Global Medical Device Nomenclature (GMDN)

Dr Barry Daniels, Technical Lead, GMDN Agency
Get from this:
To this?
Device Group
How do we define the group?

What is it?
GMDN Term Definition:

A mains electricity (AC-powered) bedside device designed to continuously detect, measure, and display a patient's electrocardiogram (ECG) through leads and sensors attached to the patient; it also typically displays heart rate. The device is typically equipped with audible and/or visual alarms that are triggered when the patient's parameters drop below or exceed pre-set limits.
GMDN Term Definition:

A mains electricity (AC-powered) bedside device designed to continuously detect, measure, and display a patient’s electrocardiogram (ECG) through leads and sensors attached to the patient; it also typically displays heart rate. The device is typically equipped with audible and/or visual alarms that are triggered when the patient’s parameters drop below or exceed pre-set limits.

Intended use

Technology

Important attributes
  e.g.,
  Sterility
  Use frequency
  Power source
Give the group a name

GMDN Term Name: **Electrocardiographic monitor**

GMDN Term Definition:
A mains electricity (AC-powered) bedside device designed to continuously detect, measure, and display a patient's electrocardiogram (ECG) through leads and sensors attached to the patient; it also typically displays heart rate. The device is typically equipped with audible and/or visual alarms that are triggered when the patient's parameters drop below or exceed pre-set limits.
GMDN Code: 35195

GMDN Term Name: Electrocardiographic monitor

GMDN Term Definition: A mains electricity (AC-powered) bedside device designed to continuously detect, measure, and display a patient's electrocardiogram (ECG) through leads and sensors attached to the patient; it also typically displays heart rate. The device is typically equipped with audible and/or visual alarms that are triggered when the patient's parameters drop below or exceed pre-set limits.
GMDN Code: 35195
GMDN Term Name: Electrocardiographic monitor
GMDN Term Definition:
A mains electricity (AC-powered) bedside device designed to continuously detect, measure, and display a patient's electrocardiogram (ECG)…
Device group = GMDN Term
But all Electrocardiographic monitors have a different DI
GMDN Supporting global harmonisation

- **Used by:**
  - 70 national Medical Device Regulators
  - 4000+ Manufacturers worldwide
  - US FDA implementation of UDI Rule
    - All medical devices sold in the US will need a GMDN code
  - European Commission only use GMDN
    - New MD regulation due 2015 (UDI Europe)
  - Regional Trade Associations (EUCOMED/ EDMA/ ADVAMED/ GMTA) recommend GMDN
- **Complies with ISO15225**
What do manufacturers do?

- **Find** GMDN Terms at [www.gmdnagency.org](http://www.gmdnagency.org)
- **Provide** the GMDN Code to:
  - Regulators as a data element in DI record (GUDID)
  - Customers / Distributors / Data Pools
- **Maintain** the data as part of an ongoing process via GMDN membership
When you can’t find a GMDN Term?

- Please ask us for assistance
- Submit a New Term Request
  - On-line Request Application
  - Attach your product data
  - We discuss with you during the process
How should you manage GMDN Term changes?

- Who needs to receive notifications? (update your account)
- How is this communicated internally?
- GMDN is a data element in the DI record that can be edited after the Grace Period.
- Labelers are required (per UDI Rule) to keep their device information current and correct with any data that may have changed.
Collective Terms

- GMDN uses **Collective Terms (CT’s)** to group/organize related Preferred terms:
  - By clinical application (e.g., cardiovascular devices)
  - By name (e.g., prosthesis, scissors, catheter)
  - By attribute (e.g., Material, Invasiveness, sterility, Use frequency)

- A hierarchical categorisation ...
Hierarchical classification
Collective Terms

Nomenclature
GMDN terms

Collective Term
  - Collective Term
  - Collective Term
  - Collective Term
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  - Collective Term

GMDN Term
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Many to many

Collective Term
- GMDN Term
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- GMDN Term

GMDN Term
- Collective Term
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- Collective Term

