



Current state of medical device nomenclature and taxonomy systems in the UK: spotlight on GMDN and SNOMED CT

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Summary

A standardised terminology for describing medical devices can enable safe and unambiguous exchange of information. Proposed changes to EU-wide medical devices regulations mandate the use of such a system. This article reviews two important classification systems for medical devices in the UK. The Global Medical Device Nomenclature (GMDN) provides a classification system specifically for medical devices and diagnostics, and facilitates data exchange between manufacturers and regulators. SNOMED CT is the terminology of choice in the NHS for communicating, sharing and storing information about patients' healthcare episodes. Harmonisation of GMDN and SNOMED CT will encourage use of single terminology throughout the lifetime of a device; from regulatory approval through clinical use and post-marketing surveillance. Manufacturers will be required to register medical devices with a European device database (Eudamed) and to fit certain devices with a Unique Device Identifier; both are efforts to improve transparency and traceability of medical devices. Successful implementation of these elements depends on having a consistent nomenclature for medical devices.

Introduction

Medical devices (including *in vitro* diagnostic devices) are becoming ever more important tools in the National Health Service (NHS) as we strive for provision of safe and effective care whilst ensuring the appropriate allocation of finite resources. Devices can offer innovative and cost-effective solutions to healthcare problems across an enormous range of specialities; from cheap single-use items such as bandages and wound care products to hugely expensive capital equipment such as a positron emission tomography (PET) scanner. The National Institute for Health and Care Excellence (NICE) established the

Medical Technologies Evaluation Programme (MTEP) in 2009 to help the NHS adopt efficient and cost-saving medical devices and diagnostics more rapidly and consistently.¹ NICE has since published Medical Technology Guidance on 13 devices and diagnostics (data from February 2013), and positive recommendations for adoption have been issued for devices including Cardio-Q (Deltex Medical) oesophageal Doppler monitor for cardiac output and fluid status monitoring,² Pipeline embolization device (Covidien) for the treatment of complex intracranial aneurysms,^{3,4} and PleurX peritoneal catheter drainage system (Carefusion) for drainage of malignant ascites.^{5,6}

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Medical device nomenclature: why?

Classification systems such as nomenclatures (sets of rules used to systematically name objects or properties), taxonomies (hierarchical nomenclatures) and coding systems have been established for pharmaceutical and disease concepts and have a long track record. For example, the Anatomical Therapeutic Chemical (ATC) classification controlled by the World Health Organisation (WHO) Collaborating Centre for Drug Statistics Methodology serves as a tool for drug utilization research in order to improve quality of drug use. The WHO International Classification of Diseases (ICD) is a classification for diagnoses and other health-related problems and is widely used for storing patient information for clinical and epidemiological purposes. However, similar structures for medical devices have yet to be widely adopted.

A standardized and unambiguous system for naming and coding medical devices is critical in an environment increasingly dependent on electronic data records for sharing and storing patient information. Summary Care Records (SCRs) are being introduced in the NHS in England,⁷ and despite the controversy surrounding delays and failures in implementing fully integrated detailed care records in the NHS⁸ a universal language for communicating clinical information is essential. Devices are becoming ever more integral to public health and medical care and the regulatory process must ensure effective monitoring of their safety.⁹ Recent highly publicized cases such as substandard PIP breast implants^{10,11} and safety concerns surrounding implantable metal-on-metal hips,^{12,13} have drawn attention to the process of medical device regulation in the EU. The UK Department of Health has called for evidence on the potential for a national implant registry for a review of cosmetic procedures regulation.¹⁴ Such a registry would require an accepted and consistent nomenclature of certain high-risk devices. Proposed updates to the European Union (EU) medical device regulations,¹⁵ which would come into effect from 2015 to 2019, require fitting of a unique device identification (UDI) to all medical devices sold in the EU. The update also calls for expansion and improved transparency of a European medical device database, Eudamed. 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. This article reviews the current state of medical device nomenclature (with an emphasis on the UK).

Desirable features of a taxonomy or nomenclature

The following points outline the key elements of a taxonomy or nomenclature for medical devices and diagnostics: (i) a clear and unambiguous terminology, accompanied by an accurate and informative description of each technology; (ii) universal and exhaustive coverage that can encompass new and innovative devices; (iii) hierarchical and structured yet flexible enough to have multiple hierarchies in situations where cross-speciality use is likely; (iv) a coding system associated with each device or level, enabling reliable communication, data manipulation and removal of linguistic barriers; (v) an appropriate and informative level of granularity (i.e. the number of subdivisions necessary to identify a unique device) and specificity (i.e. the depth of information provided); (vi) interoperability with systems used by other healthcare providers and stakeholders, such as the NHS, Medicines and Healthcare products Regulatory Agency (MHRA), manufacturers, EU standards agencies, Food and Drug Administration (FDA).

