GS1

GS1 Healthcare Provider Advisory Council Webinar

National Agreements on unique coding of medical devices supported by industry, healthcare providers and the Ministry of Health

Tom Pereboom, Chair ADC Working group (Netherlands) with the Ministry of Health

September 2017

Welcome and thank you for attending!

- Welcome to our August 2017 webinar.
  Thank you to our guest speaker Mr Tom Pereboom, Manager CSSD MC Groep; President Sterilization Association of The Netherlands; Chair ADC Working group (Netherlands) with the Ministry of Health

- Some housekeeping for today:
  - All attendees will be on mute
  - If you have questions during the presentation, please type them into the questions area and these will be monitored then answered at the end of the call

- After the webinar:
  - Within a week, the recording will be posted to: http://www.gs1.org/healthcare/hpac_webinars
  - All previous webinars are also posted to this location, so please feel free to use this resource and share the link

The GS1 Healthcare Provider Advisory Council (HPAC)

Focus is on thought leaders and adopters of GS1 Healthcare Standards from the global clinical provider environment. Their final goal is to improve patient safety, cost efficiency and staff productivity through implementation of GS1 standards.

A forum for sharing and discussion

- About the practical realities of implementation of GS1 Standards in the care giving environment in regards to the impact on clinical care and patient interaction

Identification of projects and case studies

- That support the adoption of GS1 Standards in healthcare providers and retail pharmacies
- For publication, presentation and sharing

A source of expertise and advice

- To those involved in GS1 standards development, the wider Healthcare stakeholder community and senior executives/decision-makers to gain their buy-in and support for implementation of GS1 Standards

HPAC Activities

Webinars

- Monthly webinars open to all stakeholders interested in learning about GS1 standards implementation in the care giving environment.
- http://www.gs1.org/healthcare/hpac_webinars

Awards

- Twice per year
- Provider Best Case Study Award
- Provider Recognition Award
- The prize is travel / accommodation to attend the next GS1 Healthcare conference
- http://www.gs1.org/healthcare/hpac

GS1 Healthcare also holds two global conferences per year. The next conference will be in Chicago from October 17-19, 2017, with significant Healthcare Provider participation on the agenda.

Presenting today

Tom Pereboom

Manager CSSD MC Group (hospital)

President Sterilization Association of The Netherlands (SVN)

Chair ADC Working group (Netherlands) Ministry of Health

Who is Tom, some details on work......

€ Professional background

MC Groep

Present hospital of employment
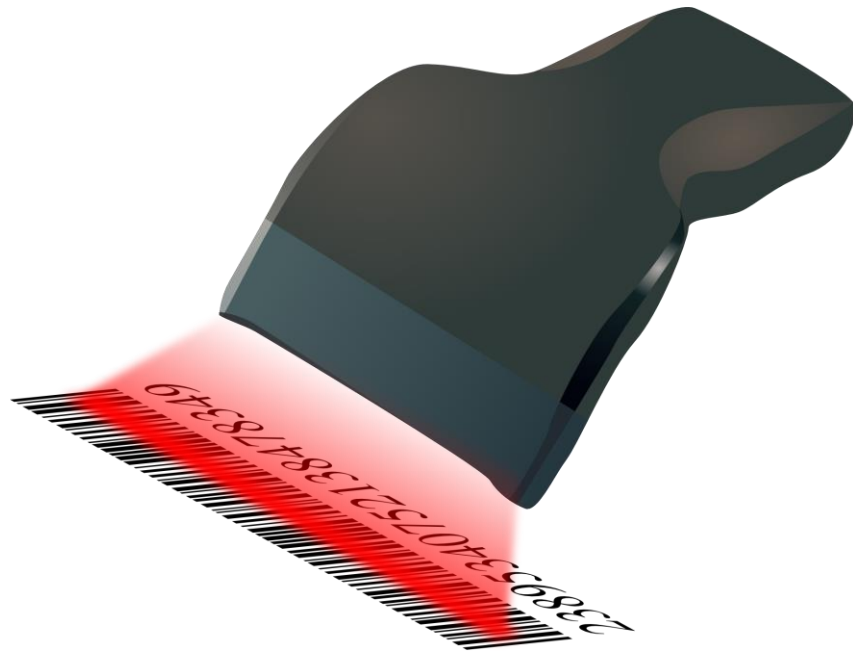
SVN
STERILISATIE VERENIGING NEDERLAND

President Dutch Sterilization Association

ADC (Agreement) is:

National Agreements on unique coding of medical devices supported by industry, healthcare providers and the ministry of health

Learning objectives of the webinar

- Why these national agreements?