Collective Term
- GMDN Term
- Collective Term
- Collective Term
Hydrogel dressings
- Dermatological hydrogel dressing
- Wound hydrogel dressing, non-sterile
- Wound hydrogel dressing, non-sterile, antimicrobial
- Wound hydrogel dressing, sterile
- Wound hydrogel dressing, sterile, antimicrobial
13215 General-purpose infusion pump

Collective terms by use

Collective terms by attribute

Collective terms by name
Searching
or
Higher level groups

Collective Terms

- Clinical Specialties
  - CT156 Orthopaedics
- Device Applications
  - CT1006 Orthopaedic devices
  - CT125 Implantable joint prostheses and associated devices
  - CT1372 Implantable joint prostheses
  - CT837 Implantable hip prostheses
  - CT1112 Total hip prostheses
Changes to GMDN data

- Develop new terms (average 2-3 day)
- We only modify existing Terms (average 1-2 day)
  - To increase the scope / improve the definitions
- We obsolete Terms (average 10/m or 0.5% per year)
  - To remove ambiguity / term overlap
- GMDN is dynamic and current to keep up with innovation
- Members are notified about changes
Unique Device Identification

- Pack / product marking of ‘unique’ identifier
- Marking also includes production identifiers (e.g. Batch No., Expiry Date, Serial No...)
- **Machine** readable (e.g. bar code) and human readable
- Linked to other product data in a database (e.g. make, model, etc.)
UDI Database

- The GMDN code is one of the 25 mandatory core data elements identified in the IMDRF ‘UDI System for Medical Devices’ draft Guidance Document.
- Data for each device is provided by the manufacturer to the UDI Database (UDID).
- The UDID data could be distributed by:
  - Public access website
  - Bulk data download (e.g. Hospitals)
GMDN and UDI Relationship

Pack / Device – Unique Device Identifier
(e.g. 12345678909874)
GMDN and UDI Relationship

Pack / Device – Unique Device Identifier
(e.g. 12345678909874)

Generic Device Group - GMDN Term
(e.g. GMDN Code 47071)

- Hudson
  - 12345678909874

- Brooks
  - 19876543218976

- Woods
  - 32345678908765
GMDN & UDI for Regulation

- Post Market surveillance
  - Identify systematic (generic) product failure
  - Support rapid product recall
- Better Regulation
  - Speed up Pre-market approval
  - Identify products quickly
  - Detailed information on imports and exports
  - Quickly identify trends about new equipment use and problems
GMDN speeding up pre-market approval

<table>
<thead>
<tr>
<th>GMDN</th>
<th>Make</th>
<th>Test Method</th>
<th>Date</th>
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GMDN speeding up pre-market approval

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New Applicant

Hudson

Jones

Previously Approved Device
GMDN speeding up product recall

Product Failure

Hudson

Regulator Device Register

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<tr>
<th>GMDN</th>
<th>Make</th>
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GMDN speeding up product recall

Regulator Device Register

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Product Failure

Investigate this product too?
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<tbody>
<tr>
<td>Brand Name</td>
<td>XIENCE Alpine Everolimus Eluting Coronary Stent</td>
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<tr>
<td>GMDN Term</td>
<td>System 4.00 mm x 38 mm / Over-The-Wire</td>
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UDI November 2015

- 320 000 records (DIs)
- (585 000 next month)
- Unique companies: 600
- Unique brand names: 11 000
- Sterile: 160 000
- Single-use: 290 000

- **Unique GMDN terms:** 1700
- Active implantables: 50
- Non-active implantables: 500
- IVD: 250
GMDN Agency working with the FDA

Analysing user data and improving definitions

- Eliminating the need to identify more than one GMDN term per product
- Improving the accuracy of manufacturers selection of GMDN Terms
Case 1 – Try not to use multiple terms!

