GMDN

A white paper by the GMDN Agency:

Medical Device Nomenclature – What Next Globally?

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Medical Device Nomenclature - What Next Globally?

Overview

A nomenclature of medical devices is a system designed to generically name and group all medical devices and related health products. The World Health Organisation (WHO) states that, according to different classification and nomenclature systems, there are between 5,000 to 24,000 different groups of medical devices. They range from simple to complex, and from inexpensive to costly. The number and types of devices are increasing exponentially[1].

The global market for medical devices is vast. This paper explores the requirement for robust data tools to cope with this challenge, particularly a standardised medical device nomenclature. It discusses the necessity of a nomenclature, the absence of a single global standard, and the reasons why existing nomenclatures have not been mapped. It presents an in-depth analysis of the current prominent medical device nomenclatures – the Global Medical Device Nomenclature (GMDN), European Medical Device Nomenclature (EMDN), United Nations Standard Products and Services Code (UNSPSC), and Universal Medical Device Nomenclature System (UMDNS)[1], highlighting their key features and differences.

It also provides an unbiased summary on the topics of nomenclature standardisation and mapping. It sheds light on the usage of existing nomenclatures and emphasises why all stakeholders, including manufacturers and labellers, should be concerned about data quality.

Medical devices, especially those that are high-risk or high-volume, play a crucial role in healthcare. Their safety and efficacy should be closely monitored. This is achieved, in part, through an effective nomenclature that ensures quality in device-to-Term assignment.

The paper poses critical questions that should be addressed when considering the approach to medical device nomenclature, including whether a nomenclature should be stable or dynamic (the 'nomenclature dilemma') and the requirements for achieving and maintaining high-quality device-to-term assignments.

Review of Medical Device Nomenclatures

There are a vast number of medical devices, including implantables, capital equipment, consumables, home-use devices, and *in vitro* diagnostic (IVD) devices[2].

Medical device nomenclatures are designed for the naming and categorising of medical devices, to provide healthcare professionals, regulators, manufacturers, and other stakeholders with a common language to communicate and share information. Their utility extends into various areas such as product registration, hospital inventory management, post-market surveillance, adverse event reporting, efficacy and cost analysis, and procurement procedures.

All medical device nomenclatures consist of coded "Terms" that include a generic medical device description in which similar devices can be grouped. However, these nomenclatures differ in their approach. Although sometimes referred to as a classification system or grouping system, they are collectively referred to most commonly as nomenclatures, and this name will be used throughout this paper for convenience. The primary nomenclatures used worldwide are the Global Medical Device Nomenclature (GMDN), the European Medical Device Nomenclature (EMDN), the Universal Medical Device Nomenclature System (UMDNS), and the United Nations Standard Products and Services Code (UNSPSC)[1].

The GMDN is maintained by the GMDN Agency, a non-profit organisation, a charity based in the UK. Access is based on membership however this is available free of charge to regulators, healthcare providers, and academic researchers, and with free and paid membership options available for manufacturers, and other users. Currently, the GMDN is used for product registration and information exchange in more than 70 countries, including the USA within the Global Unique Device Identification Database or GUDID), Canada, UK, Australia, South Africa, Brazil, Colombia, and Russia.

The GMDN is dynamic and is updated in real-time based on information submitted by manufacturers and published on the GMDN Agency's website. All GMDN Terms are mutually exclusive, with each Term uniquely identified by a sequentially allocated 5-digit code, a name, and a definition. Each definition outlines the clinical intended use and clinically relevant attributes of the devices represented by the Term. The GMDN Terms (nomenclature) are further organised in a multi-hierarchical classification system of Categories (Figure 1)[3].

