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Abstract —**Medical devices have different nomenclatures for their classification. Some of the most significant nomenclatures are the Universal Medical Device Nomenclature System (UMDNS) and the Global Medical Device Nomenclature (GMDN) by the Emergency Care Research Institute (ECRI). In Italy the main are CIVAB and "Classificazione Nazionale Dispositivi Medici" (National Classification for Medical Devices – CND). The aim of this study is to create a system to automatically decode several device models from CIVAB to UMDNS code. All medical devices are coded with a table which is based on their definitions presented in these nomenclatures. The coding is lastly applied to a list of models of medical devices, developed by different companies.**

Keywords — **UMDNS, CIVAB, ECRI, coding, medical device**

I. Introduction

One of the most important aspects for medical devices manufacturers and developers is represented by the set of national laws of the countries in which their devices are sold. The classification of a medical device in Europe is performed according to the definition of the European Directive CE 2007/47 that defines it as "any instruments, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease
- diagnosis, monitoring, treatment or alleviation of or compensation for an injury or handicap
- investigation, replacement or modification of the anatomy or of a physiological process
- control of conception

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological, or metabolic means, but which may be assisted in its function by such means". [1]

Medical devices have different nomenclature around the world, but the most important are:

- The Emergency Care Research Institute (ECRI) nomenclature called Universal Medical Device Nomenclature System (UMDNS)
- The Global Medical Device Nomenclature (GMDN)

Every country has its own laws and nomenclatures. For example in Italy the main classifications are the "Classificazione Nazionale Dispositivi Medici" (National Classification for Medical Devices – CND) and the older CIVAB classification [2].

The aim of this study is to create an automated system to parse CIVAB nomenclatures to UMDNS for a list of devices collected in a database.

II. Materials and methods

CIVAB is used by various Italian Healthy Companies and it is made out of a string of eight alphanumerical characters. The first three characters represent the class technology of the medical device, the second three digits represent the manufacturer and the last two ones represent the model of the device. For example the code *"DEF-PHY-LK"* represent the Lifepak 10 defibrillator, developed by Medtronic Inc.

UMDNS includes medical devices and materials, such as reagents and instruments for clinical analysis. This nomenclature is composed by two elements: the *preferred terms* and the *entry terms*.

An unique 5-digit numeric code (Universal Medical Device Code – UMDC) corresponds to each *preferred terms*, which are assigned randomly and sequentially to medical devices. The *entry terms* are negative numbers representing synonymous, quasi-synonymous, lexical variants, initialisms or acronyms of the *preferred terms*. The UMDNS has a hierarchical structure: the difference between the levels is a single term. Every *preferred term* has a definition, which describes the applications of the medical device and its materials or technologies.

Preferred terms are linked each other and with *entry terms* according to a relationships, conceived by ECRI [3]. An example of this relationship is reported in the following table.

Table 1 Example of the relationships in UMDNS nomenclature

UMDNS Code Synonymous	Device Name Synonymous	UMDNS Code	Device Name
-2345	Defibrillator Paddles	11132	Defibrillators

-1368	Stimulators, Cardiac	11132	Defibrillators
-238	Cardioverters	11132	Defibrillators
11127	Testers, Defibrillator	11132	Defibrillators
20168	Monitors	11132	Defibrillators
18484	Stimulators, Electrical, Cardiac	11132	Defibrillators

UMDNS is used to create another international nomenclature called GMDN, described in the ISO standard 15255 "*Nomenclature – Medical device nomenclature data structure*".GMDN use a *preferred terms* structure just like UMDNS [4][5].

The system is originally made by 10 starting (6 for CIVAB nomenclature and 4 for UMDNS nomenclature) and a coding table.

A. CIVAB tables

- *dbo_CND_Coding;*
- *dbo_CNDCodingDeviceDescriptions;*
- *dbo_sch_Manufacturers;*
- *dbo_sch_DeviceDescriptions;*
- *dbo_sch_DeviceModels;*
- *dbo_DeviceDescriptions.*

The tables *dbo_CND_Coding* and *dbo_DescrizioneApparecchiCodificaCND* are used to parse medical devices from CND to CIVAB codes. In the table *DeviceDescriptions* take place the descriptions for the medical devices. The most important table is *dbo_sch_DeviceDescriptions* which contains the CIVAB coding for medical devices.

B. UMDNS tables

- *UMDNS_Alphabetic_Concept_List;*
- *UMDNS_Concept_Definitions*
- *UMDNS_Concept_Relationship;*
- *UMDNS_Manufacturer_Names.*

This tables are downloadable from the ECRI website. The table UMDNS_Concept_Definitions contains all description of the *preferred terms*, while the table UMDNS_Concept_Relantionship contains the relationships between the *preferred terms* and the *entry terms*.

