previous actions, the new “Anaphylaxis” sub-section was constructed, with 11 entities classified under 7 main headings: Anaphylaxis due to allergic reaction to food, Drug-induced anaphylaxis, Anaphylaxis due to insect venom, Anaphylaxis provoked by physical factors, Anaphylaxis due to inhaled allergens, Anaphylaxis due to contact with allergens and Anaphylaxis secondary to mast cell disorders (Figure 1 and 2).

Timely, in order to consolidate the new classification model addressed to the allergic and hypersensitivity conditions according to the ICD-11 revision timeline, we here propose real-life application of quality assurance methodology to evaluate sensitivity and accuracy of the “Anaphylaxis” subsection.

## **Methods**

### **APPLYING FIELD-TESTING METODOLOGY TO REACH QUALITY ASSURANCE**

We first selected all the consecutive inpatients’ files documented as allergies from the University Hospital of Montpellier (CHRM) electronic database for the period of one year (2014). All patients’ data are routinely collected in the French hospital information system and coded by professional non-physician coders using the ICD. The data accessed in the current study have been coded based on the ICD-10. Files have been selected based on pre-established ICD-10 allergy corresponding codes (22) registered by the Departments of specialties with whom overlapping allergy and hypersensitivity conditions co-exist (Pulmonology, ENT, Ophthalmology, Dermatology, Pediatric, Gastroenterology, Emergency and Intensive Unit Care). The data have been blindly extracted from the database by a professional from the Medical Information Department. All the data have been collected in an anonymous way. As the study is based on a database analysis and the data were anonymized

before research coding, this study falls under the chapter X according to the French law and an informed consent is not needed (23). For this study, ICD-10 related to anaphylaxis have been identified as having any of the T78 *Adverse effects, not elsewhere classified* codes (T78.0 to T78.8), and T80.5.

In the second step of the process, two trained allergists clinically independently validated the retrospectively accessed cases. Discordances have been solved by opened discussions. Allergy specialists confirmed the allergy diagnosis, additionally considered all comorbidities related to allergy or hypersensitivity and blind the files after the selection. All cases in which the ICD-10 codes and/or clinical diagnosis were not related to allergic and hypersensitivity conditions have been excluded. In this evaluation, we asked for the coders to give their impressions regarding the sensitivity of each code added under the new ICD-11 frame and asked to justify if they thought it was not sensible enough.

The same sample with clinical diagnosis have been manually blind-coded by two trained coders based on the online ICD-10 2015 version (22) and current ICD-11 beta draft (May 2015 frozen version) (21), both with online English versions. Data were anonymous from now onwards. The degree of inter-rater agreement was assessed using Cohen's kappa.

The here presented methodology (Figure 3) has been extensively discussed and acknowledged by the WHO RSG and the information, research and regulatory affairs' departments of the CHRUM.

## Results

### REACHING QUALITY ASSURANCE FOR THE NEW ICD-11 ANAPHYLAXIS SUBSECTION

From all 2,318 files accessed from the electronic database as having ICD-10 codes related to allergic or hypersensitivity conditions, 673 had some of the anaphylaxis ICD-10 codes (Figure 3).

After the clinical allergy validation, 309 files (46%) from 209 patients had anaphylaxis and allergic or hypersensitivity comorbidities description. Three situations resulted in the 364 eliminated files: (i) descriptions resembling allergic or hypersensitivity conditions, but not considered as real allergies or hypersensitivities (*e.g.*: food intolerance or Munchausen Syndrome); (ii) transversal analysis in which

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the description of allergic or hypersensitivity conditions were reported before or after the time of the evaluation, and (iii) unclear described diagnosis (e.g.: files containing initial hypothesis of anaphylaxis, but clinical evaluation and management of an episode of isolated bronchospasm). We have no discordances in the clinical evaluation. From overall 309 files, 89 (29%) have been validated as anaphylaxis and 220 (71%) as allergic or hypersensitivity comorbidities (Figure 3). Most of comorbidities (65%) were allergic or hypersensitivity conditions involving skin or mucous or non-anaphylactic food hypersensitivity conditions and allergic or hypersensitivity conditions involving the gastrointestinal tract (Figure 3). From the transversal file evaluation, 34 (38%) of the anaphylaxis cases had the etiology described, 91% associated to drugs and foodstuff. Most of the cases experienced anaphylaxis grade II (more than one system involved; not life-threatening) and grade III (more than one system involved; life-threatening) (Figure 4).