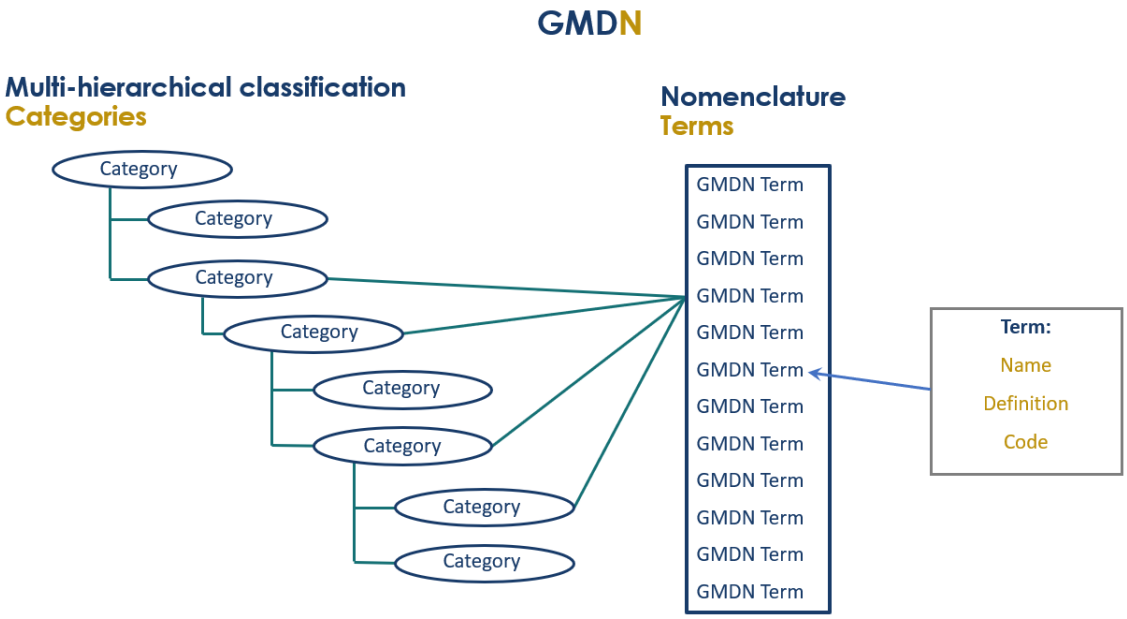

Figure 1. *Diagram showing the GMDN hierarchical structure. The GMDN Terms are organised in a multi-hierarchical classification system of Categories (they belong in Categories of more than one branch of the hierarchy).*

The EMDN, based on the Italian medical device classification, CND (Classificazione Nazionale Dispositivi medici), was developed for the registration of products in the European Database on Medical Devices (EUDAMED) and is available free of charge to all members of the public via the European Commission website and is updated annually. Each EMDN Term consists of a code and a name, without a definition. The code is alphanumeric, allocated to the Term depending on its related specialty (e.g., C for cardiocirculatory, G for gastrointestinal) and positioned in a single-hierarchical classification system (also known as intelligent numbering).

Within EMDN the Terminal (lowest) level Terms can exist at any level of the hierarchy and are not mutually exclusive. The Terminal level includes Terms named 'other' or 'various' [in other classification systems these are known as 'not elsewhere classified' (NEC) or 'not otherwise specified' (NOS)] that are intended to group devices that are not adequately described by the rest of the available specifically named Terms (Figure 2)[4].

The UNSPSC is managed by GS1 US, for the UN Development Programme (UNDP) for classification of products and services across different sectors (not only for medical devices) and can be used in procurement for cost analysis. A previous version of UNSPSC (dated 2020) is available free of charge, while the most recent version is available for a fee. UNSPSC Terms consist of a unique 8-digit code (allocated sequentially), a name, and a definition. These are organised as a single-hierarchical classification system (Figure 2). The lowest-level Terms are not mutually exclusive, and the definitions do not include clinically significant information[5]. UNSPSC is updated annually[6].

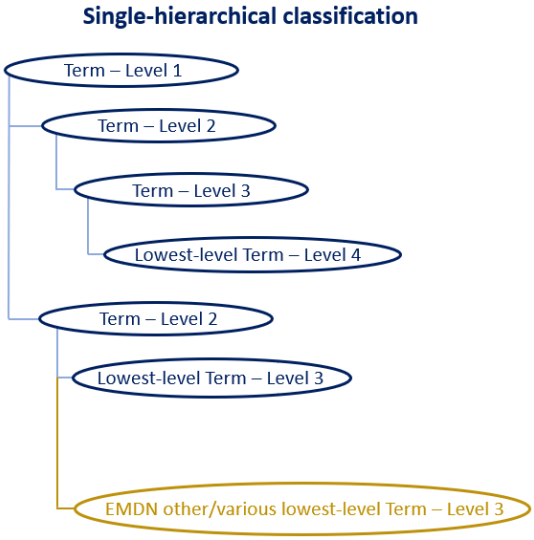

Figure 2. *Diagram showing a single-hierarchical structure adopted by both EMDN and UNSPSC.*

