



Agency / Organization	ECRI
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WHO thanks you very much for your participation in the meeting to discuss the standardization of medical devices nomenclature, as mandated by WHA74.

Please find below the survey for the Nomenclature Agencies, as mentioned during our meeting. Please provide all the evidence required for every statement provided (for example, website screenshots, links to your website or attach the documents required).

I. General questions on nomenclature structure, access, and copyright

1. Please provide an overview of the processes used for: code development and maintenance, requests for updates, change control procedures, communication, and distribution of update versions. Who performs them and the periodicity?

ECRI Institute created the Universal Medical Device Nomenclature System (UMDNS) in 1971 and has continually updated the taxonomy and nomenclature. UMDNS' scope is broad and includes almost everything found in a healthcare facility's inventory including capital equipment, implants, supplies, software, clinical laboratory equipment, in vitro diagnostics/genetic tests, homecare, and assistive devices. Although UMDNS includes combination products, substances that work purely metabolically are outside the scope of the nomenclature. As of August 2021, UMDNS comprises 43,497 concepts (12,959 preferred terms; 30,538 entry terms). This includes a substantial expansion of the in vitro diagnostic genetic testing category and the addition of a category for purchased services. UMDNS is an international standard under ISO/IEC 15459.

Our current development platform is the Apelon DTS, version 4.7.1

ECRI Institute has dedicated full- and part-time staff to the maintenance and development of UMDNS. In addition, a large portion of ECRI's employee base (> 500 professionals) serve as reviewers across their areas of expertise. ECRI includes healthcare industry experts in the external review process for its publications. In the case of device-related publications, manufacturers and other experts comment on UMDNS terms as part of the draft document. Hospital-based stakeholders contribute feedback in the form of term requests. The UMDNS team holds formal monthly meetings but confer as needed to meet the needs of internal and external stakeholders. Users of UMDNS are encouraged to send suggestions and questions to UMDNS@ecri.org.

2. Please describe in detail the structure of your nomenclature - hierarchy, levels, etc.

UMDNS is an ontology with approximately 30 roots and then a hierarchy of more than 12,000 concepts. We also include more than 30,000 search terms which point users to the correct concept.

UMDNS adheres to best practices for nomenclature development including concept permanence, mutual exclusivity, defining concepts, and avoiding ambiguity. ECRI has created internal documents to codify its approach, including decision algorithms, templates, and detailed instructions. In 2005, under contract to the U.S. FDA, ECRI created nomenclature development guidelines for use by Center for Devices and Radiologic Health (CDRH) nomenclature staff.

UMDNS is a polyhierarchical taxonomy maintained using Apelon TDE/DTS decision logic. It comprises preferred terms and codes, entry terms, hierarchical structure (parent-child, sibling relationships), attributes and definitions. Attributes provide additional axes of classification, such as clinical specialty, capital equipment, trackable device, etc. Universal Medical Device Codes (UMDC) are unique 5-digit numeric codes; assigned sequentially, these codes intentionally do not carry inherent meaning to permit extensibility. UMDNS concept definitions describe the device and its intended purpose. Constructed in a standardized way, these definitions help prevent ambiguity, redundancy, or overlapping of concepts for similar devices.

UMDNS incorporates multiple relationships between terms. In addition to the hierarchical parent-child and sibling relationships, UMDNS includes one-to-one and one-to-many relationships between entry terms (cross-references) and preferred terms (formal UMDNS). In addition to lexical variants, entry terms include broad grouping concepts and phrases from common parlance. For example, a search for CT scanners leads users to [13469] Scanning systems, computed tomography and its child terms. Users are also referred to related terms such as Software, Computed Tomography [26874] and Modular Medical Facilities, Mobile, Computed Tomography [17878].

The UMDNS hierarchy permits indexing at differing levels of granularity to meet stakeholder needs and has been incorporated into benchmarking systems. Depth varies by technology; in some facets, there may be seven or more levels to the hierarchy. Take, for example, BRCA genetic test panels for breast cancer.

- In Vitro Diagnostics and Laboratory Equipment [HT-1011]
 - IVD Panels [36948]
 - IVD Panels, Human Genetics [35450]
 - IVD Panels, Human Genetics, Cancer [35845]
 - IVD Panels, Human Genetics, Cancer, Familial [35858]
 - IVD Panels Human Genetics, Cancer, Familial, Breast, Basic Test, Genes BRCA1/BRCA2 [35859]
 - IVD Panels Human Genetics, Cancer, Familial, Breast, Basic Test, Genes BRCA1/BRCA2, Del/Dup [35860]
 - IVD Panels Human Genetics, Cancer, Familial, Breast, Basic Test, Genes BRCA1/BRCA2, Mutation [35861]

Since UMDNS is an ontology, software that incorporates UMDNS facilitates analysis at multiple levels. In this example, the most specific terms 35860 and 35861 classify a test at the individual item level. However, through the parent-child linkages analyses could still include items with this code at broader levels, depending on the algorithms. In this way, UMDNS represents individual items while maintaining the ability to track total spend in a given area (e.g. BRCA test panels, cancer test panels, genetic test panels, panel tests, IVDs).