From all 309 entities, 20 (6.5%) had characteristics of anaphylaxis and combinations of ICD-10 codes were required to reach anaphylaxis ICD-11 codes (e.g. wheezing and hypotension or hives, tachycardia and wheezing but no ICD-10 corresponding anaphylaxis code).

Utilizing the ICD-10, the correspondence between the two coders was perfect for 162 codes from all 309 entities (52.4%) (Cohen-kappa value 0.63) and for 221 codes (71.5%) (Cohen-kappa value 0.77) with the ICD-11 beta draft. There was a high agreement regarding the question on sensibility of the ICD-11 usability (Cohen-kappa value 0.75). The main reasons for which the coders indicated that the new ICD-11 frame was not sensible enough were related to the lack of additional severity classification or allergens description, which will eventually be corrected.

## Discussion

### LESSONS FROM THE FIELD-TESTING METHODOLOGY

We here propose the first attempt of real-life application to validate the new ICD-11 “Anaphylaxis” subsection. Clearer was the improvement of accuracy reaching 71.5% of agreement when ICD-11 was used. Field-testing is one of the quality assurance methodologies to reach accuracy and sensibility proposed by the WHO to validate the ICD-11 framework. The proposed method of validation intends to prove

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stability, accuracy and sensitivity of the new ICD-11 frame, taking clinically validated conditions as the reference for this procedure. By individual mapping allergic and hypersensitivity conditions in ICD-10 and 11, it was possible to ensure stability since most of the entities had corresponding codes in both editions of the ICD. The blinded-coding is a qualitative method, which permitted to demonstrate accuracy and sensitivity of the new model. This process allowed us to better understand the possible discrepancies and difficulties the end-users may face and correct before the official ICD-11 release.

Even with substantial structural changes to unify and accommodate the “Allergic and hypersensitivity conditions” section into the ICD-11, we have been able to show a high coding correspondence between ICD-10 allergic and hypersensitivity codes sample and the ICD-11 beta draft framework, reaching high sensibility and reassuring international coders and WHO that no previous codes (and patients) will be lost when longitudinal studies will be performed. The main reasons for which the coders indicated that the new ICD-11 frame was not sensible enough were related to the lack of additional severity classification or allergens description, although already in the working platform are still not implemented in the 2015 frozen version (21). The ICD-11 logic prioritizes the post-coordination, allowing the incorporation of more detailed classifications to the stem term. The additional classifications, such as topography, severity and chronological scale are now available in the “Extension codes” chapter (*e.g.: L27.0 Generalized skin eruption due to drugs and medicaments of ICD10 = Drug eruption heading + XB13 Generalized of ICD-11*). Although this manuscript presents some technical aspects of classification and new ICD-11 concepts, its aim is also to serve as a step forward to reach quality assurance of the new model and as an introduction to ICD-11 for ICD end-users in the allergy community using anaphylaxis as an example.

The number of excluded files based on the clinical evaluation calls the attention of pitfalls in ability of documenting (medical records and registries) and coding, which hamper reliable epidemiological data. For this reason, the core ALLERGY in ICD-11 operational team (LKT, MC, PD) intends to implement educational tools to cover this gap, following the ICD-11 logic. Educational efforts will also help



to address the decrease of under-recognition of anaphylaxis by patients, caregivers, and health professionals.

The CHRUM covers a population counted with 270,000 inhabitants for direct referrals and 2,700,266 inhabitants for tertiary referrals. Considering the mean number of total hospitalizations at the CHRUM (40,000 hospitalizations/year), 6% were related to allergic or hypersensitivity conditions based on the ICD-10 codes, 29% having anaphylaxis related codes. The clinical evaluation was able to confirm 89 cases/year. With the evaluation proposed, we are not able to estimate if these numbers can be reproduced over the years, but it provides the basis to estimate an average rate of 0.32 (95% CI: 0.8–0.95) anaphylaxis cases per thousand population per year. Although restricted to a French region, this data supports that anaphylaxis, as a severe life-threatening allergic condition, ***should be formally added into the list of rare diseases*** in order to support awareness and quality clinical management of patients by building up a network of reference and related competence centres spread in all regions as it already exists for every rare disease in France.

Some limitations of the current study may have to be considered. There is a low risk of having the classification tuned up until the end of the revision process due to regular ICD-11 beta draft platform updates. Although limited to one institution only, we intend to extend the inclusion of new centres and the generated data follows the WHO ICD-11 revision agenda in order to reach global comparability with the presented results. The CHUM is known for performing drug hypersensitivity work-up and patients from this French region are advised for this reason. Although we are aware that it may have had influence in the quantitative data, it may not have influenced the qualitative field-testing methodology application and coding procedure. The inclusion of additional centres from the international network may allow us to objectively understand how the characteristics of patients' data can affect the quality assurance process.

