NAMCO Healthcare Technology

GS1 The global language of business

Registries for Implants, a development

René Drost

23 April 2013

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European Parliament (1)

Summer 2012:

European Parliament demands a central registry.

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…

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European Parliament (2)

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

(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],

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Content

- Introduction
- Registry for implants
- Observations
- Barriers
- Recommendations

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Hospitals in The Netherlands

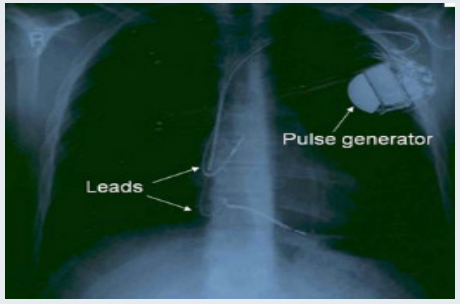
- Hospitals
  - approximately 90
  - including 8 academical
  - complex governance systems
  - various cooperation models
- Commercial hospitals
  - approximately 200
  - increasing in numbers
- IT:
  - 10+ different Hospital Information Systems
  - in combination with various ERP systems

Implant Dossiers

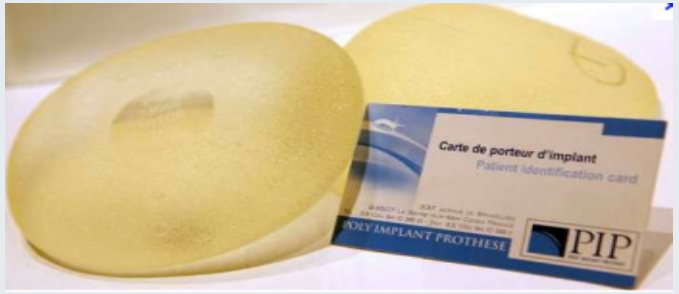
- There are dossiers with serious problems of implants
- Baseline shall be: at all times a safe product

Heartvalves (BSCC)

Metal-on-Metal Hip Implants



Internal Defibrillator (ICD)



(PIP) Breast Implants

Initiatives

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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Meer informatie
Met vragen kunt u terecht bij Postbus 51: bel 0800-8051 (gratis) of kijk op www.postbus51.nl. De medewerkers zijn op werkdagen telefonisch bereikbaar van 08.00 tot 20.00 uur

April 2011

Medische Technologie at risk?

Ministerie van Volksgezondheid,
Welzijn en Sport

Medische Technologie at risk?

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

Expertgroep Medische Technologie

Risk Assessment

- 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 collegaes
- Risk = Probability * Impact * Volume * Un-detectability * Un-availability of a solution

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Risk Assessment

Onderwerp: Risico analyse; wat is het risico als het betreffende implantaat getraceerd moet worden.
Eerste kwalitatieve benadering; lijst niet uitputtend

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

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

Supply Chain Management

http://www.rijksoverheid.nl/documenten-en-publicaties/convenanten/2011/12/23/convenant-veilige-toepassing-van-medische-technologie-in-het-ziekenhuis.html

Vereniging van ziekenhuis instrumentatietechnici (VZI), Nederlandse Vereniging voor Technisch facilitair management in de Gezondheidszorg (NVTG), NEVI-Zorg, Vereniging van Deskundigen Steriele Medische Hulpmiddelen (VDSMH) en de Werkgroep Instrumentatie Beheer Academische Ziekenhuizen (WIBAZ). Het convenant is mede tot stand gekomen met adviezen van NAMCO Healthcare Technology, Medicta, Kerteza, Meditain en Biomedisch Technologen in de zorg (BMTZ).

Invoering en toezicht

Bij de concrete invoering van deze veldnormen in de praktijk zal sprake zijn van een gefaseerde aanpak. Dit implementatieplan kenmerkt zich door heldere en realistische data waarop onderdelen van de veldnorm moeten zijn ingevoerd. De Inspectie voor de Gezondheidszorg (IGZ) zal in haar toezicht op de uitvoering van het convenant dit plan betrekken.

