Registries for Implants, a development

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23 April 2013
Calls for the introduction and implementation of essential and immediate specific measures…

...encouraging patients, patients’ associations, patient groups and healthcare professionals to report all adverse event...

...establish tools that, while providing data protection, ensure traceability of medical devices and long-term monitoring of their safety and performance, such as a ‘Unique Device Identification’ system, an implant register…
European Parliament demands a central registry.

…establish a single European database that brings together information about the medical devices available on the market…

…to consider the possibility of establishing an efficient tracking system for medical devices used as implants, particularly for the most dangerous medical devices such as those in class III;
RECOMMENDATIONS

COMMISSION RECOMMENDATION
of 5 April 2013

on a common framework for a unique device identification system of medical devices in the Union

(Transposed EEAs law)

(6) UDI mechanisms, based on different national and/or regional traceability requirements, have already been developed and there is a risk that further diverging UDI mechanisms may be developed at these levels.

Whereas:

(1) Traceability of medical devices throughout the whole supply chain contributes to patient safety by facilitating vigilance, market surveillance and transparency in this sector.

(2) The current regulatory framework for medical devices

(6) UDI mechanisms, based on different national and/or regional traceability requirements, have already been developed and there is a risk that further diverging UDI mechanisms may be developed at these levels.

(7) In future certain information contained in the UDI code could feed the Electronic Health Record according to Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (4) and the Digital Agenda for Europe (5).
- Introduction
- Registry for implants
- Observations
- Barriers
- Recommendations
Hospitals in The Netherlands

- Hospitals
  - approximately 90
  - including 8 academical
  - complex governance systems
  - various cooperation models

- Commercial hospitals
  - approximately 200
  - increasing in numbers

- IT:
  - 10+ different Hospital Information Systems
  - in combination with various ERP systems
There are dossiers with serious problems of implants

Baseline shall be: at all times a safe product

- Heartvalves (BSCC)
- Internal Defibrillator (ICD)
- Metal-on-Metal Hip Implants
- (PIP) Breast Implants
Netherlands Government took initiatives in the field of:

- Risk Management
- Supply Chain Management
Dit is een uitgave van
Ministerie van Volksgezondheid,
Welzijn en Sport

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APRIL 2001

Medische Technologie at risk?

Onderzoek naar risico’s bij medische technologie en
mogelijkheden om deze te voorkomen of te reduceren

Expertgroep Medische Technologie
Risk traditionally defined as: Probability * Impact

But a better understanding of risk includes:

- Volume of the failures per year: attention in the media is bad for reputation
- Detectability of the failure: there’s valuable time to win
- Availability of a solution: are we willing to share our knowledge and our solutions with colleagues

Risk = Probability * Impact * Volume * Un-detectability * Un-availability of a solution
Onderwerp: Risico analyse; wat is het risico als het betreffende implantaat getraceerd moet worden.
Eerste kwalitatieve benadering; lijst niet uitputtend

<table>
<thead>
<tr>
<th>Implaantaat</th>
<th>Beschrijving van het mogelijke defect (abnormale situatie)</th>
<th>Kans op defect</th>
<th>Impact van het defect</th>
<th>Kans op detectie van het defect</th>
<th>Aantal ingrepen in Nederland per jaar (indicatief)</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Borstimplantaat</td>
<td>Lekken of scheuren waardoor siliconen in het lichaam terecht komen</td>
<td>HI</td>
<td>HI</td>
<td>LO</td>
<td>1</td>
<td>2.560</td>
</tr>
<tr>
<td>2. Cement</td>
<td>Giftige stoffen in het materiaal, cement houdt niet</td>
<td>VLO</td>
<td>MED</td>
<td>VHI</td>
<td>100</td>
<td>2.500</td>
</tr>
<tr>
<td>3. Gebitsimplantaat</td>
<td>Giftige stoffen in het materiaal</td>
<td>VLO</td>
<td>MED</td>
<td>LO</td>
<td>10</td>
<td>2.000</td>
</tr>
<tr>
<td>4. Hartklep</td>
<td>Technische defecten</td>
<td>MED</td>
<td>VHI</td>
<td>MED</td>
<td>1</td>
<td>1.250</td>
</tr>
<tr>
<td>5. Stent</td>
<td>Technische defecten</td>
<td>MED</td>
<td>MED</td>
<td>MED</td>
<td>1</td>
<td>625</td>
</tr>
<tr>
<td>6. Meshes</td>
<td>Giftige stoffen in het materiaal</td>
<td>LO</td>
<td>MED</td>
<td>VLO</td>
<td>1</td>
<td>500</td>
</tr>
<tr>
<td>7. ICD's</td>
<td>Technische defecten, breuk in leads</td>
<td>MED</td>
<td>VHI</td>
<td>HI</td>
<td>1</td>
<td>500</td>
</tr>
<tr>
<td>8. Pacemakers</td>
<td>Technische defecten, breuk in leads</td>
<td>MED</td>
<td>VHI</td>
<td>HI</td>
<td>1</td>
<td>500</td>
</tr>
<tr>
<td>9. Heup</td>
<td>Verplaatsen, materiaal slijt</td>
<td>MED</td>
<td>HI</td>
<td>HI</td>
<td>1</td>
<td>400</td>
</tr>
<tr>
<td>10. Knie</td>
<td>Verplaatsen, materiaal slijt</td>
<td>LO</td>
<td>HI</td>
<td>HI</td>
<td>1</td>
<td>160</td>
</tr>
<tr>
<td>11. Zenuwimplantaat</td>
<td>Technische defecten</td>
<td>LO</td>
<td>HI</td>
<td>VHI</td>
<td>1</td>
<td>80</td>
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<td>12. Ooglenzen</td>
<td>Giftige stoffen in het materiaal</td>
<td>VLO</td>
<td>MED</td>
<td>VHI</td>
<td>1</td>
<td>25</td>
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<td>13. Gehoorimplantaat</td>
<td>Technische defecten</td>
<td>LO</td>
<td>VLO</td>
<td>VHI</td>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td>14. ICM</td>
<td>Giftige stoffen in het materiaal</td>
<td>LO</td>
<td>MED</td>
<td>HI</td>
<td>0,1</td>
<td>10</td>
</tr>
</tbody>
</table>

