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Preventive Healthcare through Air Pollution Exposure Modeling: the example of PULSE in Pavia

Does a medical device nomenclature suitable for all purposes exist? Twenty years of Italian experience with the CND and its adoption in EUDAMED at European level

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***Abstract*— There are many purposes for using a nomenclature of medical devices.**

The Italian CND is a free public available nomenclature, arises from a comparison with existing nomenclatures and is structured to allow a connection with other systems.

Since 2007 the CND is used, in the Italian database, for regulatory affairs in order to register and classify homogeneously medical devices from a technical and economics point of view; in 2019 the CND has been adopted from European Commission as official nomenclature.

It is not possible to think that a nomenclature can meet all needs. However, it is possible to guarantee the interoperability of different classification systems by adopting a single hierarchical nomenclature as a common basis from which to develop different "subclassifications" for different purposes.

Aim of this paper is to present the Italian experience in the development of the national medical device nomenclature and its extension to the European level.

***Keywords*— Medical Device legislation, European Union, classification, nomenclature**

I. Introduction

Advances in medical device (MD) technology have been dramatic in recent years resulting in both an increased number of medical devices (estimated to be approximately 500,000 different devices in Europe) and an increase in the invasiveness and critical function which devices perform [1].

According to the World Health organization, at present, there is no common standard name for each type of medical device, an inconsistency that causes confusion between the various types of devices, affects traceability and has an adverse impact on health care delivery [2]. Globalization of the medical device market and trading across economic borders requires prioritization of regulatory convergence which should be accompanied by a common and consistent language with which to communicate device information [3]. To describe and identify these medical devices in an unambiguous manner, there is a need for a common method [4]. A standardized classification and nomenclature of medical devices will serve as a common language for recording and reporting medical devices across the whole health system at all levels of health care for a whole range of uses. Standardization of nomenclature is also essential for defining and naming innovative technologies, classifying the devices for regulatory approval (registration) and for streamlining procurement of these products (2 OMS).

The advent of the European directives, initiated a new era, where national and indeed international bodies were given the opportunity to cooperate and harmonize their efforts in achieving the one thing that they all needed, namely, a standardized method of identifying the products placed in the global market. Many nomenclature systems (CNMD, EDMA, ISO 9999, JFMDA, NKKN, UMDNS), all built upon different structures, and used locally or nationally for diverse purposes and with unusual approaches, were chosen to develop the Global Medical Device Nomenclature (GMDN) [4].

On 19th April 2010, the EU Commission adopted the decision of establishing the European Databank on Medical Devices (Eudamed). The aim of the European databank for medical devices was to strengthen market surveillance by providing competent authorities with fast access to information on manufacturers and authorised representatives, devices and certificates and to vigilance data, to share information on clinical investigation data, as well as to contribute to a uniform application of those Directives, in particular in relation to registration requirements [5]. With the New Regulation on Medical Devices, Eudamed was formally established and the Commission was recommended to ensure that an internationally recognised medical devices nomenclature is available free of charge to manufacturers and other natural or legal persons required by this Regulation to use that nomenclature [6].

On 4th March 2019, the EU Commission adopted the Italian National Nomenclature of Medical Devices (Classificazione Nazionale dei Dispositivi medici, CND) as a base for the development of the European Medical Device Nomenclature (EMDN) to support the activity of the future European database of medical devices EUDAMED [7].

The aim of this paper is to present the Italian experience in the development of the Italian national medical device nomenclature and its further extension to the European level.

II. METHOD

Since 90's, Italy started to define a nomenclature that allow to classified biomedical technologies in a standard way (CIVAB): even through, this nomenclature did not include all the world of medical devices.

