GS1 Ireland Healthcare User Group (HUG) Information Day

UDI from an Irish healthcare perspective
Recall management and asset management

Ronnie McDermott, HSE

28th March 2017
User Group (HUG) Information Day

“UDI from an Irish healthcare perspective”

Recall management and Asset management

Tuesday 28th March 2017

Ronnie McDermott, MSc, Clinical Engineering, HSE, National Medical Device Equipment Advisor, Acute Services.
Presentation Format

- Medical Device Evolution
- Assurance Drivers
- HSE Medical Device eAlert System
- HSE Medical Device Equipment Asset Management System
Modern medical technology which dates its origins to the first half of the 19th century, only took off in earnest over the last 50 years.

Medical devices have become an essential part of health care and a vital component of the numerous activities carried out by health-care providers.

Without medical devices, routine medical procedures—from bandaging a sprained ankle, to diagnosing cancer or heart and lung transplant —would be impossible.

Opening up new possibilities for diagnosis and therapy.

But also raising questions of appropriateness, safety, effectiveness and provision of assurances.
Assurances - Key Drivers

EU Legislation & Standards
- Medical Device Vigilance System

Regulation:
- Health Products Regulatory Authority (HPRA) - Competent Authority Ireland
- Health Information Quality authority (HIQA) - “National Standards for Safer Better Healthcare”

HSE Policies & Guidance
Any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient, or user or of other persons or to a serious deterioration in their state of health.

Reference: Article 10 of the MDD
The European medical device vigilance system was set up under the medical device directives (93/42/EEC, 90/385/EEC, and 98/79/EC) to minimise risks to the safety of patients, users and others.

The Directives include requirements for medical device manufacturers to report certain types of events to the competent authority (CA). In Ireland the Health Products Regulatory Authority (HPRA) is the competent authority for medical devices.

The respective European competent authority publishes notices relating to the safety and/or quality of medical devices.
In Ireland the Health Products Regulatory Authority (HPRA) is the competent authority for medical devices.

The HPRA publishes notices relating to the safety and/or quality of medical devices.

The recipients of the safety communication have a responsibility to ensure that the communication reaches the most appropriate personnel within their organisation and to ensure that the issue outlined in the notice is considered, the risks assessed and the appropriate / recommended actions are completed.
3.1.6: Safe and effective management of medical devices and other equipment in accordance with legislative requirements, national policy, national guidelines where they exist, and best available national and international evidence.

- having the systems in place to identify, manage and learn from:
  - risks associated with medical devices and equipment
  - patient safety incidents associated with medical devices and equipment
  - alerts from the Health Products Regulatory authority
HSE Recognise
The Need to Have

➢ Systems in place for the management of Medical Device Equipment across the HSE organisation.

➢ Uniform coordinated approach across the organisation with responsibilities at local, Group/CHO and National level.

➢ A set of standard processes and a supporting ICT application to manage the Medical Device Safety notifications as distributed by the HPRA.

➢ To provide a coordinated standardised asset management system that delivers traceability of medical equipment
Medical Device Equipment Management Policy & Best Practice Guidance

Medical Device Equipment Management Policy
(Incorporating Medical Device Equipment Management Best Practice)

<table>
<thead>
<tr>
<th>Document Reference number</th>
<th>OGR030</th>
<th>Document developed by</th>
<th>National Quality Improvement Division</th>
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<tr>
<td>Revision number</td>
<td>02</td>
<td>Document approved by</td>
<td>Senior Management Team</td>
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<td>Responsibility for implementation</td>
<td>All Health Sector Employees</td>
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<tr>
<td>Revision date</td>
<td>September 2017</td>
<td>Responsibility for review and audit</td>
<td>National Medical Device Equipment Management Committee</td>
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HSE Medical Device Equipment Management
Best Practice,
Guidance for Service Areas.
HSE National Medical Device Alert System
Objectives.

➢ To Develop a system that delivers medical device safety notifications to the appropriate personnel for consideration of action.

➢ Track the various stages and processes through which notifications must pass.