- How to involve relevant parties: industry and healthcare providers

- The important role of ICT

- How do the agreements relate to the EU MDR?

Members of working group 'unique coding of medical devices'

PIP breast implants example   -1-

UK study showed in 2010:

- French Poly Implant Prostheses (PIP):
  - Used industrial silicone gel unsuitable for medical use
  - Chance of rupture is 2 x higher
  - Leading to health issues in women
- Implanted in previous years >> several 1000 women
- Recall and re-surgery needed
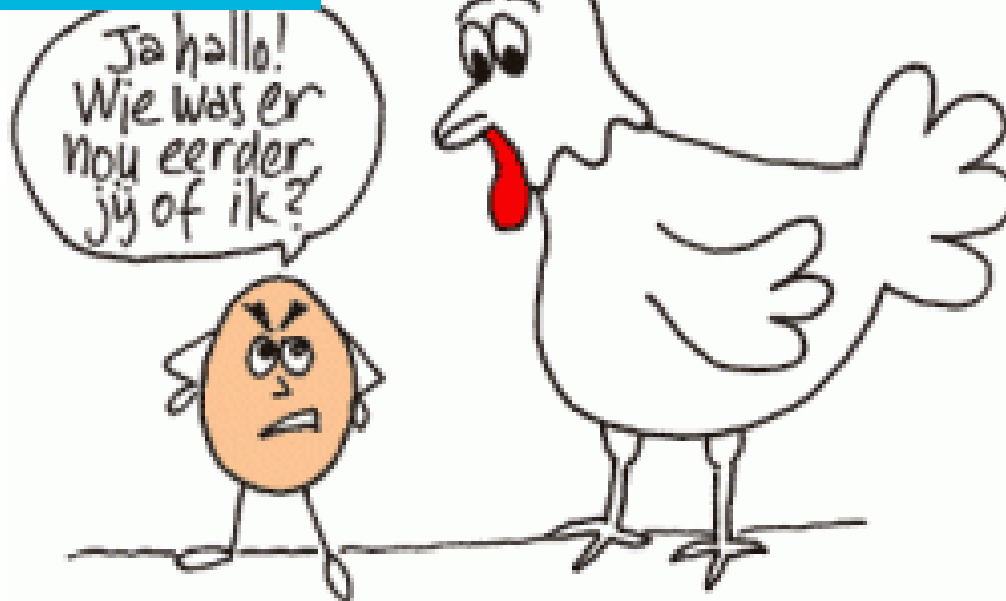
PIP breast implants example   -2-

Severe permanent patient harm
Traceability issues
Hospitals face major costs and litigation
Manufacturer bankrupt
Director jailed

Why this agreement (ADC)?