In the 00's, in according to the UE directives, the competent office decided to create a wider nomenclature including most of the medical devices placed on the market. Following which, was made a benchmarking with the other existing nomenclatures in the medical field [8] (Table I):

- **UNITED NATIONS COMMON CODING SYSTEM (UNCCS)**: designed for the identification of both goods and services and used in supplies and tenders; 6 characters hierarchical coding system.
- **CIVAB**: was made from a project related to biomedical technologies with aim of developing a standard coding to support the purchase, management and maintenance of biomedical equipment; the coding is associated with an alphanumeric speaking code (3 class characters, 3 manufacturer characters, 2 model characters).
- **UNIVERSAL STANDARD PRODUCTS AND SERVICES CLASSIFICATION (UNSPSC)**: multi-sector standard, evolution of the UNCCS, for classification of products and services, for achieving company-wide visibility of spend analysis, as well as, enabling procurement to deliver on cost-effectiveness demands and allowing full exploitation of electronic commerce capabilities; 8 characters hierarchical coding.
- **UNIVERSAL MEDICAL DEVICE NOMENCLATURE SYSTEM (UMDNS)**: used in applications ranging from hospital inventory and work-order controls to national agency medical device regulatory systems and from e-commerce and procurement to medical device databases; facilitates identifying, transferring, and communicating data about medical devices; not hierarchical 5 numeric codes nomenclature.
- **EUROPEAN DIAGNOSTIC MANUFACTURERS ASSOCIATION'S IN-VITRO DIAGNOSTIC PRODUCT CLASSIFICATION (EDMA)**: used to code in vitro diagnostic medical devise, grouping reagents and instrumentation (accessories); represents the interests of IVD'S european manufacturers for the purpose to support the collection and analysis of market statistics; now is called as GIVD classification; 4 characters hierarchical classification.
- **GLOBAL MEDICAL DEVICE NOMENCLATURE (GMDN)**: it provides a nomenclature used for the exchange of information of medical devices; the list of terms is updated through member modification requests; not hierarchical 5-digit list of numeric codes.

TABLE I
OTHER EXISTING NOMENCLATURES IN THE MEDICAL FIELD IN THE 00'S

Nomenclature	CIVAB, UMDNS GMDN
Classification	UNCCS, UNSPSC, EDMA

The Italian Financial Law 2003, among other things, established that medical devices should be classified in uniform classes and sub classes with an indication of the reference price. It has been giving the responsibility for this classification to the National Commission for Medical Devices (CUD), technical advisory body of the Ministry of Health.

The first version of the Classificazione Nazionale dei Dispositivi Medici (CND) was defined by the CUD in July 2005 and approved with the Ministerial Decree of 22 September 2005 [9].

Subsequently, the Italian Financial law of 2006 involved the State - Regions Conference, [10] for the approval of the national nomenclature.

The new CND version, was established by Italian Ministry of Health Decree of 20 February 2007. Since that date the CND became the official nomenclature of products identified as medical devices in accordance with European Legislation and national transposition standards [11] and valid at National level.

TABLE II
SEQUENCE OF MINISTERIAL DECREES THAT INTRODUCED THE NEW VERSIONS OF THE CND

CND Version	Ministerial Decree
1	22 September 2005
2	20 February 2007
3	13 March 2008
4	12 February 2010
5	7 October 2011
6	29 July 2013
7	8 June 2016
8	13 March 2018

The construction, the maintenance and the updates of the CND have been based on the following three fundamental principles [12]:

A. Participative approach: The medical device sector is very complex and heterogeneous, that's the reason why, it requires highly differentiated and qualified expertise in the field of MD. Besides, it has become necessary, for a reliable nomenclature for medical devices, the contribution of a broad participation of all stakeholders (economic operators and healthcare professional).

B. Qualified validation of proposals: Nomenclature proposals are technically validated to establish the actual need considering:

- other existing nomenclature systems available also at international level
- consumption and expense information
- assessment with sector experts from the different disciplines

C. Formal adoption and free public availability

The nomenclature has an alpha-numeric structure which is developed in a multi-level hierarchical tree and it clusters medical devices in three main levels:

- **Category:** the first hierarchical level. There are 22 categories identified by a letter and each ones includes devices for anatomical district (8), functional use (9) and other criteria (5).
- **Group:** the second hierarchical level. There are 146 anatomical/function groups, identified by a two-digit numbers from 01 to 99 for each category.
- **Type:** the third hierarchical level. There are, if necessary, until 5 levels of detail which one identified by a two-digit numbers.

Each medical device is classified by an alphanumeric code made of a letter referring to the "Category", a couple of numbers referring to the "Group" and a series of other couples of numbers referring to the "Type" to a maximum of 7 levels (Figure 1).