Challenges of characterising medical technologies

Medical devices have several characteristics that set them apart from pharmaceuticals and other clinical interventions, and in some cases can complicate their classification. Devices can be modified over time and a nomenclature needs to be capable of describing such modifications or updates where these offer an innovative change to clinical management. Also, devices are found in disparate healthcare settings and are used by a range of healthcare professionals, and patients and carers. Medical equipment is operator-dependent, and the speciality, skill-level and area of use will affect the outcome. Devices are often multi-component and may include consumables and the choice of device component or consumable is often dictated by the clinical pathway in which it is applied.

Methods

Evidence for the original NICE-commissioned report was gathered using a thorough but non-systematic search of published and grey literature sources. Expert testimony was also used where the authors considered the opinion relevant to the review topic.

Global Medical Device Nomenclature (GMDN)

Background to GMDN

The introduction of European Directives (directives 90/385/EEC,¹⁶ 93/42/EEC,¹⁷ 98/79/EC¹⁸) for medical device regulation in the 1990s emphasized the need to implement an internationally recognized nomenclature. In response, the GMDN project was initiated to encourage international harmonization of medical device classification. It encompassed six pre-existing nomenclatures including the Universal Medical Device Nomenclature System (UMDNS) and the European Diagnostic Manufacturers Association (EDMA) *in vitro* diagnostic product classification. Rules governing its structure are published in an International Standard.¹⁹ The overarching goal of GMDN is to provide a standardized nomenclature for medical devices and diagnostics to improve identification and unambiguous data exchange between authorities, manufacturers, healthcare providers and conformity assessment bodies to support patient safety. GMDN has applications in areas such as: (i) communication and record keeping between manufacturers and regulatory bodies; (ii) collation of post-market surveillance data; and (iii) inventory purposes. GMDN is now maintained and updated by the GMDN Agency and access to codes is granted through a payable licence. More than 1700 (2011) medical device manufacturers have licences to use the GMDN and that figure is increasing by 20–25% each year (GMDN Agency, personal communication).

Structure of GMDN

The 'Preferred Term' is the most important device term within the GMDN and is the valid description of a group of devices (a collection of generic device types). Currently, there are more than 20,000 terms in the database. In addition, 'synonyms' and

Table 1.

Example of a GMDN Preferred Term for medical devices.

GMDN Code: 35965

GMDN Term Name: Hydrocephalic valve

GMDN Definition: A non-active implantable device that functions as part of a hydrocephalic shunt system and is used to reduce the increased pressure from the excessive accumulation of cerebrospinal fluid (CSF) around the brain, by controlling the flow of the fluid. The operating pressure is typically pre-set prior to implantation (by the manufacturer or the surgeon), and the valve is activated when the ventricular (brain) pressure rises above the pressure setting of the valve. Some valve designs may facilitate re-adjustment of the pressure settings in situ using, e.g. a dedicated programmer.

'multiple-linked synonym terms' have been added to the nomenclature as navigational tools to aid searching for the appropriate Preferred Term. Each Preferred Term has an arbitrary five-digit GMDN Code and a Definition that describes the device's physical description and intended use (Table 1). The GMDN Preferred Term does not differentiate between device models or those from different manufacturers which have the same intended use and technology.

The Preferred Terms are in a flat structure and to add context and optional hierarchies Collective Terms (CTs), with accompanying codes, have been integrated into the GMDN. CTs have been grouped under a series of headings which are reflective of high-level tiers such as the speciality or technology associated with a generic device group. For instance, within the group 'Device Applications' there are 20 CTs, e.g. CT954 encodes 'In vitro diagnostic medical devices' and CT998 encodes 'Dental devices'. Each Preferred Term code can belong to multiple CTs which form a poly-hierarchical structure. Requests for new Preferred Terms can be made online through the GMDN Agency and will be reviewed for suitability by the Agency's team in two to three weeks.