The UMDNS is managed by the Emergency Care Research Institute (ECRI), based in the US, and is available free of charge for non-commercial users. It may be used to facilitate identifying, processing, filing, storing, retrieving, transferring, and communicating data about medical devices. UMDNS Terms consist of a unique 5-digit code (allocated sequentially), a name, and a definition. These Terms are mutually exclusive (nomenclature) and are organised in a multi-hierarchical classification system. Each definition includes the intended clinical use and clinically important attributes of the devices represented by the Term[7,8]. UMDNS is updated biweekly [9].

Table 1 gives an overview of the main differences of the primary medical device nomenclatures.

GMDN	EMDN	UNSPSC	UMDNS
Nomenclature in multi-hierarchical classification system	Single-hierarchical classification system	Single-hierarchical classification system	Nomenclature in multi-hierarchical classification system
Mutually-exclusive Terms	Not mutually-exclusive Terms	Not mutually-exclusive Terms	Mutually-exclusive Terms
Terms include definitions with intended use and important clinical attributes	No Term definitions	Terms include definitions that are not clinically relevant	Terms include definitions with intended use and important clinical attributes
Updated in real-time	Updated annually	Updated annually	Updated bi-weekly
Free and paid options available (funded by registered members)	Free (funded by the European Commission)	Free and paid options available (funded by registered members)	Free and paid options available (funded by registered members)

Table 1. *Summary of the main differences of the Medical Device Nomenclatures.*

Optimal Features of a Medical Device Nomenclature

Within both industry and regulation there has been much discussion regarding what makes the ideal nomenclature, we at the GMDN Agency believe several key features are of importance if you are to successfully group medical devices for efficient information exchange and data analysis.

Of prime importance is the ability of a nomenclature to appropriately group medical devices with the same or similar intended use and clinically relevant features, within the lowest-level Term (a Term with no children). This can allow for an efficient exchange of information about similar devices. Such grouping requires lowest-level Term mutual exclusivity (i.e., the scope of a Term cannot overlap another Term meaning that a medical device cannot simultaneously be described by more than one lowest-level Terms). Mutual exclusivity is difficult to achieve as the Term scope can be interpreted differently by different users. A Term definition is crucial to achieving a common understanding of a nomenclature Term.

It is useful to have an organised hierarchy of higher-level Terms (categories) to group the lower-level Terms. This is useful to allow for data exchange and analysis at different levels of detail. Furthermore, a multi-hierarchical structure of higher-level categories can group devices by a range of device attributes (e.g., single-use versus reusable, implantable versus non-implantable, metal versus synthetic polymer devices). This becomes extremely powerful for device analysis (Figure 3).

