THE GLOBAL MEDICAL DEVICE NOMENCLATURE

Brockton Hefflin, MD, MPH
Larry Kessler, ScD

Center for Devices and Radiological Health
U.S. Food and Drug Administration

Global Medical Device Nomenclature Overview

- Present a Brief History
- Describe its Development
- Describe its Current Status
- Discuss its Maintenance, Licensure Terms, FDA Utilization, other Pertinent Issues

Global Medical Device Nomenclature
Brief History

- Initiated 1993 by European Committee for Standardization to Meet EU Requirements of Medical Device Directives
  - product certification/registration
  - vigilance reporting
  - product recall
- Draft Standard Developed, with ISO, 1996
  - Nomenclature-specification for a nomenclature system for medical devices for the purpose of regulatory data exchange
  - EN 1874 & EN ISO 15225
- GMDN Project Initiated, 1997

GMDN Standard

- Structure
  - Device Category: *active implantable*
  - Generic Device group: *pacemaker*
  - Device Type: *manufacturer, model*
- Basic Naming Conventions
  - base concepts & qualifiers
  - types of terms (preferred, template, synonym)
- Data Files
  - numeric codes
  - field length (terms/definitions)

Nomenclature Systems Used in Development

- Universal Medical Device Nomenclature System (ECRI)
- Norwegian Nomenclature (NKKN)
- Classification Names for Medical Devices and In Vitro Diagnostic Products (FDA)
- Japanese Nomenclature (JFMDA)
- European Diagnostic Manufacturers Association's In Vitro Diagnostic Product Classification (EDMA)
- International Organization for Standardization's Technical Aids for Disabled Persons Classification (ISO 9999)

Candidate List of Medical Device Terms

- 13,000 Terms for Generic Device Groups
- Identification of Equivalent Sets of Terms

Example: Concept = Carbon Dioxide Absorber

ECRI - Anesthesia Unit Absorber, Carbon dioxide
NKKN - Anaesthesia, Absorber, Carbon dioxide
FDA - Absorber, Carbon Dioxide

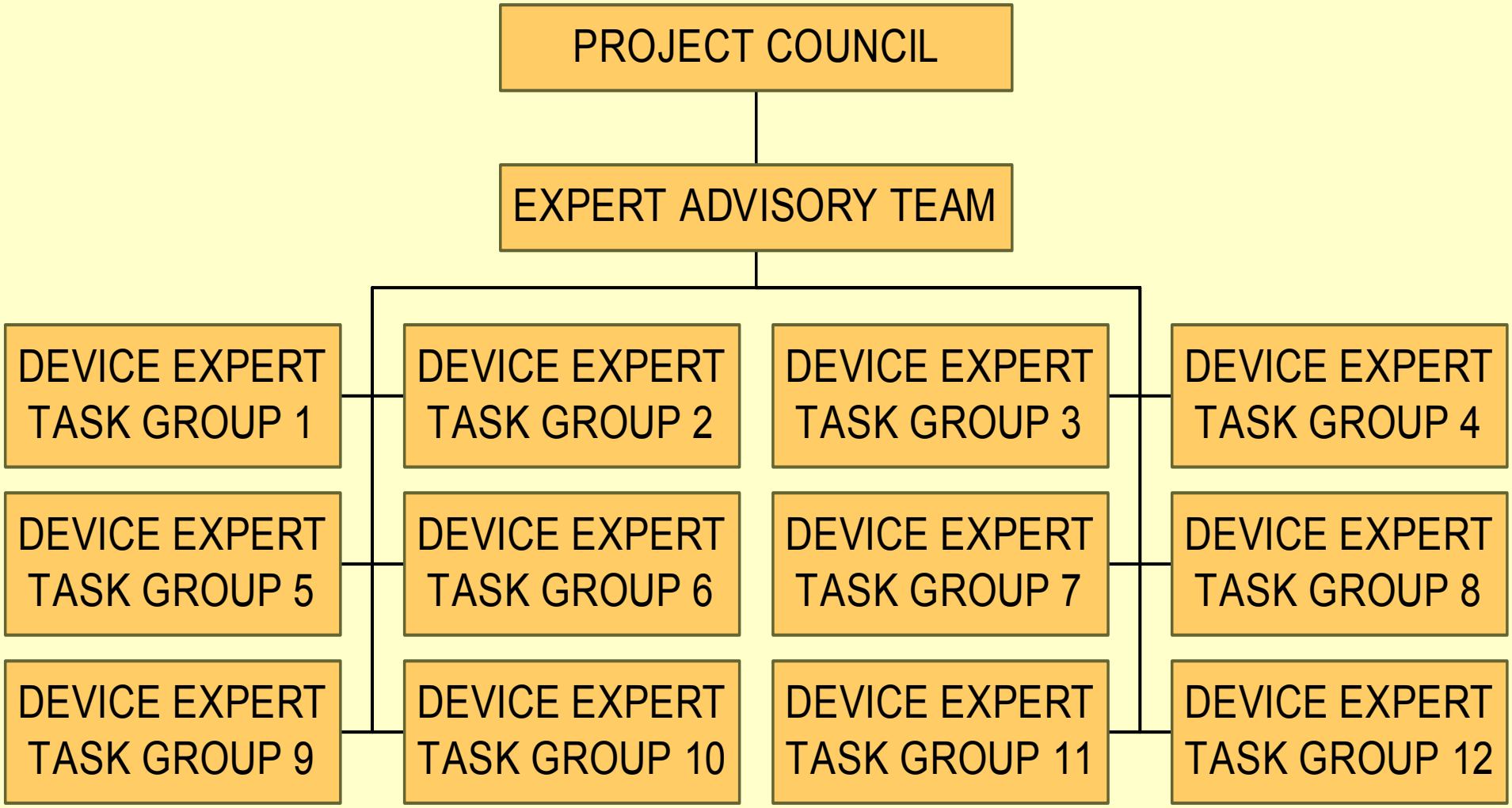
- automated processing
  UMLS SPECIALIST Lexicon
- manual review