NVZ vereniging van ziekenhuizen

Roelf H. de Boer
voorzitter

Nederlandse Federatie Universitair Medische Centra

Drs. Elmer B. Mulder
voorzitter

Revalidatie Nederland

Mr. Paula Swenker
voorzitter

NVZ vereniging van ziekenhuizen
NFU NEDERLANDSE FEDERATIE VAN UNIVERSITAIR MEDISCHE CENTRA
Revalidatie Nederland

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November 2012: Letter to Parliament

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

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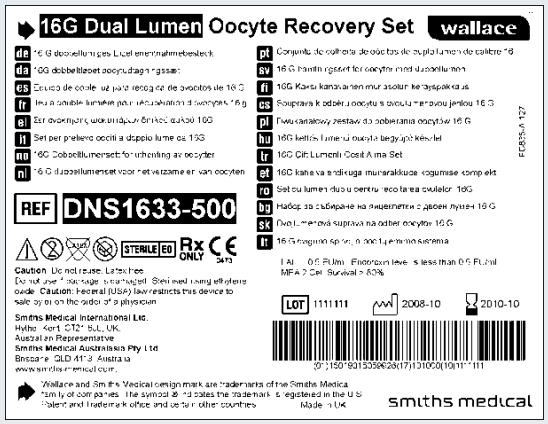
Initial setup: combination of UDI and UPI

UDI:

- Manufacturer
- Lotnumber
- Serial number
- Expiry date

UPI:

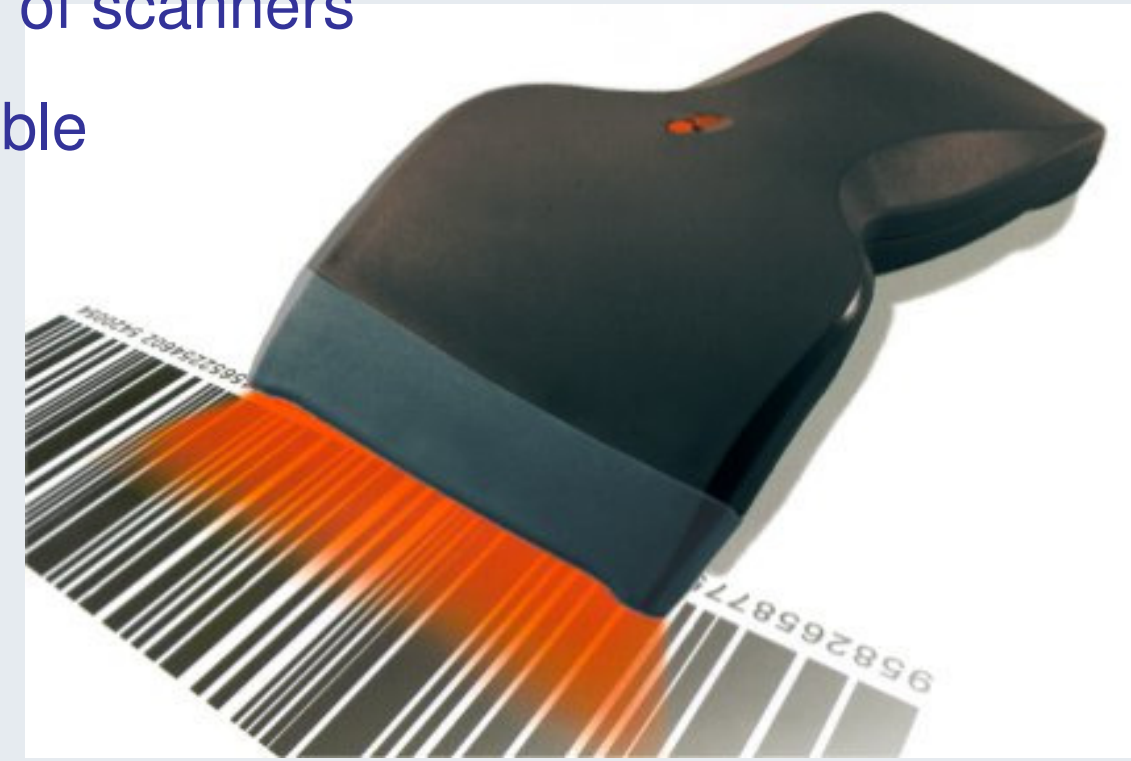
- Patiënt BSN
- Doctor
- Hospital
- Implantation date