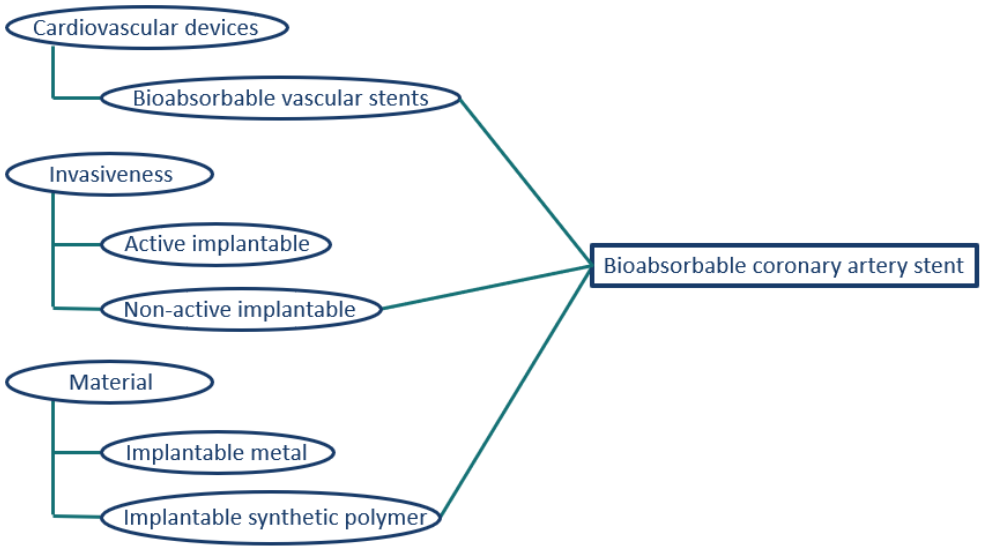

Figure 3. *Diagram showing an example of a multi-hierarchical structure of Terms. The lowest-level Term 'Bioabsorbable coronary artery stent' is linked to higher-level groupers (categories) that group based on different features (Bioabsorbable vascular stents, Non-active implantable, Implantable synthetic polymer).*

Some stakeholders would prefer a nomenclature to change infrequently, releasing controlled versions periodically (stable). This requires less data maintenance, and concepts stay consistent for longer periods. Medical technology however innovates and evolves constantly. There is a recognition that nomenclature should be up-to-date and reflective of modern technologies and innovations. Therein lies the "nomenclature dilemma", a nomenclature cannot be simultaneously up-to-date and stable. There is a strong argument in favour of a dynamic up-to-date approach to nomenclature development, so that innovative technologies can be distinctly named and grouped from the outset. This enables optimal analysis of innovation, wherein lies some of the highest risks and benefits for healthcare.

As a global tool, it is also important to have translations of Terms in languages other than English. This can broaden its reach and impact and encourage the adoption of the nomenclature to facilitate communication across different global regions.

The optimal features of a medical device nomenclature are summarised in Table 2.

Summary of Optimal Features
▪ Mutually exclusive lowest-level Terms ▪ Term definitions with clinically significant information ▪ Multi-hierarchical structure ▪ Real-time Term evolution (dynamic) in line with medical device evolution ▪ Availability in multiple languages

Table 2. *Summary of the optimal features of medical device nomenclatures.*

Mapping the different Medical Device Nomenclatures

Medical device nomenclatures have been around for decades. Historically each region or institution would design and create their own, however, from 1991 onwards the first international workshop on medical device nomenclatures was held to create the GMDN. Initial work was started by the European Standards Organisations (CEN) and was supported by the Global Harmonisation Task Force (now the International Medical Device Regulators Forum - IMDRF) to help accelerate the harmonisation of medical device regulation globally[3].

In each jurisdiction, it is down to the corresponding regulator to sets out the nomenclature to be used. If regulators cannot agree on a common nomenclature there becomes the requirement for different nomenclatures globally. For manufacturers and distributors selling internationally, this means more time and energy spent assigning products to different nomenclatures across jurisdictions. Meanwhile, the regulators lack a common language/grouping system for multi-regional analysis.

The most viable solution, outside of a universally adopted nomenclature, would be a mapping between the nomenclatures to support information exchange. With the different features of the nomenclatures discussed above, mapping becomes a huge challenge for which the resources are not readily available. Continuous development, validation, and maintenance of the map would have significant associated costs with no clear industry steer on how this would be funded or who would manage the ownership of the mapping.

In 2023, The GMDN Agency published a feasibility study where each general medical device GMDN Term was directly mapped to the closest available EMDN lowest-level Term to achieve the best possible one-to-one map. The results showed a low level of correspondence between the two nomenclatures, with only 26% of the GMDN Terms corresponding to a specifically named EMDN Terminal Term and 74% corresponding to an 'other'/'various' named EMDN Terminal Term (Figure 4)[10]. This correspondence to an 'other'/'various' Term provides ineffective comparison analysis between EMDN and GMDN users (figure 5).