Because uses of UMDNS vary widely, commercial availability is not a requirement for concept inclusion nor are terms necessarily retired as technologies advance. For example, UMDNS was one of the terminologies applied to the U.S. Agency for Healthcare Research and Quality (AHRQ) Healthcare Horizon Scanning System (HHSS 2010 – 2015). HHSS identified devices at Phase II and only tracked the devices until one year after they received FDA approval/clearance. Conversely, devices may remain in use in developing countries long after they have become obsolete in other portions of the globe. UMDNS maintains active status for these terms as long as the devices remain in use somewhere.

3. Please provide a copy of your license agreement including any subscription or other costs associated with the use of your nomenclature.

In the recent past ECRI required an Annual Membership with tiered price structure. We are revising this policy and reinstating free use for non-commercial purposes. A revised license is forthcoming.

4. Please describe how codes, names and descriptions are accessed by user groups.

Downloadable Excel and text files are posted on a website twice a month. An XML export of the entire UMDNS is provided to the U.S. National Library of Medicine (NLM) for incorporation into the Unified Medical Language System (UMLS) Metathesaurus annually.

4.1 Is a login/ registration/ subscription required?

Yes, all of the above. Once we reinstitute free access users will still need to create an account with a unique login.

4.2 Are their APIs available?

Not at this time. Possible future development.

4.3 Is the full dataset (codes, names, descriptions, hierarchies) downloadable?

4.3.1. No, explain:

4.3.2. yes, only partial, explain conditions:

4.3.3 Yes, only with previous registration or login, explain.

Users request a free license and receive a username and password that give them access to the UMDNS download site.

4.3.4. Yes, can be open and downloaded by anyone, anywhere.

4.4 Is the information freely available?

UMDNS will be freely available for non-commercial use. Non-commercial use includes use by regulatory bodies and healthcare systems.
4.5 Which electronic platform are you using?
Our current development platform is the Apelon DTS, version 4.7.1. Downloadable Excel files are posted on a website twice a month. An XML export of the entire UMDNS is provided to the U.S. National Library of Medicine (NLM) for incorporation into the Unified Medical Language System (UMLS) Metathesaurus annually.

II. Work for convergence/ standardisation /access

<p>1. Please describe the ways your organization currently supports WHO in the work for convergence and standardisation of medical device nomenclature by completing the following.</p> <p>Please select the applicable options you make available (open access) and describe any conditions tied to that option.</p> <p>b) <input checked="" type="checkbox"/> the codes</p> <p>c) <input checked="" type="checkbox"/> the terms</p> <p>d) <input checked="" type="checkbox"/> the definitions</p> <p>e) <input checked="" type="checkbox"/> the hierarchy*</p> <p>The hierarchical relationships are present in the download files. However, at this time the only externally available view of the hierarchy is through the NLM UMLS.</p>
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2. For each item not checked above, please describe how you will be willing to make each item available to support convergence and meet WHO Member States requirements.

3. Does your Agency map to other existing Nomenclatures? (Please select the applicable option(s), when applicable).																				
<table border="1"> <thead> <tr> <th>Nomenclature</th> <th>Yes</th> <th>No</th> <th>N.A.</th> </tr> </thead> <tbody> <tr> <td>EMDN</td> <td></td> <td></td> <td></td> </tr> <tr> <td>GMDN</td> <td></td> <td></td> <td></td> </tr> <tr> <td>UMDNS</td> <td></td> <td></td> <td>x</td> </tr> <tr> <td>UNSPSC</td> <td>x</td> <td></td> <td></td> </tr> </tbody> </table>	Nomenclature	Yes	No	N.A.	EMDN				GMDN				UMDNS			x	UNSPSC	x		
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4. If you answered "yes" to the question 3 of section II, please indicate the periodicity of mapping updates. Please provide your answer in the table below, when applicable:																
<table border="1"> <thead> <tr> <th rowspan="2">Mapping with the following nomenclature</th> <th colspan="4">Periodicity of mapping updates</th> <th rowspan="2">Comments</th> </tr> <tr> <th>Once a year</th> <th>Twice a year</th> <th>Quarterly</th> <th>Other</th> </tr> </thead> <tbody> <tr> <td>EMDN</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>	Mapping with the following nomenclature	Periodicity of mapping updates				Comments	Once a year	Twice a year	Quarterly	Other	EMDN					
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	Once a year	Twice a year	Quarterly	Other												
EMDN																

GMDN					
UMDNS					
UNSPSC				x	We last updated the mapping when the revised segment 42 was released. However, identifying relevant UNSPSC codes is part of our concept/term development process.

5. If you answered “yes” to the question 3 of section II, please indicate if you fully or partially mapped nomenclature(s). If it is a partial mapping, please be so kind to indicate which section(s) were mapped.