He, who was here first, you or me??!!
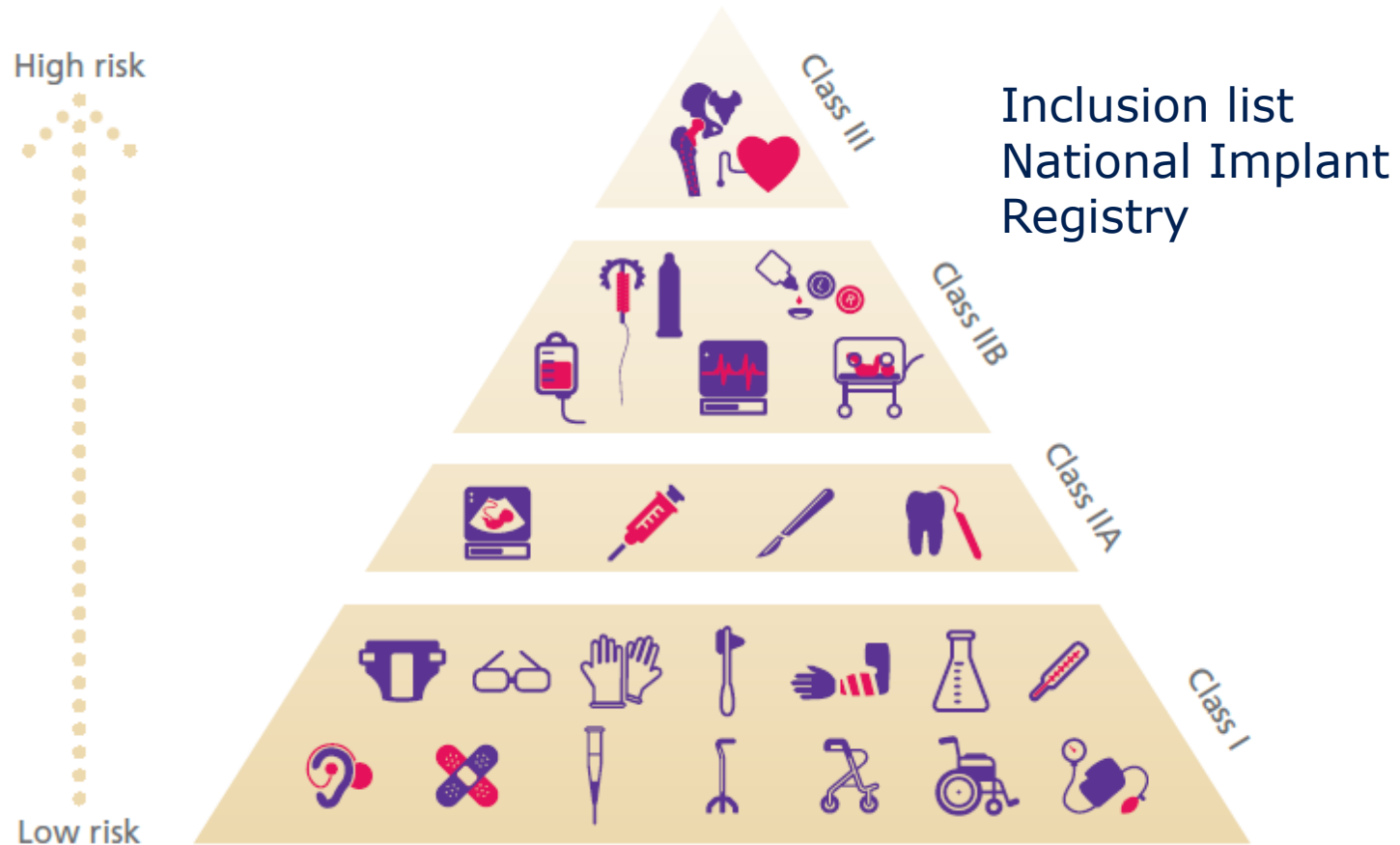

Link to official document (in Dutch):

https://www.rijksoverheid.nl/ministeries/ministerie-van-volksgezondheid-welzijn-en-sport/documenten/kamerstukken/2017/06/21/kamerbrief-over-eenduidige-codering-medische-hulpmiddelen

Goals of the agreement

- Safer

- Efficient

- International adopted standards in healthcare: HIBCC, ICCBBA, GS1

- MDR article 27 UDI: unique device identifier

Definition of scope

High risk

Class III

Class IIB

Class IIA

Class I

Low risk

Inclusion list
National Implant
Registry

Logistieke keten medische hulpmiddelen

Logistical chain medical devices

Source material → Grondstoffen

manufacturer → Fabrikant

Distributor or wholesaler → Distributeur of groothandel

Hospital Central warehouse → Centraal magazijn ziekenhuis

Care giver → Zorgverlener

Voorraad operatiekamer

Stock operating theatre

Toepassing bij de patiënt

use at bedside/ patient

Traceability

Traceability

Information

Information

Quality

Planning

Expected results for healthcare providers when implenting the agreements

- Scanning of UDI → a flawless basic registration in your hospital system.

- Facilitate the 100% recall within the healthcare organization.

- Registration of medical devices improves therefore the quality of data improves. This facilitates exchanging required product information with national registries.

