How to Model

UDI GHTF Data Elements in HL7

(HL7 SPL Release 5)

Todd Cooper
Co-Chair, HL7 Health Care Devices WG
**Background**

**Todd Cooper**

- Co-Chair, HL7 Health Care Devices WG
- Convenor, ISO TC215 WG7 Health Informatics – Devices
- Chair, IEEE 11073 General Committee
- Board, Integrating the Healthcare Enterprise (IHE) International
- Co-Founder, IHE Patient Care Device (PCD) Domain
- Co-Chair, ISO/IEC JWG7 “80001” Standard
- Principal, 80001Experts, LLC

- **Medical Device Informatics & Interoperability**
- At heart … a *software engineer* … medical device guy … standards dude!
- From San Diego … “*America’s Finest City!*”
Acronymosity

Global Harmonization Task Force
Working Towards Harmonization in Medical Device Regulation

UDI  Unique Device Identification
SPL  HL7 Structured Product Labeling
CPM  HL7 Common Product Model

Integrating the Healthcare Enterprise

www.GHTF.org
www.HL7.org
www.IHE.net
The label of Medical Device 123 Size 45:
Device Identifier (Device XYZ123)
Production Identifier (Lot #ABC)
Expiration date (MMDDYYYY)
Sterile; Latex free

Minimum Data Set
For each Device Identifier:
- Manufacturer and model
- GMDN Code
- Other attributes

Manufacturer
(Acme)

GS1 GDSN
or
Web based tool
or
Bulk HL7 SPL

You are here!

FDA Managed

FDA’s UDI Database

Public User Interface

Business Rules

FDA

How to Model UDI GHTF Data Elements in HL7
(From Jay Crowley, FDA CDRH, 2011.04.06)
GHTF UDI
Data Elements
✓ Abstract UDI data elements defined in the GHTF draft guidance document @ www.ghtf.org/adwg/ahwg-proposed.htm.

Comments due by 2011.04.30!

✓ Abstract data model elements are mapped to international standardized interchange formats, such as HL7 SPL / CPM

✓ Implementation technology independent!
# GHTF UDI Data Elements

<table>
<thead>
<tr>
<th>Device Identifier</th>
<th>&lt;Size, Volume, Length, Gauge, Diameter&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer Name</td>
<td>[Additional Product Description]</td>
</tr>
<tr>
<td>Manufacturer “Address”</td>
<td>Storage &amp; Handling Conditions</td>
</tr>
<tr>
<td>&lt;Contact Information&gt;</td>
<td>Labeled as Single Use (SUD)</td>
</tr>
<tr>
<td>Nomenclature system</td>
<td>Sterility</td>
</tr>
<tr>
<td>Nomenclature term / code</td>
<td>&lt;Restricted Number of Reuses&gt;</td>
</tr>
<tr>
<td>&lt;Trade / Brand Name&gt;</td>
<td>Labeled as Containing Latex</td>
</tr>
<tr>
<td>&lt;Device Model Number&gt;</td>
<td>&lt;Authorized Representatives&gt;</td>
</tr>
<tr>
<td>Control method (e.g., S/N, lot, …)</td>
<td>&lt;License/Marketing Authorization or Registration Number&gt;</td>
</tr>
<tr>
<td>Device ID location</td>
<td>[URL for Additional Information]</td>
</tr>
<tr>
<td>&lt;Packaging Parent/Child Relationships&gt;</td>
<td>&lt;Critical Warnings / Contraindication&gt;</td>
</tr>
<tr>
<td>&lt;Alternative Device Identifiers&gt;</td>
<td></td>
</tr>
</tbody>
</table>

*How to Model UDI GHTF Data Elements in HL7* (From GHTF Draft Proposal for a draft guidance on Unique Device Identification (UDI) System for Medical Devices, 2010.11.04)
HL7 SPL Mapping
How to Model UDI GHTF Data Elements in HL7

You do not have to be an HL7 v3 Expert Modeler!