Mapping with the following nomenclature	Extent of mapping		
	Full mapping	Partial mapping	Sections mapped (if partial mapping)
EMDN			
GMDN			
UMDNS			
UNSPSC		x	Segment 42 (medical devices)

6. Please describe the challenges you face for mapping

Mapping is a time consuming and resource-intensive process and must be prioritized in accordance with ECRI’s strategy and other work.

Mappings must be curated to maintain their usefulness.

7. Has your agency calculated the costs of mapping to other existing nomenclatures? Please present your estimates.

Nomenclature to be mapped against your nomenclature	Estimate cost of mapping (in dollars)
EMDN	
GMDN	
UMDNS	
UNSPSC	

III. Translations to other the official Languages of the UN

1. In which languages is your nomenclature available?

English

2. Is your agency willing to work on translations?

We are willing to provide feedback to translators, but not undertake a translation ourselves. The amount of support will vary – more may be provided if ECRI is compensated for the work.

3. Has your agency calculated the cost of translating your nomenclature into the six UN official languages (English, Spanish, French, Russian, Chinese, and Arabic)? If yes, please provide the estimates in the table below.

Six UN official languages	Estimate cost of nomenclature translation (in dollars)
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English	-
Spanish	
French	
Russian	
Chinese	
Arabic	

4. Is your Agency willing to work on mapping to other existing nomenclatures? (Please select the adequate option(s), when applicable).

Nomenclature	Yes	No	N.A.
EMDN	x		
GMDN	x		
UMDNS			x
UNSPSC	x		

IV. Unique Device Identification

1. Have your nomenclature terms been assigned UDI-DIs (device identifiers of UDIs)? (Please select below the applicable answer)

Yes	Indirectly. ECRI maintains a dataset of products at the catalogue level. UMDNS codes have been assigned. ECRI plans to associate UDIs with the catalogue level products.
No	

2. If yes, please indicate if the following sentences are true or false (Yes or No) and provide the solicited elements, if applicable:

a. <i>Our nomenclature is required in UDI regulatory requirements.</i> Please provide a link to the regulation - No	
b. <i>Our nomenclature is not required in UDI regulatory requirements. However, we have assigned some or all of our nomenclature terms to UDI-DIs.</i> Please provide a file with this assignment.	

3. If not, are you willing to work to assign UDI-DIs to your Nomenclature terms? (Please select below the applicable answer)

Yes	x
No	

V. Financial information

1. How is the development, maintenance and updating your nomenclature funded (please describe what are the sources and mechanisms of funding)?

UMDNS is the classification backbone of ECRI's device-related offerings. As such, ECRI considers UMDNS development part of our infrastructure.

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2. What is the cost of development, maintenance and updating your nomenclature per year? (please select the adequate statement).	
Less than 100.000 dollars	
Between 100.000 and 250.000 dollars	
Between 250.000 and 500.000 dollars	
Between 500.000 and 1.000.000 dollars	
Between 1.000.000 and 2.000.000 dollars	
More than 2.000.000 dollars	
Comment:	

3. How many FTE annually do you need for the development, maintenance and updating your nomenclature?
ECRI's UMDNS team includes 2 FTE, but is supported by inputs from additional ECRI SME's. The pool we draw from includes hundreds of engineers, subject matter experts, and clinical experts.

3.1 Is the electronic platform used for (please select the applicable options)?	
a) only nomenclature of medical devices	x
b) other products related to medical devices	x
c) other products besides medical devices	UMDNS includes physical objects found in health care settings (e.g. furniture, infrastructure, computing equipment) and purchased services.
d) comments:	

3.2 When was the latest update on your electronic platform?
March, 2021. ECRI uses the most recent version of the Apelon DTS

3.3 How often do you update the data?
Data is updated continually within the development system. Upload files are updated twice a month.

VI. Nomenclature use to promote public health/patient safety/device evaluation

1. Has your agency developed initiatives with governments/regulatory agencies to promote public health/patient safety/device evaluation
Yes.

VII. Nomenclature to be used in WHO document and electronic platforms

2. Are you willing to provide access to code, name, definition or hierarchy to WHO so that it can be used in:
WHO publications? WHO electronic platforms? a. MEDEVIS https://medevis.test.evidenceprime.com/ b. EDL https://edl.medevis.test.evidenceprime.com/

- c. UHCC <https://www.who.int/universal-health-coverage/compendium#:~:text=The%20UHC%20Compendium%20is%20a,health%20services%20and%20health%20interventions.>
- d. ICD 11 <https://icd.who.int/en>

WHO supports open access to the published output of its activities as a fundamental part of its mission and a public benefit to be encouraged wherever possible.

More info: [Copyright \(who.int\)](https://www.who.int/copyright)

Please comment: Yes, for non-commercial use

VIII. Final comments, if any

ECRI will once again make UMDNS non-commercial licenses available without a fee. We believe that this supports the spirit of ECRI's mission to advance effective, evidenced-based healthcare globally. At ECRI, we envision a world where safe, high-quality healthcare is accessible to everyone.