Applications of GMDN

GMDN's role is set to expand as the recently proposed changes to the EU's medical device regulations come into force. It will be further embedded

in the regulatory framework through two mechanisms. Firstly, the updated regulations propose that manufacturers fit their devices with an alphanumeric UDI to enable traceability, and particularly to report serious incidents and field safety actions.¹⁵ UDI implementation will be proportionate to the risk posed by the specific medical device. The UDI will provide access to detailed information on the medical device such as lot/batch number, name and address of manufacturer, product description and sterility information. Importantly, the data element of the UDI includes a GMDN code (or other internationally recognized nomenclature code). In parallel, the US Food and Drug Administration (FDA) released a proposed rule in July 2012 that medical devices which are distributed in the US are fitted with a UDI.²⁰ The FDA's UDI requirements reflect those of the European Commission, and GMDN is part of the proposed minimal dataset. Plans to establish a publically accessible database with certain data elements of the FDA UDI are being finalized. The European Commission leads an *Ad Hoc* Working Group in order to ensure that the US and EU UDI systems will be globally compatible and in line with GHTF recommendations on the use of GMDN.²¹

A central European device database is the second GMDN-related constituent of the proposed updated regulations in the EU, which is designed to streamline and standardize the registration process across member states as well as enhance transparency. The regulations require that manufacturers and importers must register themselves and their device in a database. The Eudamed was established, and its use made mandatory in May 2011,²² to reinforce market surveillance and store registration information, certificates, and data on clinical investigations, and more recently to capture UDI information. At present Eudamed is not publically accessible, although recent proposals state that 'a large part of the information in Eudamed will become publicly available'. Recognition of the use of the GMDN in relation to Eudamed notifications was outlined by the European Commission in 2010.²³

SNOMED CT

In recent years, emphasis has been placed on the ability to safely and securely access and

share information on patients' health within healthcare systems. SNOMED CT (Systemized Nomenclature of Medicines – Clinical Terms) is a terminology which enables communications between healthcare professionals in a clear, unambiguous and standardized manner. It has now been approved as the Fundamental Standard for Clinical Terminology within the NHS in England.²⁴ The International Health Terminology Standards Development Organisation (IHTSDO) has responsibility for SNOMED CT's maintenance and development and it is free to use in IHTSDO Member Countries. The UK Terminology Centre (UKTC) is responsible for the UK management of SNOMED CT.²⁵

SNOMED CT provides concepts with associated identifiers (codes) for a huge range of clinical information. SNOMED CT supports the communication of data covering most settings, for example prescribing, referrals, hospital discharges and business processes. The primary purpose of SNOMED CT is to provide a terminology and coding system to store clinically relevant information in electronic health records. By using just a single terminology clinical staff can record patient information in a consistent and unambiguous way. Records can then be shared and interpreted in a standardized and safe manner between healthcare systems and healthcare professionals. This key attribute provides clear benefits to patients, but also can reduce administrative burden on clinicians by re-using appropriate information, facilitating effective evaluation of healthcare systems, and enabling linkage across a range of NHS IT systems.

Structure of SNOMED CT

SNOMED CT provides terms (known as 'Concepts', of which there are more than 300,000) for recording clinical information such as diseases, findings, procedures, microorganisms, pharmaceuticals and physical objects. Concepts (and their accompanying six to 18 digit codes, known as 'Concept Identifiers') in SNOMED CT are arranged in multiple hierarchies in an 'is a' format. For example, Carotid Stent 'is a' Arterial Stent 'is a' Intraluminal Vascular Device 'is a' Vascular Implant (Table 2). The uppermost headings of the hierarchies include 'clinical

Table 2.
Example of SNOMED CT hierarchical concepts for a medical device.*

- Device (49062001)
- Clinical equipment/device (272181603)
- Biomedical device (63653004)
- Implant, device (40388003)
- Cardiovascular implant (303617005)
- Vascular implant (303617005)
- Intraluminal vascular device (360044008)
- Arterial stent (360046005)
- Carotid stent (413766009)

*This is the current structure in SNOMED CT and is subject to change further to implementation of changes outlined below (i.e. integration of GMDN content and application of new relationships and model).

finding/disorder', 'procedure/intervention', 'body structure', 'pharmaceutical/biologic product', and 'specimen'. The concept of 'device' falls under the heading of 'physical object'. SNOMED CT can be embedded within software applications, and with its depth of coverage and multiple levels of granularity SNOMED CT can facilitate multifaceted applications such as: (i) recording and retrieving patient information in electronic records and other clinical systems in the NHS; (ii) point-of-care clinical decision support aid; (iii) monitoring individual patient outcomes; (iv) exchange of coded information between local and national healthcare providers (with appropriate safeguards in place); (v) public health monitoring; (vi) research, audit and analysis purposes.