HL7 Implementation Guide Provides Mappings & Format Specifications

GHTF UDI Data Elements (abstract)

HL7 SPL / UDI XML-Based Labels

Don’t Panic!

GS1 Healthcare Conference @ Bethesda, MD ~ 2011.04.07
### GHTF UDI to HL7 SPL

**HL7 SPL (rel 5)**
Implementation Guide + General WG Information

@

wiki.hl7.org/index.php?title=Medical_Product_Information_(SPLr5)

**Note: Extended to support UDI.**

<table>
<thead>
<tr>
<th>Structured Product Labeling Release 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implementation Guide for FDA Establishment Registration, Listing, and UDI Submission</td>
</tr>
<tr>
<td>Version 1 Revision 201008271159</td>
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<table>
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<td>2</td>
<td>SPL Header</td>
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<td>Stylesheet and schema location</td>
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<tr>
<td>2.2</td>
<td>SPL identifying information</td>
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<tr>
<td>2.3</td>
<td>Labeler and manufacturing information</td>
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<td>3</td>
<td>SPL Body</td>
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<td>Product data elements</td>
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<td>Product</td>
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<td>3.1.2</td>
<td>Kits, Parts, Components and Accessories</td>
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<td>3.1.3</td>
<td>Active ingredient</td>
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<tr>
<td>3.1.4</td>
<td>Inactive ingredient</td>
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<td>3.1.5</td>
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<td>UDI Device Identifier Marker</td>
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<td>Marketing category</td>
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<td>DEA schedule</td>
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<td>Route of administration</td>
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<td>Solid Oral Drug Product characteristics</td>
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<td>3.1.13</td>
<td>Device Characteristics</td>
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<td>3.2</td>
<td>Content of labeling</td>
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<tr>
<td>3.2.1</td>
<td>Sections and subsections</td>
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<tr>
<td>3.2.2</td>
<td>Labeling text</td>
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<tr>
<td>3.2.3</td>
<td>Highlights text</td>
</tr>
</tbody>
</table>

How to Model UDI GHTF Data Elements in HL7

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3.1 Product data elements

Information: The listing data elements for products are provided.

128 site and product codes are for licensed minimally manipulated cell products. GS1 GTIN and HIBCC codes are used for device item codes. FDA Substance Registration System (SRS) is used for the ingredient and active moiety Unique Ingredient Identifier (UNII). The FDA submission tracking system is used for application numbers. The Code of Federal Regulations is used for monograph citations. The National Cancer Institute Thesaurus (NCIt) is used for dosage form, product characteristics, DEA schedule, unit of presentation, route of administration and equivalent codes. The Unified Codes for Units of Measure (UCUM) is used for the unit of measure. HL7 confidentiality code “B” is for business confidential information. The Global Medical Device Nomenclature (GMDN) is for device nomenclature codes.

The following is for a device:

```xml
<subject>
  <manufacturedProduct>
    <manufacturedProduct>
      <code code="Device Item Code" codeSystem="Item Code System"/>
      <name>proprietary name <suffix>suffix to name</suffix></name>
      <desc>Brief description of product (< 512 characters)</desc>
      <asSpecializedKind>
        <generalizedMaterialKind>
          <code code="GMDN code" codeSystem="2.16.840.1.113883.6.276" displayValue="GMDN display name"/>
        </generalizedMaterialKind>
      </asSpecializedKind>
    </manufacturedProduct>
  </manufacturedProduct>
</subject>
```
UDI SPL Support Files (in process) provided on-line @

How to Model UDI GHTF Data Elements in HL7

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How to Model UDI GHTF Data Elements in HL7
GS1 Healthcare Conference @ Bethesda, MD ~ 2011.04.07

@ www.PragmaticData.com/spl/form/
UDI – The Big Picture

The label of Medical Device 123 Size 45:
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GS1 GDSN

Web based tool

Bulk HL7 SPL

Distribution

One Definition – Multiple Applications

FDA

FDA Managed

HL7 SPL

Business Rules

FDA’s UDI Database

Public User Interface

How to Model UDI GHTF Data Elements in HL7
(From Jay Crowley, FDA CDRH, 2011.04.06)
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The Bigger Picture

(Welcome to my world...!)
Support All Care Contexts

How to Model UDI GHTF Data Elements in HL7

Broad mix of communication and medical technologies – must coexist!