Data collection

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 in the field

Observations “Registries”:

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

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Observations in the field

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 in the field

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

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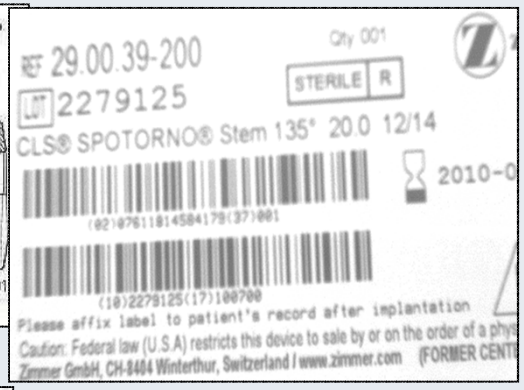
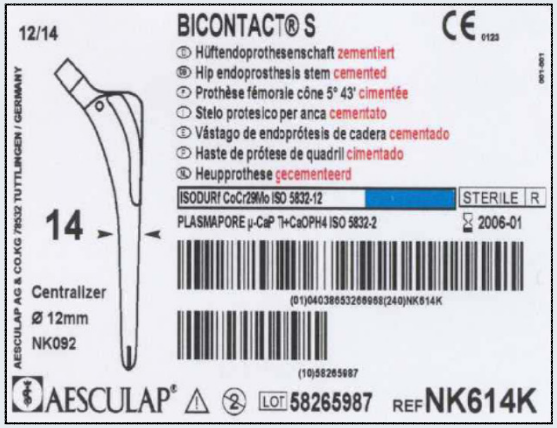
Observations in the field





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 in the field

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

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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

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Conclusions

- 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

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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

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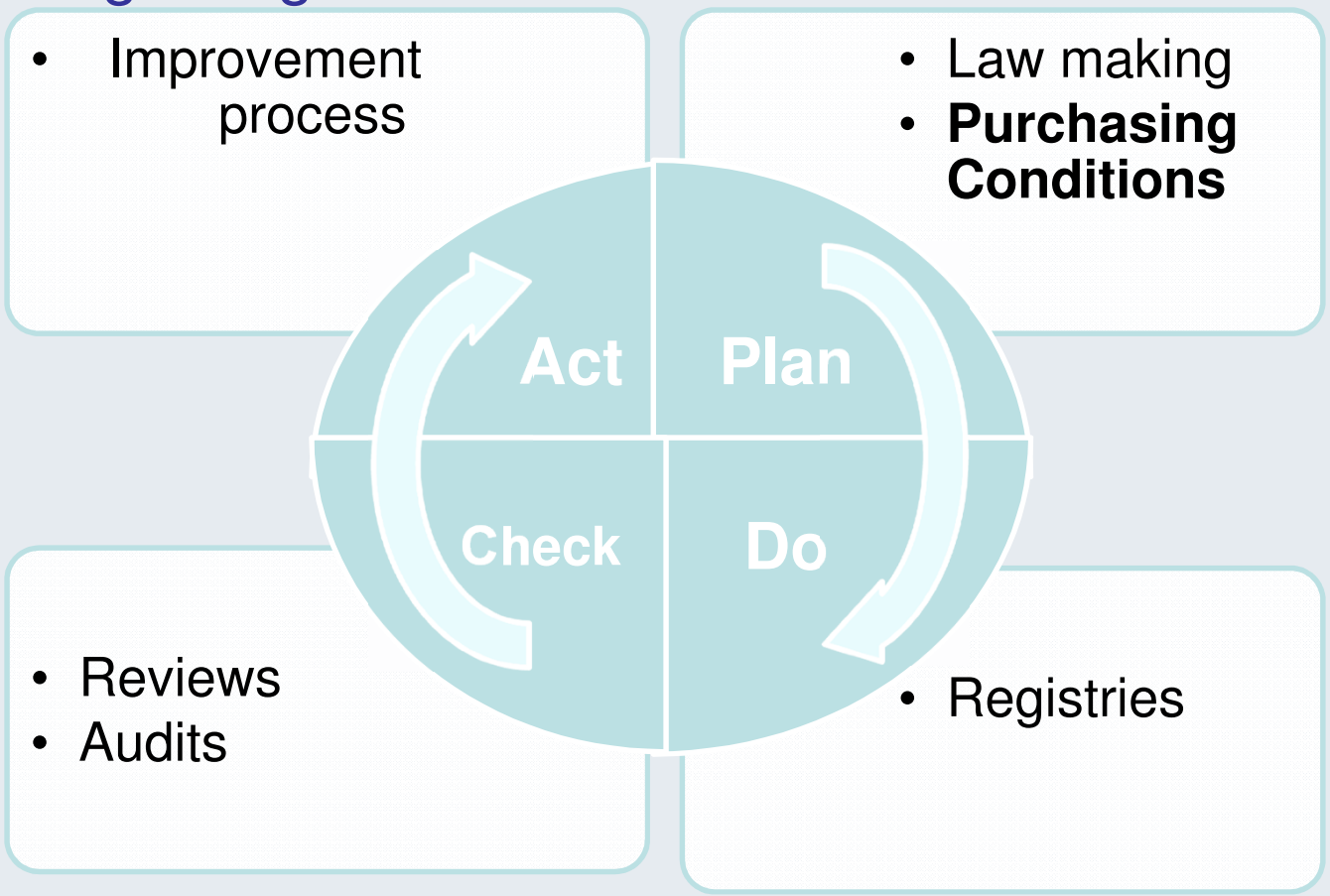
Recommendation for Hospitals (2)