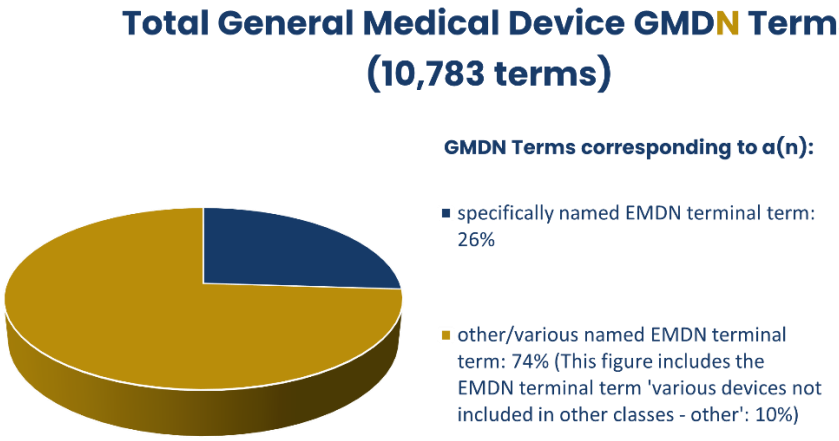

Figure 4. *Pie chart summarising the correspondence of the GMDN Terms and EMDN Terminal Terms describing all the general medical devices. It includes correspondence to the broadest EMDN Terminal Term 'Various devices not included in other classes – other'. Taken from the GMDN Agency website* [10].

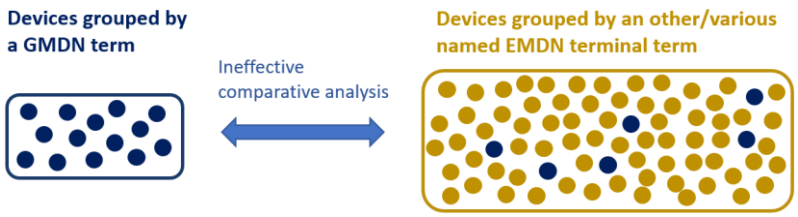

Figure 5. *Diagram showing the correspondence of a GMDN Term to an other/various named EMDN Terminal Term. The GMDN Term covers a narrow range of devices (in blue), while the other/various named EMDN Terminal Term covers a potentially broader range of devices (in gold), including some of the devices covered by the GMDN Term. This does not allow for an effective exchange of information based on grouping devices with similar features. Taken from the GMDN Agency website*[10].

The European Commission has suggested that they provide a map between the EMDN and GMDN, this however is yet to be published[11]. The WHO has completed a feasibility study using artificial intelligence/machine learning techniques to create a map using data of alternative assignments of GMDN, EMDN, UNSPSC, and UMDNS to 13,129 products that exist in public databases (AccessGUDID and the Italian Ministry of Health database). This study neatly highlights the many-to-many relationship between the Terms of the different nomenclatures (Figure 6) [1,12].

Many-to-many relationship between the Medical Device Nomenclatures

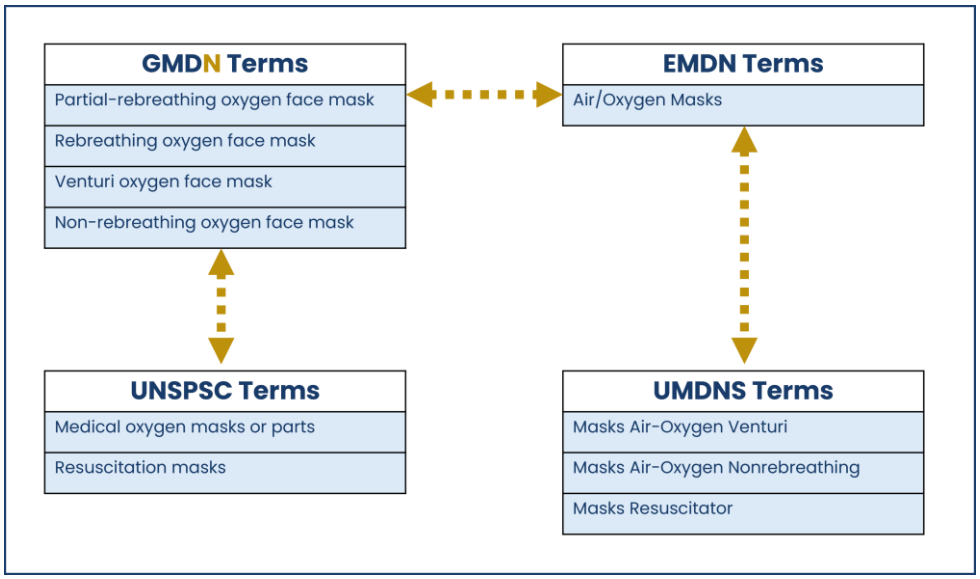

Figure 6. *Diagram showing an example of the mapping between GMDN, EMDN, UNSPSC and UMDNS carried out by WHO. It illustrates the many-to-many relationship between the different nomenclatures. In this example, the nomenclatures group the air/oxygen masks under Terms that have different levels of detail. This can potentially be an obstacle for exchange of information and global harmonisation of medical devices.*