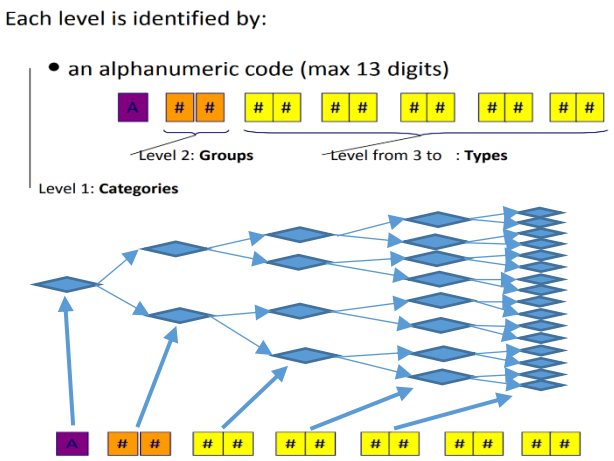

Figure 1: Representation of the CND structure

The nomenclature covers the whole panorama of medical devices, not only biomedical equipment (Z category) and in vitro diagnostic devices (W category).

The CND nomenclature is one of the tools used for the governance of the medical device sector characterized by extremely high complexity and fragmentation. It aims to support the improvement of patient safety and the quality of health systems by enabling information to be communicated in a standardized manner.

It allows more effectively monitoring the consumption and use of devices, a better evaluation of accidents and to obtain a reference prices for homogeneous classes of medical devices making the purchasing processes more transparent by the national health system.

The CND is used in:

- marketing activities
- vigilance and market surveillance
- analysis and definition of economic planning policies

The CND system, which represents the basis of the Italian information system for the registration of medical devices, constitutes an official, freely and available reference to all stakeholders: being a hierarchical nomenclature and therefore not very flexible to changes, specific items have been inserted to code the equipment accessories (hardware "80", software "82", consumables "85") and devices that cannot be included in a specific type (other "99").

Although the shallow depth of the nomenclature levels, the periodic updates allow the creation of new branches with the possibility of including devices that were previously in the item "99".

A device with multiple functionalities could create ambiguity in the coding and make the choice fall on more terminal item: in this case, multiple choice is not possible and it is necessary to refer to the main intended use.

III. Discussion

There are basically two different approaches for medical devices "categorisation": nomenclatures (NOM) and a classifications (CLA). NOM give more detailed and specific information on the single element. The granularity of the information of each term of a NOM is not predefined. On the other hand, the granularity of a CLA is intrinsically related to its hierarchical structure. In choosing between the two approaches, a tradeoff must be considered: NOMs tend to describe DMs in more detail but do not allow easy management of large amounts of information, on the other hand, CLAs are more rigid and less flexible in describing DMs but allow for easier management of the information, due to a hierarchical structure that brings together and organizes the articles provided.

The choice in the construction of the CND was oriented on the second approach in consideration of the huge number of devices on the market (millions of different MDs) and related information that was intended to manage. It was decided to lose in descriptive precision to privilege the ability to organize and manage information in a simple and easily understandable way at all levels of the health system. For devices that are not complex in terms of technical and functional characteristics, classifying in a single terminal branch is quite easy; for devices with more complex technical characteristics and / or more functionalities, making a univocal classification and in a terminal branch could be more complicated.

IV. Conclusion

For its features, the CND has been adopted by the European Commission as official nomenclature for the future databank EUDAMED and will be reviewed, updated and renamed as European Medical Devices Nomenclature (EMDN).

The revision of the current CND with other existent nomenclatures will ensure that the new EMDN will be articulated in a way comparable with the other systems.

The experience of the Italian database of medical devices shows that the CND allows the classification of DMs for regulatory purposes and for monitoring expenditure, however it cannot be said that it is in itself usable for any purpose (for example, in the experience of the Italian Arthroprosthesis Registry, the CND is supported by further elements that allow to technically characterize the DMs of interest). The CND (and EMDN at European level) constitute a "classification root" from which specific systems can be developed for particular purposes and ensure interoperability between them.

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