C. Coding Table

The coding from CIVAB to UMDNS is based on the definitions of the medical devices, presented in both nomenclatures. The codified medical devices belong to the follow categories:

- Medical Devices (CEI 62-5);
- Defibrillators;
- Electrosurgical Unit;
- Illumination's Devices;
- Infusion pump.

This table is made by these fields:

- *ID;*
- *ID_CIVAB;*
- *CIVAB's code;*
- *Description;*
- *Synonymous CIVAB's code;*
- *Synonymous of the description;*
- *UMDNS code;*
- *Device Name;*
- *Principal UMDNS code;*
- *Not presented;*
- *Notes*

The field *Synonymous of the description* is filled with a component of the medical device or with the same name of the *Description* field. The *Notes* fields describes if the relative preferred term is a synonymous or it is related with an entry term. The highest level of the hierarchical structure for multi-preferred-terms devices is carried in the *Principal UMDNS code* field.

D. Application to dbo_sch_DeviceModels table

The coding system is applied to *dbo_sch_DeviceModels* table: it contains all the devices' models developed and produced by worldwide companies. Every model has CIVAB code with descriptions, synonymous and company name.

A SQL function selects all models available for a given description of medical device and automatically links them to the relative *preferred term*.

For example a monopolar-bipolar check and an application field search is made for the UMDNS *preferred term* "electrosurgical units".

III. RESULTS AND DISCUSSIONS

The coding from CIVAB to UMDNS reports some difference.

For some medical device there is one related *preferred term*. For example the CIVAB description "COLPOSCOPIO" has a single *preferred term* "10-960 Colposcopes".

Other devices have more than one *preferred term* because UMDNS considers technological aspects or applications that CIVAB excludes. For example the CIVAB description "BRONCOSCOPIO" has 4 *preferred*

terms because it is an endoscope, which can be flexible or rigid.

Other devices are associated to the *preferred terms* because they are associated to the *entry terms* too. For example CIVAB's "FOTOCHERATOSCOPIO" is related to the *preferred term* "16-347 Keratoscopes".

Besides other medical devices do not have any *preferred term* because there is no definition in UMDNS database which referred to them. These results are shown in Table 2.

Table 2 Example of coding of medical device from CIVAB to UMDNS

CIVAB code	CIVAB description	UMDNS Code	DEVICE NAME
BRS	BRONCOSCOPIO	10491	Bronchoscopes
BRS	BRONCOSCOPIO	15073	Bronchoscopes, Flexible
BRS	BRONCOSCOPIO	15074	Bronchoscopes, Rigid
BRS	BRONCOSCOPIO	20476	Endoscopes, Respiratory Tract
CPS	COLPOSCOPIO	10960	Colposcopes
FCS	FOTOCHERATOSCOPIO	16347	Keratoscopes

The application of the coding to *dbo_sch_DeviceModels* table shows that one model can be linked to one or more *preferred terms*. UMDNS classifies some models in a narrower way because it specifies technological details or applications that CIVAB excludes. For example the Berchtold's ELEKTROM 200 model is an electrosurgical unit, monopolar and bipolar (UMDNS Code: 18-231).

Otherwise other models have two or more codes, especially for the application. In fact some models have two or three *preferred terms* because UMDNS classified them according to their application.

Other models are wrongly classified in the CIVAB database: this coding also allows to correct these errors and to associate the exact description to the model.

Models which can not be described in details (from application or technological aspect) have the principal *preferred term* in the hierarchical structure.

Future works are about developing an unique UMDNS code (like CIVAB already does) and classify medical devices according to GMDN coding. Therefore healthcare institutions will be able to know model, description and brand of a given medical device model by using this unique code.

IV. Conclusion

This study concerns an automated system which parses medical devices from CIVAB to UMDNS coding.

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Conflict of interest

The authors declare that they have no conflict of interest

References

1. Directive CEE 2007/47
2. CIVAB at www.salute.gov.it
3. UMDNS at www.ecri.org
4. Anand K, Saini SK, Singh BK, Veermaram C (2010) Global Medical Device Nomenclature: The Concept for Reducing Device-Related Medical Errors J. Young Pharm. 2010 Oct-Dec; 2(4): 403–409
5. Miniati, R., Dori, F., Iadanza, E., Fregonara, M. M., & Gentili, G. B. (2011). Health technology management: a database analysis as support of technology managers in hospitals. Technology and health care: official journal of the European Society for Engineering and Medicine, 19(6), 445–54. doi:10.3233/THC-2011-0642

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