Medical Device Nomenclatures in use

Regulators use medical device nomenclatures to manage their workflows as part of the pre-market registration process and with growing utility in post-market surveillance. The future vision for some regulators is to accelerate regulatory approval pathways through regulatory reliance (this is when a regulatory authority in one jurisdiction considers and gives significant weight to assessments performed by another regulatory authority), especially for innovative medical devices that meet specific clinical needs. This will require enhanced post-market surveillance to ensure safety is maintained. The mandating of a nomenclature code by the regulator during device registration is not only useful to the regulator but also fundamental for

downstream data use. The future vision is that every regulator has a UDI database for medical devices that shows the assignment to the nomenclature code and is made publicly available to downstream users. The first publicly available Unique Device Identification (UDI) database is AccessGUDID. This US data holds (at the time of writing) 4.3 million medical devices with assignments to, in this case, GMDN Terms.

Nomenclature serves a variety of downstream users (figure 7), not least the WHO. The WHO produces MeDevIS[13], which is a Priority Medical Devices Information System. It is an open-access WHO electronic database of Medical Devices. It is intended to serve as a clearinghouse to provide guidance on appropriate medical devices according to the levels of care, setting, and intended health intervention, which can be tailored to the specific needs of the country or region. The WHO have mapped the WHO descriptions of essential devices within MeDevIS to both the EMDN and GMDN. This includes lists for general medical devices and IVDs; the latter being the Essential Diagnostics List (EDL).

Medical device nomenclature has a powerful role in medical equipment management. Clinical engineers around the world require a grouping system to manage sometimes very large inventories of medical equipment. At this time many healthcare facilities are using locally created medical device classification systems, however, there is a big push towards harmonisation. For example, in Sweden clinical engineers are reliant on the GMDN for the management of their equipment at the non-proprietary level. A national database called MTP-Reg[14] collects and holds medical equipment data, in the form of Make and Model, linked to the appropriate GMDN Term. This data is then made available to healthcare facilities across Sweden. This database is linked to the Swedish database for adverse events enabling post-market surveillance using GMDN. The UMDNS codes also serve clinical engineers, with ECRI (who manage UMDNS) linking data attributes specifically useful to clinical engineers to these nomenclature Terms.

The predecessor to the EMDN (CND) has been used within clinical engineering in Europe (especially Italy). The use of EMDN in clinical engineering is expected to grow in Europe as

EUDAMED is rolled out providing EMDN to device assignment data. In the UK the GMDN is now a data standard (DAPB4004), and assignment is mandated by the MHRA. This registration data will be made available to stakeholders via the upcoming Product Information Management Data Platform (PIM) and can allow clinical engineers to leverage UDI data linked to GMDN Terms.

An example of nomenclature being used within purchase and tendering is the work done by the Gulf Health Council (GHC)[15]. One of the functions of the council is to achieve coordination and integration in the field of standardised procurement and central registration. The GMDN has partnered with the GHC and an independent service provider to provide a map between GHC tender descriptions and GMDN Codes. The GHC publishes a tender list for a specific clinical specialty (e.g., orthopaedics) and this list is based on detailed non-proprietary product

descriptions. Mapping these descriptions to GMDN Terms means that those manufacturers who have accurately assigned their products to GMDN Terms can tender. These tenders are implemented by many healthcare facilities in the Gulf region so have a significant commercial impact.

The regulatory use of nomenclature data is well established as a pre-market registration tool that helps regulators manage submissions. The use within post-market surveillance and real-world evidence gathering is gaining traction. A research group has been established in the UK, and funded by Innovate UK[16], part of UK Research and Innovation, to research improvements in capturing post-market medical device intelligence to improve patient safety within the UK.

Regulators could provide pathways that enable innovative devices to get to patients more quickly, by changing the balance of pre-market and post-market safety and performance evaluation. This will rely on a close link between regulation, hospitals, and manufacturers, with quality data, including Term assignment to an agreed nomenclature, at the heart.