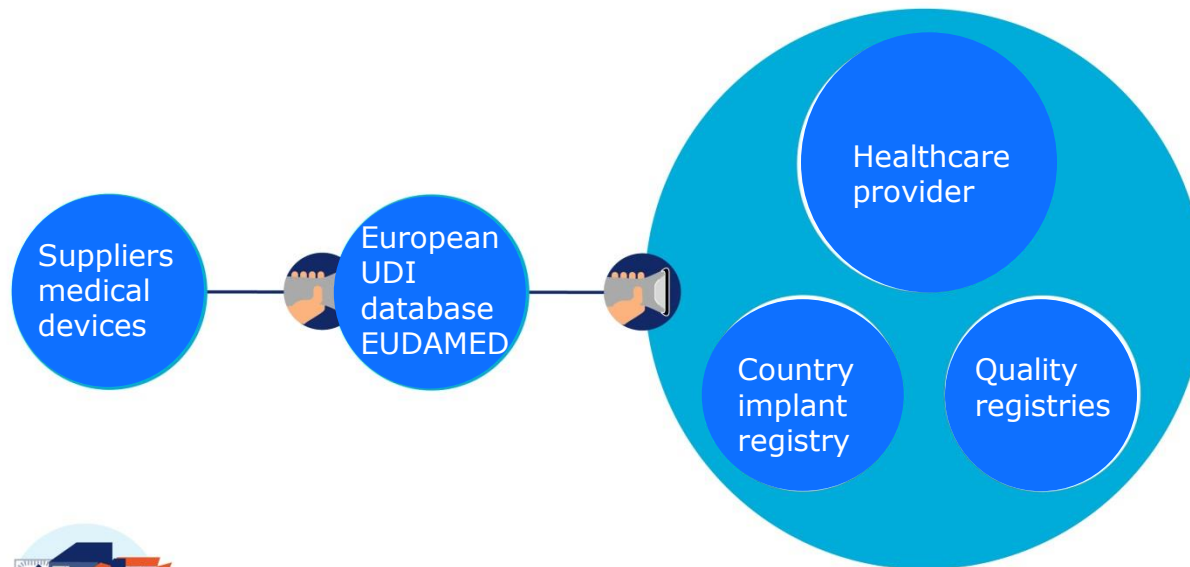- New information improves supply chain management.