The NHS Dictionary of Medicines and Devices (dm+d) is a dictionary containing unique identifiers (codes) and associated textual descriptions for representing medicines and medical devices in information systems and electronic communications. The unique codes used in dm+d are all SNOMED CT concept identifiers and dm+d represents the UK drug extension of SNOMED CT to enable coding and description of branded products available in the UK. Presently, only devices used in the primary care setting, such as wound and stoma care products, are included within dm+d; the longer term goal is to expand the device content much more widely.

Integration of GMDN and SNOMED-CT

The remits of GMDN and SNOMED CT are different; GMDN has been designed for use primarily by regulators and manufacturers, whilst the broader objective of SNOMED CT is to provide a common language for communication of clinical information within the healthcare setting. However, the advantages of harmonizing these existing nomenclatures so that a single terminology can be used throughout the lifetime of a device and across multiple medical device stakeholder sectors are evident.

In April 2012, the IHTSDO and GMDN Agency confirmed a cooperation agreement between the organizations with the intention of using GMDN as the foundation for the medical device component of SNOMED CT. In practice, GMDN terms will form the basis of the SNOMED CT medical device content. Recording of relationships between the medical device concepts and clinical content will enable connections to be made between, for example, the procedure performed and the device. Integration of GMDN and SNOMED CT will result in a common language from manufacture and supply, through regulators and notified bodies, and onto healthcare providers and post-market surveillance for safety and efficacy purposes. The descriptive terms will appear across SNOMED CT and GMDN, but their coding systems will remain different and a linkage table will be provided to enable cross-referencing. At the time of writing more than 8400 GMDN terms have been included in a technology preview of the device content of SNOMED CT and the focus of the work is to now build the relationships between the device content and the existing clinical content within SNOMED CT (GMDN Agency, personal communication).

Work to expand the GMDN content in SNOMED CT is required to satisfy the wider purposes of SNOMED CT for recording patient information linked to the use of medical devices. To support this wider remit a roadmap for further development of GMDN content in SNOMED CT includes: (i) structuring the GMDN content into a SNOMED CT compliant model; (ii) developing medical device descriptions in clinical terminology and linking to additional clinical data; and (iii) adding in more layers of more granular (or more specific) medical device terms.

Implementation challenges

Large-scale IT projects have proved notoriously difficult to implement in the NHS.^{8,26} Whilst IT systems can support and empower patients and clinicians, without coherent implementation of SNOMED CT and GMDN they are unlikely to provide the anticipated benefits.

SNOMED CT implementation challenges

Systems which incorporate SNOMED CT are being increasingly deployed within the NHS and a substantial amount of patient data is now coded in SNOMED CT. As with most change there is a lag phase which is overcome as organizations and individuals recognize the benefits. The success of SNOMED CT relies on investment and upgrading of NHS hardware to support the evolution and progress made in electronic recording of clinical information. Furthermore, compatibility between local information systems must be ensured to realize SNOMED CT's potential. Perceived (or actual) lack of influence by NHS staff can be a barrier to implementation if the functionality of a new IT system does not match clinician requirements.

GMDN implementation challenges

The challenge for medical device regulators will be to put in place systems that can link the clinical outcomes within patient records to medical device product data coded using GMDN. Potential barriers to implementation include: (i) the cost of GMDN licence fees for membership, but this is scaled in favour of small companies that only pay a nominal amount (100 EUR); (ii) limited publicly available information concerning Eudamed at present; (iii) currently other naming systems are being used in the UK, e.g. UMDNS, that will require companies and hospitals to transfer to GMDN. Transition tools will hopefully smooth this conversion process.

Conclusions

GMDN offers a comprehensive and unambiguous nomenclature and coding system to describe medical devices for the purposes of regulatory

approval. SNOMED CT provides a hierarchical coded terminology for the description of almost any element of a healthcare-related episode. Both systems have been reinforced through updates to medical device regulation in the EU, in the case of GMDN, and establishment of SNOMED CT as a Standard within the NHS. Plans to finalize the interoperability of GMDN and SNOMED-CT mean that, for the first time, a consistent terminology will be available for medical devices from pre-market approval through the point of use and to postmarketing vigilance. Implementation of GMDN will help improve transparency and communication of information for regulatory purposes through the use of a mandatory European database of medical devices. Device-specific UDIs will improve traceability of products throughout their lifecycle. NICE guidance provided for the NHS will benefit from the use of coding metrics to precisely identify medical devices, consumables, and procedures. Realization of the anticipated benefits of SNOMED CT and GMDN will rely on overcoming barriers to effective implementation.

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