Device Categories for Distribution of Terms in Candidate List

- Active Implantable Devices
- Anesthetic/Respiratory Devices
- Dental Devices
- Electro-Medical/Mechanical Devices
- Hospital Hardware
- In Vitro Diagnostic Devices
- Non-active Implantable Devices
- Ophthalmic and Optical Devices
- Reusable Instruments
- Single-Use Devices
- Technical Aids for Disabled Persons
- Diagnostic and Therapeutic Radiation Devices

Global Medical Device Nomenclature

Project Organization



Device Expert Task Group Work Activities
Terms

- Select a “Preferred Term” to Represent Each Generic Device Group
- Create a Preferred Term if No Satisfactory Term Exists
- Link Remaining Terms in Equivalent Set to the Preferred Term as a “Synonym Term” or “Equivalent Term”
- Create Synonym Terms

Device Expert Task Group Work Activities Example

Candidate List Terms	Source
Fundus Camera	NKKN
Cameras, Fundus	ECRI
Fundus Camera	JFMDA

GMDN Terms	Term Type
Camera, fundus	Preferred
Fundus camera	Synonym
Fundus camera	Equivalent

Device Expert Task Group Work Activities Example

Candidate List Terms	Source
Cameras, Multi-Image	ECRI
Camera, Multi Format	FDA
Camera, laser	NKKN

GMDN Terms	Term Type
Camera, diagnostic imaging, multi-format	Preferred
Camera, multi-image	Synonym
Camera, multi format	Synonym
Camera, laser	Synonym
Laser imager, multi-format	Synonym

Device Expert Task Group Work Activities
Definitions

Based on CEN draft standard: Medical informatics - categorical structure of systems of concepts - medical devices

- express device intended use
- express target area of intended use
- describe device technical principal or working method
- describe materials/components involved
- describe device form/shape/physical state

Device Expert Task Group Work Activities Example

"Camera, fundus" - *Definition*

A box-like device that holds photographic film and is used specifically to focus and record magnified images of the ocular fundus (posterior region of the internal eye) viewed through the pupil.