Scanning is key

Impact for suppliers of medical devices

Exchange product data

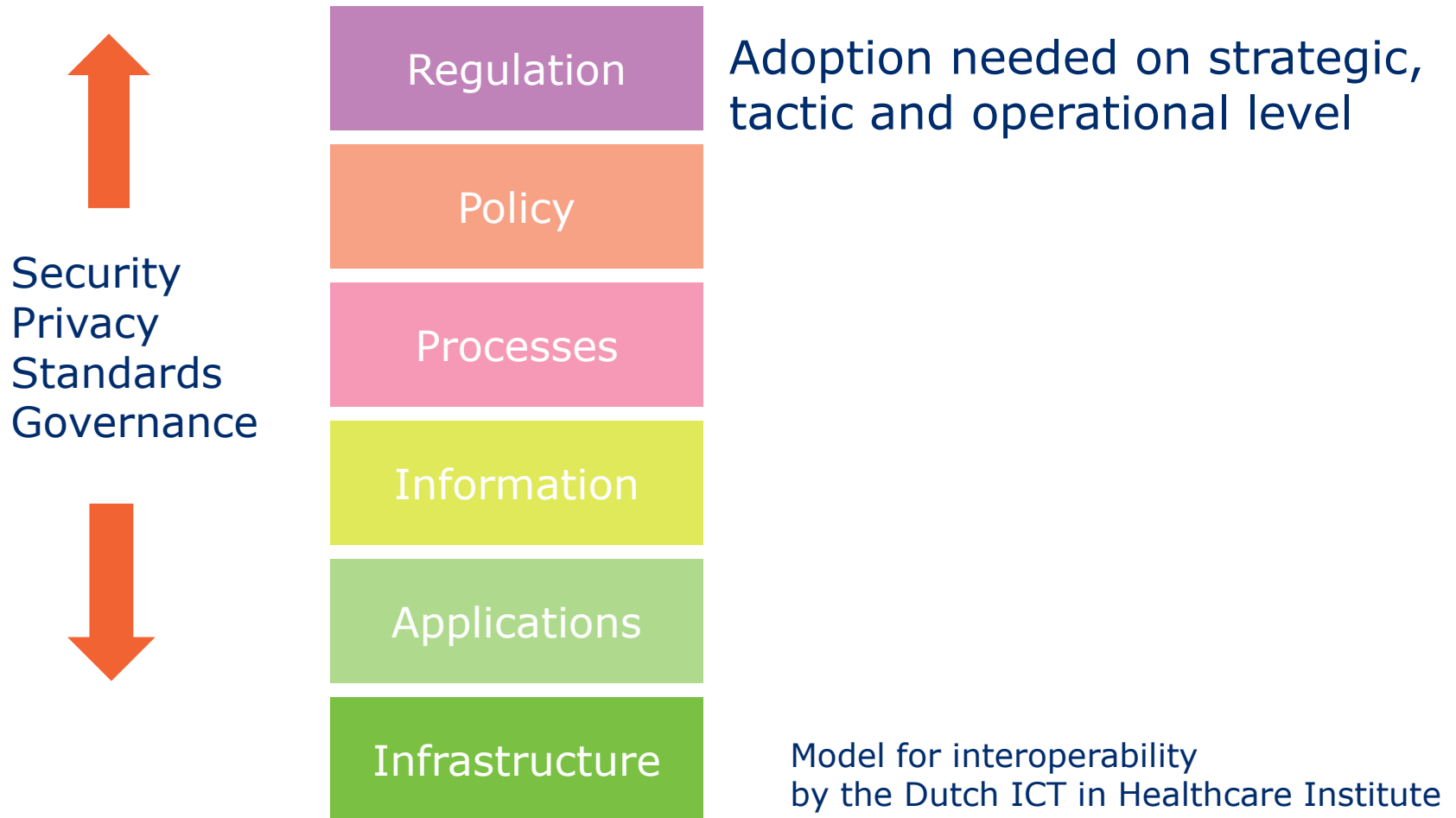Suppliers medical devices

European UDI database EUDAMED

Healthcare provider

Country implant registry

Quality registries

= unique product identification

Time line: July 1st 2018

- Unique product number
- Lot number
- Expiry date
- Serial number

Impact for healthcare providers -1-

Regulation

Policy

Processes

Information

Applications

Infrastructure

Security
Privacy
Standards
Governance

Adoption needed on strategic, tactic and operational level

Model for interoperability
by the Dutch ICT in Healthcare Institute

Impact for the healthcare providers -2-

1. Governance – Hospital Board is responsible for implementation
2. Policy and governance – responsibilities arranged well
3. Legislation and regulation – use of coding
4. Strategy – tender of software and medical devices
5. Strategy and policy – explicitely define responsibilities at each level
6. Strategy – procedure for registration of medical devices throughout the entire chain; departments and care professionals
7. Strategy – training

Impact for the healthcare providers -3-

8. Care processes – impact analysis
9. Information - registration
10. IT-applications - adjust HIS/EMR and ERP
11. Infrastructure:

    i.   Procedure to exchange master data and information

    ii.   GDSN !!!!

    iii. In the Netherlands: CIBG service (government) for registries

Impact for the healthcare providers -4- (ICT)

- Adjust Health Information system (HIS) and Electronic medical record to process:

  - Unique product number (identifier)

  - Lot number

  - Expiry date

  - Serial number

- ERP to process central data information:

  - Name and details supplier

  - Unique suppliers number

  - Product name

  - Type of packaging

  - Amount in package

  - Indicator lot number yes/no

  - Serial number yes/no

WRAP UP on Scanning of UDI

- A flawless basic registration in the hospital system
- Facilitate the 100% recall within the healthcare organization and for the entire supply chain
- Registration of medical devices improves, therefore the quality of data improves as well
- Facilitating exchange of product information with registries
- Improvement of supply chain management
- Reduce need for work arounds, like relabeling
- Give back time of healthcare professionals to direct patient care

Enhances patient safety

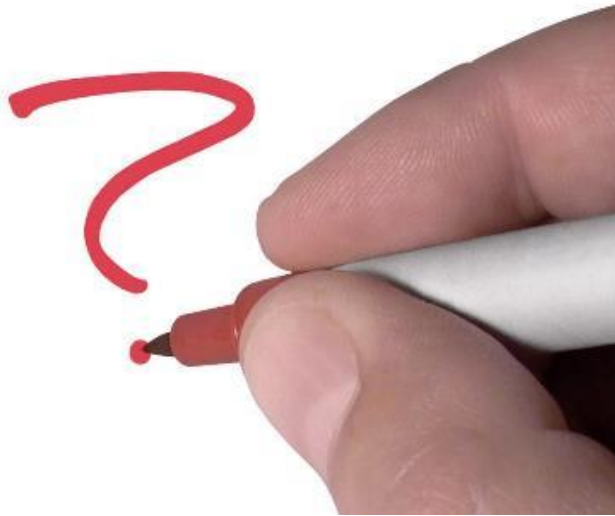# Wrap up on the learning objectives of the webinar

- Why these national agreements?

- How to involve relevant parties: industry and healthcare providers

- The important role of ICT

- How do the agreements relate to the EU MDR?

HPAC Questions and contact details

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