NHS England commissioned the National Wound Care Strategy Programme (NWCSP)[17] to improve the quality and consistency of acute and chronic wound care, after evidence of variation in UK wound care services, with underuse of evidence-based practices and inconsistency of care plans and device use. The GMDN Agency is collaborating with the programme to provide experience, expertise, and data to help create a hierarchical classification of wound care products that can be analysed to provide evidence-based decisions on best practices. GMDN Terms are being used to provide data cross-reference and consistency within the classification, with levels of clinically relevant granularity being added based on the GMDN Term e.g., dressing materials and dressing properties. GMDN Categories are being used to extract relevant data from the main data sources e.g., MHRA public access registration database (PARD)[18].

The NWSCP is providing feedback from NHS England to medical device manufacturers on the accuracy of their GMDN assignments to products, so the source data quality can be improved. The GMDN is also using feedback from this clinical group to improve the clarity and usability of the nomenclature in this area.

This data has proved invaluable to many service providers. For example, Strata[19] supports hospitals, health systems, and other healthcare providers with a portfolio of software and data solutions to help them manage budgets. They also enable them to leverage data to discover market opportunities and new areas for growth and gain insights into patient care delivery and cost and revenue drivers for healthcare organisations across the United States.

Without the GMDN ad hoc grouping loosely supported by Universal Billing (UB) or CPT-4 codes would be the only option. This is far from ideal. However, based on an agreement with the GMDN Agency[20] Strata is in helping these critical organisations group and classify complex medical device data so that they can quickly conduct analyses that enhance patient care.

Strata relies on the public-facing Global Unique Device Identification Database (Access GUDID) to provide them with the device to GMDN Code assignment data.

Strata is not only using the GMDN Terms but also the GMDN Categories (supported by the GMDN Category version support tool). For example, consider an analyst examining cost variation within a cohort of patients receiving percutaneous transcatheter placement of a drug-eluting stent on an outpatient basis. The analyst may have to look at a wide array of data that includes factors such as length of stay, co-morbidities, severity, etc., but always requires a detailed analysis of the actual stents placed in patients.

This type of analysis may require looking at 50+ unique charge items to drill down to the appropriate granular level of detail. The analyst would have to categorise the data, identify the items of interest, and then do the analysis to determine the real drivers of the cost variance. The entire process could take a day or longer to establish a clear and consistent set of data to analyse.

By adding the GMDN Categories, the analyst can easily use the GMDN hierarchy to see the 50+ items grouped into Catheterisation/Cannulation/Fluid Path Devices, Radiological Devices, Tissue Reparation Devices, etc. They could drill in further to see which were Catheters or Endovascular recanalization devices and narrow it down to a very small set of charge codes that clearly show the utilisation and cost differences behind the variance. The GMDN Database enables this process to occur naturally in a matter of minutes rather than days, with a well-crafted report that allows users to drill through the GMDN hierarchy interactively and get to the root cause of which devices are driving the variances.

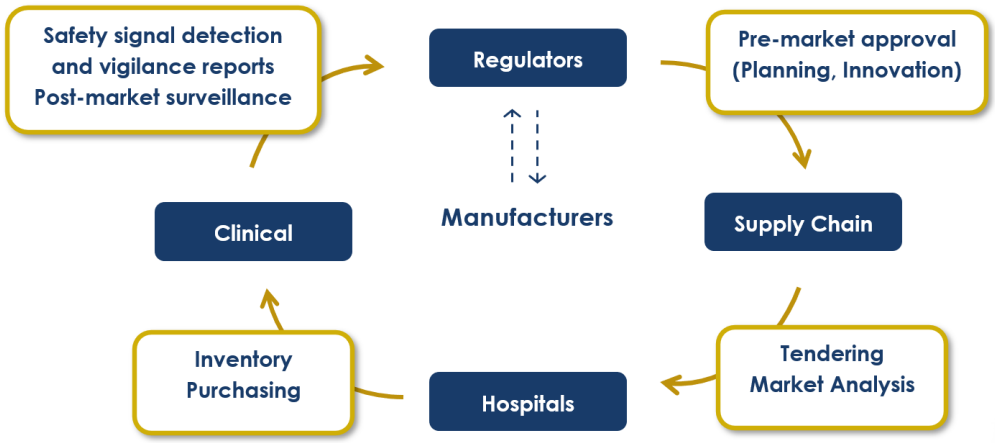

Figure 7. *Diagram showing the way in which nomenclature data may be, and in many cases is, communicated throughout healthcare.*

The importance of nomenclature assignment quality

For any use case of a nomenclature to have true value, the quality of device-to-Term assignment should be addressed. Incorrect assignment undermines the fundamental objective of a nomenclature, which is to group similar devices by type. The value of quality device-to-Term assignment cannot be understated, given the huge significance of the data analysis opportunities.