## **Conclusion**

The construction of the new section dealing with anaphylaxis means that the latter will now be recognized as a clinical condition requiring specific documentation

and management. Besides increasing the accuracy and sensibility of clinical diagnosis data, unifying the allergic and hypersensitivity conditions into a single section of the ICD, endorsed by the WHO ICD governance bodies, can be considered a strong epidemiological, economical and political move that advocates in favour of the best diagnosis and management of allergic patients worldwide. By allowing all the relevant diagnostic terms for anaphylaxis to be included into the ICD-11 framework, WHO has recognized their importance not only to clinicians but also to epidemiologists, statisticians, health care planners and other stakeholders.

#### ABBREVIATIONS:

ICD: International Classification of Diseases

CHRUM: University Hospital of Montpellier

RSG: Revision Steering Group

TAG: Topic Advisory Group

WGs: Working Groups

WHA: World Health Assembly

WHO: World Health Organization

#### DECLARATIONS:

##### ETHICS APPROVAL AND CONSENT TO PARTICIPATE

“Not applicable”

##### CONSENT FOR PUBLICATION

“Not applicable”

##### AVAILABILITY OF DATA AND MATERIAL

Data sharing not applicable to this article as no datasets were generated or analyzed during the current study. The ICD-11 beta draft platform is open to the public.

##### COMPETING INTERESTS

The authors declare that they do not have any conflict of interests related to the contents of this article.

##### FUNDING

Pascal Demoly and Luciana Kase Tanno received an unrestricted AstraZeneca ERS-16-11927 grant through CHRUM administration.

#### AUTHOR CONTRIBUTIONS':

Luciana Kase Tanno and Pascal Demoly contributed to the construction of the document (designed the study, analyzed and interpreted the data, and wrote the manuscript). Nicolas Molinari, Pierre Aubas and Sophie Bruel contributed to the methodology design and data evaluation. Nicolas Molinari, Sophie Bruel, Jean Luc Bourrain, Moises A Calderon and Pierre Aubas contributed to tuning the document and revision of the manuscript.

#### ACKNOWLEDGEMENT:

We are extremely grateful to all the representatives of the ICD-11 Revision Project with whom we have been carrying on fruitful discussions, helping us to refine the classification presented here: Robert Jakob, Linda Best, Nenad Kostanjsek, Robert J G Chalmers, Jeffrey Linzer, Linda Edwards, Ségolène Ayme, Bertrand Bellet, Rodney Franklin, Matthew Helbert, August Colenbrander, Satoshi Kashii, Paulo E. C. Dantas, Christine Graham, Ashley Behrens, Julie Rust, Megan Cumerlato, Tsutomu Suzuki, Mitsuko Kondo, Hajime Takizawa, Nobuoki Kohno, Soichiro Miura, Nan Tajima and Toshio Ogawa.

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LIST OF FIGURES

Figure 1: Anaphylaxis corresponding ICD-10 and ICD-11 codes

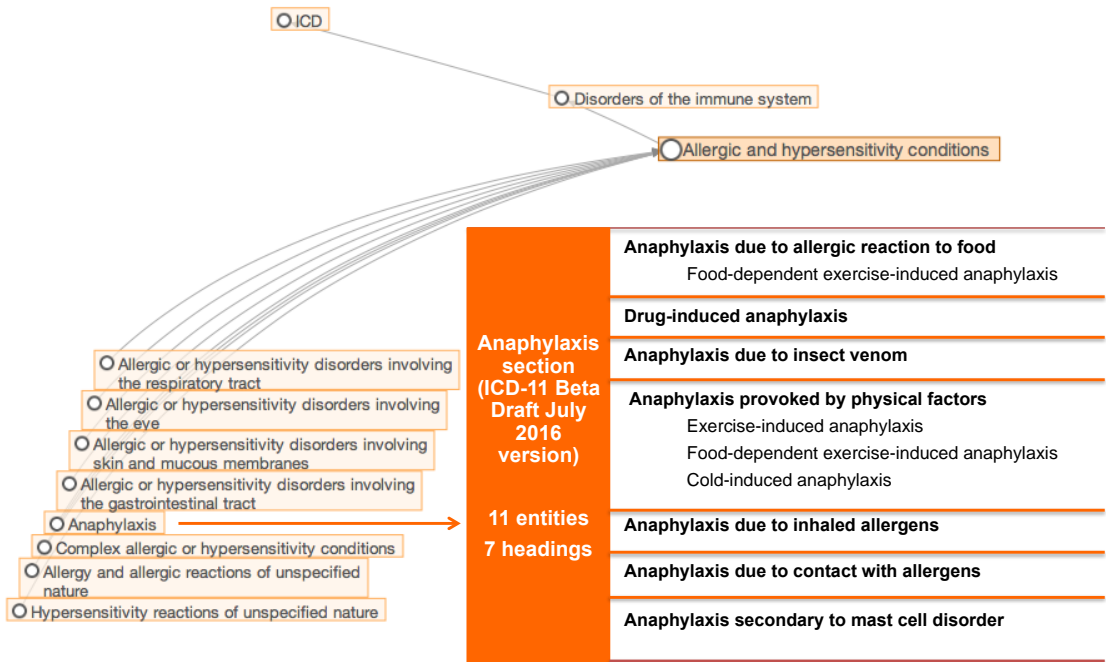
Figure 2: The "Anaphylaxis" subsection scattered into the pioneer ICD-11 "Allergic and hypersensitivity conditions" section