➢ Report on completion of actions so they can be regarded as closed.

➢ The entire system must, insofar as is practicable, be web based.
Key Definitions

**Business Administrator (BA):** The BA is a national function charged with the responsibility for circulating the notifications and monitoring the processes to ensure they work efficiently and are being adhered to.

**Designated Person (DP) / Vigilance Officer:** The DP is the person(s) nominated in a facility who has responsibility to distribute the alerts to the appropriate personnel within their organisation for consideration of action.

**Relevant Persons for Actions (RP):** The person designated by the DP as the appropriate person within their organisation for consideration of alert actions.

**Core Group (CG):** In general, core groups reflect professional groups or specific grades working within the HSE or HSE funded service providers (e.g. Occupational therapy Community, Occupational therapy Hospital, Speech & Language Hospital, Speech & Language Community etc.). Each DP must be a member of at least one core group.
The eAlert – Priority levels

Upon receipt of a notification an electronic alert is generated by the Business Administrator and sent to the appropriate “Core Groups” and “Designated Person Vigilance Officer” via automatic email for action.

A priority level is assigned to each alert in accordance with the HPRA “Traffic Light System” of red, amber and green.

An associated automated response timescale is also assigned to each notification within which the relevant action must be reported back by the “Designated Person” to the Central ICT System as being “Completed” or “Not Applicable” or “Other”.

<table>
<thead>
<tr>
<th>Priority</th>
<th>Category</th>
<th>Examples</th>
<th>Response Timescale</th>
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</table>
| Priority 1 | For Immediate Action | • Urgent product recall  
               • Urgent Information  | 1 Week due         |
| Priority 2 | Warning        | • Action required  
               • Caution in use      | 3 Week response due |
| Priority 3 | Advisory       | • Traceability issue  
               • Generic information regarding medical devices | 6 Week Response due |
The eAlert - Notification

➢ The National system notifies the relevant “Designated Persons /Vigilance Officers via their HSE email account of an alert for processing within an appropriate timescale .

➢ The Designated Person will log into the system and review the relevant notification for processing.

➢ The Designated Person will process and if applicable forward the alert to the relevant person/s within their organisation for action.
- The Designated person will choose one of the predetermined options listed for “Action Taken” on the system to close off the alert response details for the national system.

- Where actions taken are not listed in the drop down menu for the predetermined response options the “Designated Person” can detail their specific actions taken within a comments box.

- Automated reminders will be issued from the national system to “Designated Persons” who have not closed off alerts received from the national system.
Automated reminders will be issued from the national system to “Designated Persons” who have not closed off alerts received from the national system:

- Two day prior to the assigned due return date, an automatic email reminder will be sent to the “Designated Person” for non-actioned alert.

- One week post the assigned due return date, an automatic email reminder will be sent to the “Designated Person” for non-actioned alert.

- Two weeks post the assigned due return date, a further automatic reminder will be issued from the system to the “Designated Person” for non-actioned alert.
The eAlert - Closed Loop System

- Provide an organisation wide assurance in the management of medical device alerts as issued by the competent authority the Health Products Regulatory Authority (HPRA).
- Delivers notifications to the appropriate personnel for consideration of action.
- Track the various stages and processes through which notifications must pass.
- Issues automatic reminders for outstanding alerts.
- Generation of reports for Hospital Groups and CHO’s.
In November 2012, HSE Estates invested in the implementation of a National Asset management system “ECRI AIMS.”

Applicable to all Acute services and Community Healthcare Organisations under the governance of a national steering group and project team.

To provide a coordinated standardised asset management system that is managed locally across the organisation.

To provide the supporting inventory detail for equipment replacement needs.

To provide traceability of medical equipment for the management of Medical Device Alerts as issued by the HPRA.
The UDI is a series of numeric or alphanumeric characters that is created through a coding system. It allows the unambiguous identification of a specific product on the market. The UDI comprises the Device Identifier and Production Identifier.
HSE UDI Preparation.