Eluting Platinum Chromium **coronary** Stent System

**Company Name:**

**Device IDs:**
- (Primary)

**Device Sizes:**
- Device Size Text, specify: 4.00 mm Stent Diameter
- Device Size Text, specify: 28 mm Stent Length

**Model Number:**

**GMPH Terms:**
- Basic coronary angioplasty balloon catheter
- Drug-eluting **coronary** artery stent, non-bioabsorbable-polymer-coated
Case 1 – The catheter is included in the stent

Drug-eluting coronary artery stent, bioabsorbable-polymer-coated

A sterile non-bioabsorbable metal tubular mesh structure covered with a bioabsorbable polymer that contains a drug, designed to be implanted via a delivery catheter into a coronary artery (or saphenous vein graft) to maintain its patency typically in a patient with symptomatic atherosclerotic heart disease. The drug is slowly released as the polymer degrades and is intended to inhibit restenosis by reducing vessel smooth muscle cell proliferation. Disposable devices associated with implantation may be included.
Case 2 – ‘No description’

Makes it difficult for FDA to monitor accuracy.
Case 2 – There is more specific term

**Cutting/scoring coronary angioplasty balloon catheter**

A sterile, flexible tube designed for use in percutaneous transluminal coronary angioplasty (PTCA) to dilate a stenotic coronary artery and increase myocardial perfusion, by controlled inflation of a distensible balloon at its distal tip with peripheral cutting/scoring elements (e.g., microsurgical atherotomes) intended to remove stenotic material. The device is typically placed using a guidewire and guiding catheter, and its balloon is inflated by the infusion of liquid through its tubular body. The tube and balloon are typically made of polymer materials and the cutting/scoring elements are typically made of metal [e.g., nickel-titanium alloy (Nitinol)]. This is a single-use device.
GMDN Agency working with the FDA

- GMDN participation in MDEpiNet RAPID project – PVI registry

- Snomed/NLM
GMDN in Hospitals

- **Asset Management**
  - Support equipment commissioning
  - Help identify equipment location
  - Support maintenance programmes

- **Inventory Control**
  - Reduce wastage
  - Translate product labels with poor descriptions
  - Improve stock control

- Replace your existing inventory classification with an externally managed globally recognized nomenclature
Equipment Commissioning, the Nottingham experience

Medical Equipment Implementation Manager
Clinical Engineering
Nottingham University Hospitals NHS Trust
Nottingham database, Medusa

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Device Coding Standard</th>
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<td>GDN/D</td>
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<td>Fluorescent spectrophotometer</td>
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<td>Serial No</td>
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<td>MESU Electronics (QMC)</td>
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- **Device Group**: General-purpose infusion pump
- **Make**: Graseby
- **Model**: 500
- **Owner**: BSU (Library) - QMC; Clinical Engineering; Diagnostics and Clinical
- **Location**: BSU (Library) - QMC; Clinical Engineering; Diagnostics and Clinical
- **Supplier**: Smiths Medical
- **Delivery Date**: 14/02/2013
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Code Element

Name: Foot-switch, pneumatic

Code Element Level: Device Group

Code Element description:
A gas-powered pedal used by an operator of a medical device to regulate the activation and/or intensity of a parent device (e.g., a pneumatic surgical saw, pneumatic wire driver, pneumatic surgical power tool system control unit) to which it is connected typically via one or more hoses and which is dependent upon.

Device Coding Standards

Attached Device Coding Standards

<table>
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CE have implemented Approval & Commissioning processes

As part of this we send a Pre Acquisition Questionnaire (PAQ) to suppliers of medical equipment

- Purpose is to gather relevant compliance & required information to enable us to take decisions regarding supporting equipment
- One aspect of this is a question regarding GMDN code
Clinical Engineer
Uppsala University Hospital
Sweden
GMDN – Snomed link

- UDI database
- GMDN

- Linkage table

- Electronic medical record
- Snomed
Areas for our improvement
– A new website

- New look and navigation
- Data extracts
- Better management of screen Alerts and Emails
- New Term Requests – A new simpler process
- Obsolete terms
- Better searching tools
- Testing now. Due out at the end of the year!
GMDN is now the global language

GMDN is improving communication
Thank you for listening

Any questions now?

Or email: enquiries@gmdnagency.org