The manufacturer bears responsibility for ensuring quality device-to-Term assignment, as laid out by medical device regulators guidance or legislation within the European Union[21], the United Kingdom[22], the United States of America[23], and Australia[24] amongst others. With this, they can enhance and contribute to device data in regulatory and healthcare systems, not only to ensure patient safety but, as we have seen from the use case examples above, for their own operational and financial benefit. The nomenclature managing organization should have a mechanism to assist manufacturers during this assignment process and allow for the effective inclusion of novel device variations.

AI and the future for data analysis

The introduction of artificial intelligence (AI) programs into healthcare may impact on device data analysis in several ways, including mapping between nomenclatures/classifications, device-to-Term assignment support, and real-time querying for ad-hoc categorisation. All these depend on the input of quality text descriptions/definitions; despite the ability of machine-learned algorithms, they require the input of quality data. Therefore, it becomes a choice of either using an independently maintained standard nomenclature or requiring the manufacturer (labeller) to provide complete, non-proprietary, and meaningful product descriptions (including statements of intended use and technology). The latter would be a tall order for manufacturers involving a massive amount of work for legacy data.

Conclusion

There can be no doubt medical devices, most of which are either high-risk or high volume, are important for healthcare and should be monitored closely to ensure they are safe and effective. Data analysis enables conclusions about medical device safety and efficacy to be reached so long as there is a strong foundation on which to build. That foundation is standardised naming and grouping, achieved using an effective nomenclature with a keen eye on device-to-Term assignment quality. The approach to medical device nomenclature requires addressing these seven questions:

1. **Single nomenclature or multiple nomenclatures?**

The principal point of a nomenclature is that it is a single standard. If there are to be multiple categorisations in different jurisdictions, then it requires there to be effective mapping with automated equivalence. We have only seen evidence that mapping requires significant resources to create and maintain and is ultimately ineffective. Different use-cases (e.g., regulation, procurement, clinical evaluation) may have slightly different requirements from a nomenclature, but this is best provided by a single nomenclature that can be adapted (customised).

2. **Real-time updates or versioned releases?**

The timescales for new or expanded Terms to be available to industry so they can meet their regulatory obligations, as well as new requirements for regulatory/registry/clinical use, are tight, and timely availability of updates is necessary. The key to a comprehensive, up-to-date, and accurate nomenclature is that it is driven by a regulator requirement and with strong feedback from industry, rather than 'ivory tower' research groups.

3. **Tight nomenclature or loose classification?**

Crucially important to device-to-Term assignment accuracy is a nomenclature with fully defined, mutually exclusive Terms, and with no unspecified catch-all (others) groups.

4. **Registered users or transparent public access?**

Data integrity can only be achieved with a 'closed-loop' methodology, whereby the nomenclature-maintaining organisation has a clear view of all users of the individual Terms so device-to-Term misassignments can be understood and the nomenclature can be improved.

5. **Up-to-date or stable?**

The 'nomenclature dilemma' is that it cannot be simultaneously up-to-date and stable. It is expected to change to keep current. In the modern world of medical devices, a stable nomenclature can be considered inert.

6. **Proven implementation or newly developed?**

Being a data system, a nomenclature is only as good (accurate and comprehensive) as the use to which it has been put over an extended timescale. Real-world usage and proof of concept in high-profile environments act as the forge that builds a strong nomenclature through adaptation and improvement.

7. **Nomenclature or no nomenclature?**

Despite the possibility of a world where AI tools will be available for doing real-time ad-hoc categorisation, there is a requirement for a formal nomenclature because the text descriptions available at a product level are highly variable.

Regulators -in collaboration with key stakeholders- should lead a concerted, collaborative effort to adopt and use a standardised medical device nomenclature to enable meaningful device data analysis. We suggest that these questions can guide the choice moving forward.

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