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

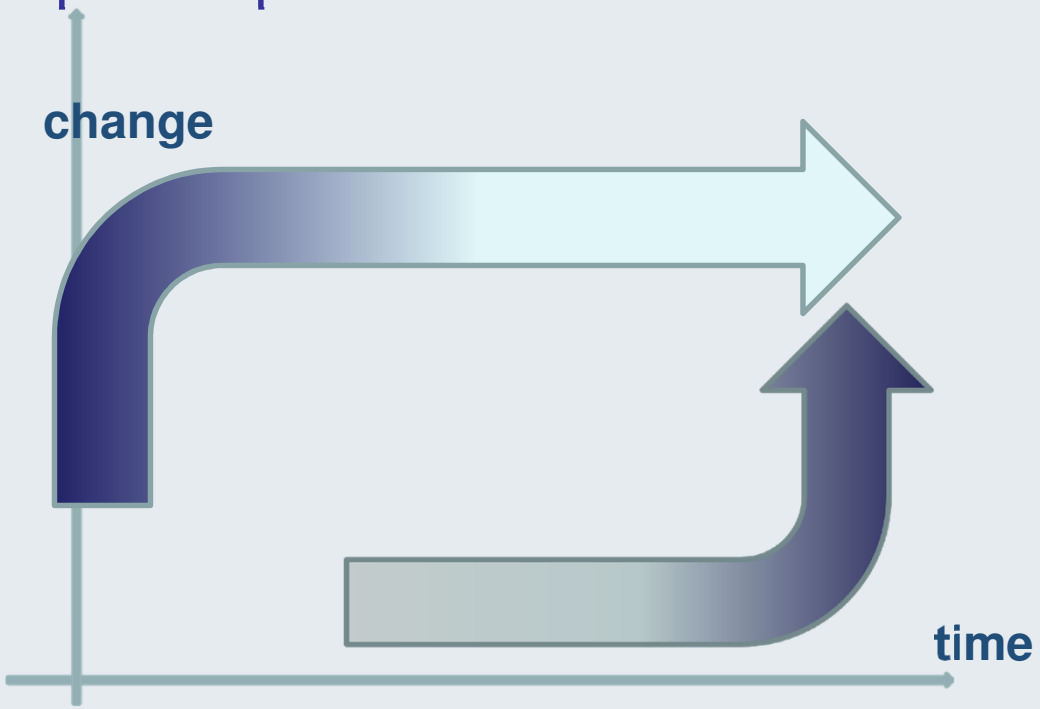


EC Document (April 2013): “Risk that incompatible or divergent initiatives in Member States frustrate the Unions objectives”

- Revision of CR 14060 may help
- Speed up!

cen EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CENELEC



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Muchas gracias!

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