Expert Advisory Team Work Activities Example

GMDN Term	Category
Camera, cine	Electro/Mech
Camera, diagnostic imaging, minifying	Radiological
Camera, diagnostic imaging, multi-format	Radiological
Camera, fundus	Ophthalmic
Camera, ophthalmic	Ophthalmic
Camera, oscilloscope	Electro/Mech
Camera, thermographic	Radiological
Camera, video	Electro/Mech

Global Medical Device Nomenclature

Camera, <specify>
- Camera, cine
- Camera, diagnostic imaging, minifying
  - *X-ray film minifier*
- Camera, diagnostic imaging, multi-format
  - *Camera, multi-image*
  - *Laser imager, multi-format*
- Camera, fundus
- Camera, ophthalmic
- Camera, oscilloscope
  - *Oscilloscope camera*
- Camera, thermographic

Camera, video, <specify>
- Camera, video, endoscopic
- Camera, video, microsurgical
- Camera, video, surgical

Global Medical Device Nomenclature
Current Status of Development

- Work Performed since September 2002
  - Base Concept Standardization
  - Improved Definitions
  - Newly linked Synonym Terms
  - Preferred Terms added for New Devices
- Comprised of 17,000 Terms
  - 6,400 preferred terms
  - 10,000 synonym terms
  - 600 template terms

Global Medical Device Nomenclature Maintenance Agency

- Structure
  - Policy Group: regulators, CEN/ISO members, industry representatives, Commission, GHTF
  - Experts: FDA, NKKN, Health Canada, Academia
  - Secretariat: BSI transitioning to Commercial Company
- Roles
  - Policy Group to provide oversight, set policy
  - Experts to develop/amend terms and definitions
  - Secretariat to maintain/publish GMDN; receive proposals, develop user guidance, publicize program

Global Medical Device Nomenclature
Regulatory Body Licensure/Distribution

- GMDN use requires signed license
- Voluntary sponsorship to assist in maintenance costs
- License valid for 12 months, automatically renewed
- Data file distributed to licensed users on CD-Rom
- Transitioning to include direct data access via the internet
- Regulatory body public access limited to word searches

Global Medical Device Nomenclature
Data Maintenance

- Maintenance Agency must be contacted to modify data
- Data continuously updated by Expert Team
- Requests for new terms dealt with as received
- Responses provided within a few weeks
- New version with updates released at least once a year

Global Medical Device Nomenclature Funding

- Regulatory body voluntary sponsorship
- License fee for all other users
- Secretariat to use GMDN as trade name in association with the sale of other products and services via the internet

Global Medical Device Nomenclature
UMDNS Issues

- **GMDN: International Nomenclature, provides Generic Descriptors for Medical Devices.**
- **GMDN: based on an International Standard – ISO 15225 – which ensures that the structure of nomenclature terms are based on a consistent, standardized format.**
- **UMDNS: one of 6 nomenclatures used to develop the GMDN.**
- **At inception of GMDN, UMDNS did not cover all devices – although it has since publication of GMDN taken many terms from GMDN to expand its scope – nevertheless GMDN is much wider in its scope.**
- **Attempting to develop plans with ECRI to merge**

Global Medical Device Nomenclature
FDA Utilizataion

- FDA investing in GMDN structure
- Beginning mapping efforts 2003
- Converting systems to use of GMDN: 2004
- Developing web-interface for industry and consumers: 2004/2005

Global Medical Device Nomenclature
International Utilizataion

- **GMDN used 70 experts from 16 countries; available for development and maintenance.**
- **GMDN adopted for use by EEA – i.e. 18 members plus 10 Eastern European countries.**
- **Japan adopted GMDN: translated the terms & definitions**
- **Australian Regulation: GMDN in its requirements.**
- **A number of South American Countries are adopting GMDN and some have already translated this into appropriate Spanish or Portuguese Language.**
- **“Asian Harmonization Working Party” starting to adopt GMDN**
- **GMDN adopted by GHTF (Global Harmonization Task Force – for medical devices) as the means of establishing generic descriptors for devices.**