- HSE have committed to the use of GS1 standards as a form of unique identification for medical devices.

- HSE national asset management system adopted GS1 standards form of identification to track all existing and future medical equipment assets.

- GS1 standards form of identification adopted to track and track reusable invasive medical devices for Central Sterile Services Department (CSSD) and Endoscopy reprocessing units.

- HSE are engaging with global medical instrument providers to the HSE on the need for GS1 standards to be afforded to facilitate traceability within the service.
The implementation of the national medical equipment asset management system “ECRI AIMS” necessitates the application of a Unique Device Identifier (UDI) for each medical device equipment.

The requirement is for a future proofed solution to include best practice from the outset.

This includes the use of RFID in combination with data matrix labeling based on a set of standards.

The HSE has adopted the use GS1 standards to track its medical device equipment assets throughout the organisation.
GS1 Standards

➢ GS1 are Global Standards of Language Information to

- Identify
- Capture
- Share

➢ A language for identifying, capturing, and sharing information automatically and accurately, so that anyone who wants that information can understand it, no matter who or where they are.
The HSE is using the GS1 Global Individual Asset Identifier (GIAI) to track its medical device equipment assets.

- **Application Identifier** – 8004 to indicate GIAI
- **GS1 Company Prefix** – A Globally unique number assigned by GS1 to each hospital / facility, 7 digit prefix.
- **Individual Asset Reference** – The serial number assigned to the asset
HSE Medical Devices
GS1 Coding Partitions

- Using the GS1 company prefix a partition has been added to facilitate the Identification of many traceable objects including medical device equipment assets.

- The partitions **999-991** are reserved for the purposes of medical device asset tracking:
  - **999** Instrument Trays
  - **998** Endoscopes
  - **997** Medical Device Equipment
  - **996** Medical Equipment in the Community Healthcare Organisation
UDI Marking of a Flexible Endoscopes

For partition 998
- All Flexible Endoscopes will be assigned a GIAI code in line with the national track & trace allocated individual asset reference

For partition 997 & 996
- sequential allocation is used for each company prefix where the individual asset reference number is incremented by 1 for each asset assigned.

The limits of the serial number (0000000 – 9999999) is not expected to be exceeded.

<table>
<thead>
<tr>
<th>To Create a Global Individual Asset Identifier for an Endoscope</th>
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<td>Step 1</td>
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"AIMS" GS1 Code Assignment
Olympus Endoscope UDI - direct part marking

- 2 D Data Matrix Label
- incorporating GS1 coding structure for National Flexible Endoscope Traceability System.
- Leading Internationally - Olympus Scopes
- All new and existing scopes will be labelled this way
- Engagement with other manufacturers.
Olympus Endoscope
HSE UDI Label
Asset Tag Design

- The Asset Labels are required for durable long-lasting identification to facilitate application to the full range of medical device equipment.

- The labels are designed to be inclusive of RFID for some applications together with non-RFID application.

- There was one primary sized tag identified during the design phase followed by a comprehensive testing process to show efficacy across the sample asset group.

- This primary tag is anticipated to broadly cover 90% plus of asset types with an RFID read range of 6-7 meters where deployed.
In March 2016 SVUH commenced a pilot project on implementation of AIMS and associated GS1 asset tag coding. The pilot was implemented by GS1 And “Vision ID” in conjunction with the Local Clinical Engineering Department.

- **Phase 1** Re badging all medical device equipment within the hospital with the national GS1 GIAl asset label. This label incorporated as standard, passive Radio Frequency Identification (RFID) technologies.

- **Phase 2** ‘RFID functionality assessment.’ This phase determined the optimum location for the RFID tag on the equipment to ensure the best visibility to the RFID readers. This involved generating an image gallery as guidance for future installations.

- **Phase 3** ‘Migration of the new asset data.’ The Universal Medical Device Nomenclature System (UMDNS) has been adopted for the national ECRI-AIMS database.
“If everyone is moving forward together, then success takes care of itself.”

Henry Ford
Thank You For Listening.

The HSE University Hospital Name

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