Wireless Technology Management Especially Challenging

(An Wittenber, Philips Medical, HITSP/TN905)

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Where’s the ID?

Complex System

How to Model UDI GHTF Data Elements in HL7
(Luis Melendez, Partners Healthcare, FDA Interoperability Workshop, 2010.01.25, www.MDPnP.org)

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#1 Problem: Patient/Device ID!

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It’s not just interfacing the infusion pumps!

Many clinical systems must be integrated - from many vendors - using many technologies!

FDA MDDS? Software as a Medical Device?

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How to Model UDI GHTF Data Elements in HL7

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What’s being done?

How are these problems being addressed?

- **Standards are ready ... implementation?**
  - Products are starting to hit the market!

- **HL7 version 2 messaging** (not Ver. 3!) is the primary transport for communicating medical device data to EHRs - **Modeling helps ensure consistency**

- **ISO/IEEE 11073** is the primary semantic content standard (both acute & personal health devices)

- **NIST** continues to develop open validation tooling

- **IHE** Develops interoperability profiles that leverage the above standards & tooling ...

**But system identifiers remain a total mess!**
Networked Device IDs

From the IHE PCD Technical Framework:

**Identifying with an EUI-64.** Namespace ID (EI-2) is optional in this case and may contain a locally unique name for the application implementing PCD actor(s). Universal ID (HD-2) contains the EUI-64 identifier as a hexadecimal string. The IEEE defined 64-bit extended unique identifier (EUI-64) is a concatenation of the 24-bit company_id value assigned by the IEEE Registration Authority, and a 40-bit extension identifier assigned by the organization having that company_id assignment. Third component (required): EUI-64.

**Identifying with an OID.** "Namespace ID" (EI-2) contains the name of the assigning authority, "Universal ID" (HD-2) containing its universal OID, and "Universal ID Type" (EI-4) containing the value ISO.

**Identifying with a URI.** The Universal Resource Identifier, defined in IETF RFC 3306, encompasses the familiar Uniform Resource Locator (the URL “internet address” of a website, for example), and the Universal Resource Name, which need not identify a web resource but uniquely identifies an entity according to a number of unique identifier schemes, including some of the others listed, such as OIDs (which can be made into URIs simply by prefixing the OID string with “urn:oid:”).

**Identifying with a DSN.** When the assigning authority is an information system or a manufacturer, it is acceptable to use a Domain Name Service name that uniquely identifies it. An IP address is a form of DSN, so it is also acceptable. These are less stable and permanent than the other Unique ID systems, which is why they are the least preferred.
IEC 80001-1 Risk Management for IT-Networks Incorporating Medical Devices...

- Full Device & Network Life Cycle Process
- 3 Key Characteristics:
  - Safety
  - Effectiveness
  - Data & System Security

Built on knowing what is where when & its operational status / effectiveness

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Analogous to Supply Chain Management, UDI facilitates continuity of monitoring and maintenance of manufacturer’s and end user’s risk control measures for networked medical technology.
80001-based Issue Management

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Conclusions

1. Aim at one UDI Model-to-SPL/CPM mapping to support many applications (supply chain + reg + clinical integration)

2. Medical Device Identification:
   - Much has been done ...
   - Standards in place & evolving ...
   - Reality? it’s still a mess!

Get Involved!!!

GS1, HL7, ISO, IEEE, IHE ...
Thank You!

www.80001Experts.com

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