Figure 3: General scheme and outcomes of the field-testing methodology applied for anaphylaxis

Figure 4: Characterization of one-year evaluation of University Hospital of Montpellier anaphylaxis cases

Anaphylaxis ICD-10 (2015 version) codes	Anaphylaxis ICD-11 (frozen May 2015 version) codes
<p><b>Chapter XIX Injury, poisoning and certain other consequences of external causes (S00-T98)</b></p> <p><b>Other and unspecified effects of external causes (T66-T78)</b></p> <p><b>T78 Adverse effects, not elsewhere classified</b></p> <p>Note: This category is to be used as the primary code to identify the effects, not elsewhere classifiable, of unknown, undetermined or ill-defined causes. For multiple coding purposes this category may be used as an additional code to identify the effects of conditions classified elsewhere.</p> <p><b>T78.0 Anaphylactic shock due to adverse food reaction</b></p> <p><b>T78.1 Other adverse food reactions, not elsewhere classified</b></p> <p><b>T78.2 Anaphylactic shock, unspecified</b></p> <p>Allergic shock NOS Anaphylactic reaction Anaphylaxis</p> <p><b>T78.3 Angioneurotic oedema</b></p> <p>Giant urticaria Quincke oedema</p> <p><b>T78.4 Allergy, unspecified</b></p> <p>Allergic reaction NOS Hypersensitivity NOS Idiosyncrasy NOS</p> <p><b>T78.8 Other adverse effects, not elsewhere classified</b></p> <p><b>T78.9 Adverse effect, unspecified</b></p>	<p><b>Chapter 04 Disorders of the immune system</b></p> <p><b>Section Allergic and hypersensitivity conditions</b></p> <p><b>Subsection Anaphylaxis</b></p> <p><b>4B50 Anaphylaxis due to allergic reaction to food</b></p> <p><b>4B51 Drug-induced anaphylaxis</b></p> <p><b>4B52 Anaphylaxis due to insect venom</b></p> <p><b>4B53 Anaphylaxis provoked by physical factors</b></p> <p>4B53.1 Exercise-induced anaphylaxis 4B53.2 Cold-induced anaphylaxis 4B53.Y Anaphylaxis provoked by other specified physical factors 4B53.Z Anaphylaxis provoked by unspecified physical factors</p> <p><b>4B54 Anaphylaxis due to inhaled allergens</b></p> <p><b>4B55 Anaphylaxis due to contact with allergens</b></p> <p><b>4B56 Anaphylaxis secondary to mast cell disorder</b></p> <p><b>4B5Y Other specified anaphylaxis</b></p> <p><b>4B5Z Anaphylaxis, unspecified</b></p>

Figure 1: Anaphylaxis corresponding ICD-10 and ICD-11 codes



**Figure 2: The "Anaphylaxis" subsection scattered into the pioneer ICD-11 "Allergic and hypersensitivity conditions" section**