VHI: Very High   10 10 1 100 >1.000.000
HI: High         8 8 2 10 100.000 - 1.000.000
Med: Medium       5 5 5 1 10.000 - 100.000
LO: Low           2 2 8 0,1 1.000 - 10.000
VLO: Very Low     1 1 10 0,01 <1.000
Expert Group recommended a centralized database for implants

Discussions in Parliament: April 2012

Decided for a phased approach:

- Phase 1: Base registry for implants
- Phase 2: Functionalities that can use the base registry as a source

Target Phase 1: Traceability of implants

- In patients as well as in stock in the hospital

Start Phase 1: scheduled in 2013

Status today: Preparations for pilot
Initial setup: combination of UDI and UPI

**UDI:**
- Manufacturer
- Lot number
- Serial number
- Expiry date

**UPI:**
- Patiënt BSN
- Doctor
- Hospital
- Implantation date
Options for Data Collection

- Manually not preferred due to expected error rates
- Automatically by means of scanners
- As “Real Time” as possible
THIS IS NOT DIFFICULT
THEN WHY DOES IT TAKE SO LONG?
Observations “Registries”:

- Report: 66+ “Formal Requests for data” to Hospitals
- There are many separate registries in place
Observations “Industry”:

- Professional “traceability systems”
- However… no further than the hospitals front door
- Sometimes manufacturer owned implants are in hospitals stock (“consigned”)
- Complexity in logistics: unused implants are returned
- “Post Marketing Surveillance” sometimes includes direct contact with patients
Observations “Hospitals and Clinics”

- No national standard in logistic procedures
- Formal choice for GS1 in January 2011 by the association of hospitals with the aim to be GS1 compliant by the end of 2012, however no significant progress since the first statement
- Barcoding or use of specific barcode standard is no requirement in purchasing processes
- Often logistics is no focus point of Board of Directors
Observations in the field
Observations “Medical Specialists”:

- Prefer separate registries for specialisms, as a start
- Prefer “all-in” registries containing more data than just implant data
- Propose approximately 80 registries, following the “Swedish model”
Observations “Patients”:

- Variety: patients, patients and clients
- Lack of structured information
- No central office for reporting complications
- Implants last often longer than the relationship between patient and doctor
- Increasing role of patients, amongst others because of the social media
- Increasing worries about privacy of the patients
Barriers for implementation

- Many organisational changes going on
- Complex IT infrastructures and many different HIS’s
- Lack of a fully shared vision in the field
- Required investments by industry (especially SME)
- A legal basis for a centralized national registry costs time to realize
Industry is well in control over its own supply chain, however until the hospitals front door

Hospitals underestimate the complexity of implementing registries

Patients are poorly organized

Governments tend to regard Healthcare as a national responsibility but in practice have limited options

There is low momentum in progress and change

Decision making costs a lot of time, money and political courage
Recommendation for Hospitals

- Do not underestimate the complexity!
  - IT-structure
  - opinion and interests of the doctors
  - various specialties
  - specific patient requirements leading to exceptions
  - various distributors
  - capacity required at logistics
Recommendation for Hospitals (2)

- Find solutions, for instance:
  - change purchasing conditions
  - option is: outsourcing of logistics

- Registries
- Reviews
- Audits
- Improvement process
- Law making
- Purchasing Conditions
- Registries
- Act
- Plan
- Check
- Do
EC Document (April 2013): “Risk that incompatible or divergent initiatives in Member States frustrate the Unions objectives”

- Revision of CR 14060 may help
- Speed up!
Muchas gracias!
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