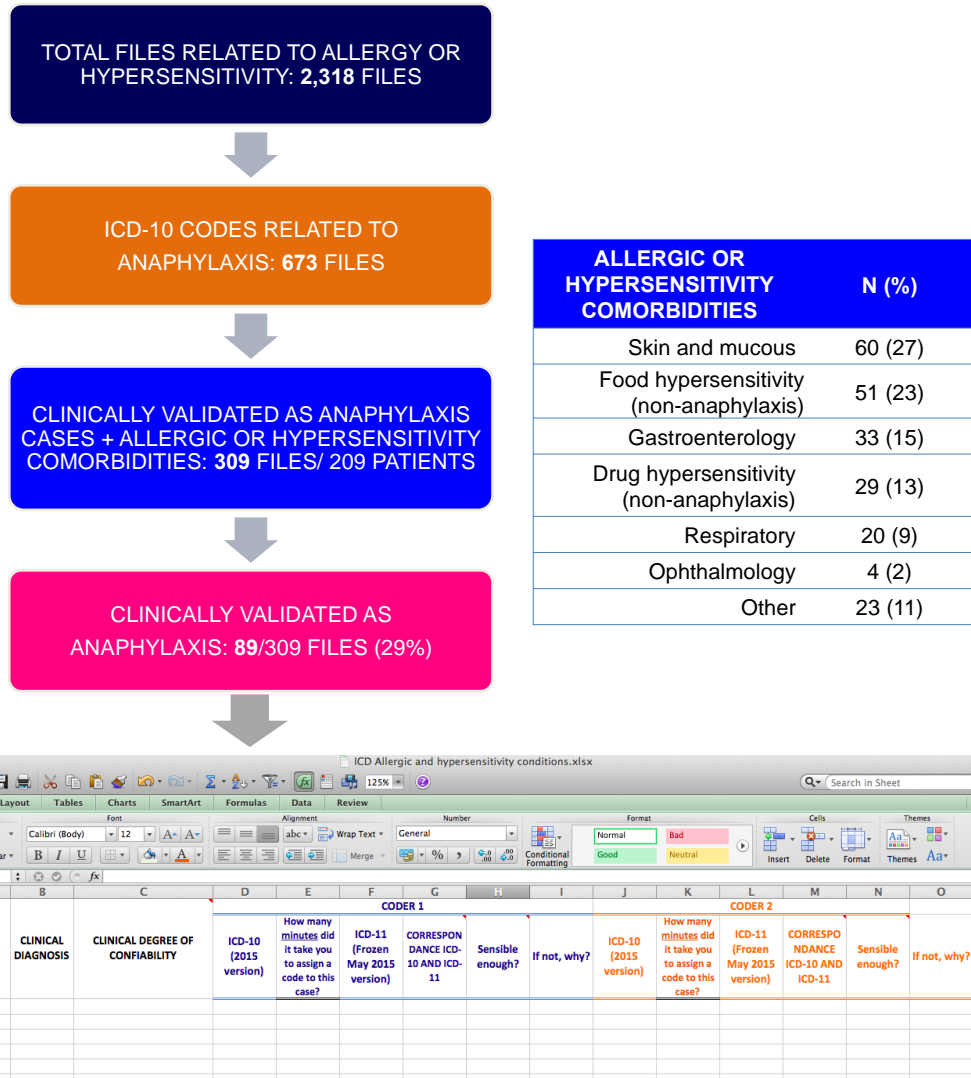


Figure 3: General scheme and outcomes of the field-testing methodology applied for anaphylaxis

## ANAPHYLAXIS CASES: 89/YEAR

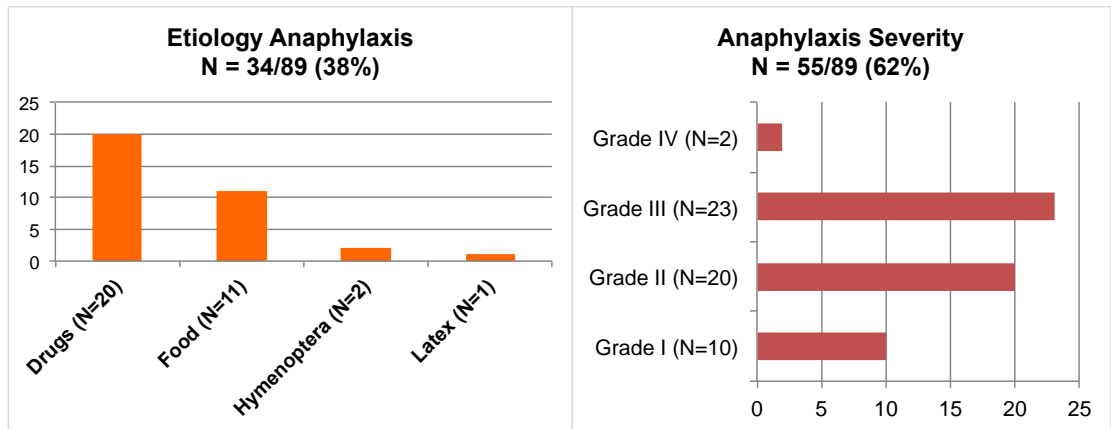


Figure 4: Characterization of one-year evaluation of University Hospital of Montpellier anaphylaxis cases