The Global Language of Business

Implant Registries – impacts for manufacturers, hospitals, governments and patients

35th Global GS1 Healthcare Conference, Noordwijk, the Netherlands

March 27, 2019

Tom Pereboom, chair SVN (Dutch Association for Sterilization); chair of the panel
Andy Crosbie, Devices Division, Medicines & Healthcare products Regulatory Agency MHRA, UK
Dr. Hinne A. Rakhorst, Medisch Spectrum Twente Enschede, Chair Dutch Association of Plastic Surgeons, The Netherlands
Henrik Stilling, Information Technology Architect, Central Denmark Region, Aarhus Hospital, Denmark
Blair Korman, Senior Project Manager Supply Chain Visibility Johnson & Johnson Supply Chain

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Mr. Tom Pereboom, chair SVN (Dutch Association for Sterilization)
chair of the panel
March 27th, 2019

Introduction and highlights for this session

- All over the globe regulation drives the unique identification of medical devices.
- The US – FDA regulation with the GUDID drives change concerning identification and registration of medical devices.
- In the EU all stakeholders in healthcare working with medical devices and instruments have to be prepared for the Medical Device Regulation (MDR) and the EUDAMED in 2020.
- Regulation in other countries and regions is expected.
- Preparation is key.
- Implants are a specific type of medical device, and for several reasons patient safety is a major concern.

Several stakeholders have focus on the patient in these processes

Introduction and highlights for this session

“Implant Registries – impacts for manufactures, hospitals, governments and patients”

From their several perspectives the presenters will highlight several issues, such as:

1. Implant registries: why are these important?
2. What is needed to set up registries that are accessible and allow for full traceability?
3. How does GS1 fit in and what can be the added value of GS1?

Ending with Q&A using sli.do.com

Q & A : SLIDO

1. Go to slido.com
2. Enter #GS1HCNoordwijk
3. Select the panel **Implants registries**
4. Go to “Questions”
5. Make sure you enter your full name so that if the questions you’ve raised are not selected, the GS1 team can revert to you
6. Post your questions

Implant Registries – impacts for manufacturers, hospitals, governments and patients

Chair:
Tom Pereboom

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The Global Language of Business

Regulatory perspective

35th Global GS1 Healthcare Conference, Noordwijk, the Netherlands

Andy Crosbie,
Devices Division, Medicines & Healthcare products Regulatory Agency MHRA, UK

March 27, 2019

Medicines & Healthcare products Regulatory Agency

Implant Registries - Impacts for manufacturers, hospitals, governments and patients

Regulatory perspective

35th Global GS1 Healthcare Conference - Noordwijk - 26-28 March 2019

Andy Crosbie – Manager, Post Market Surveillance Strategy - MHRA



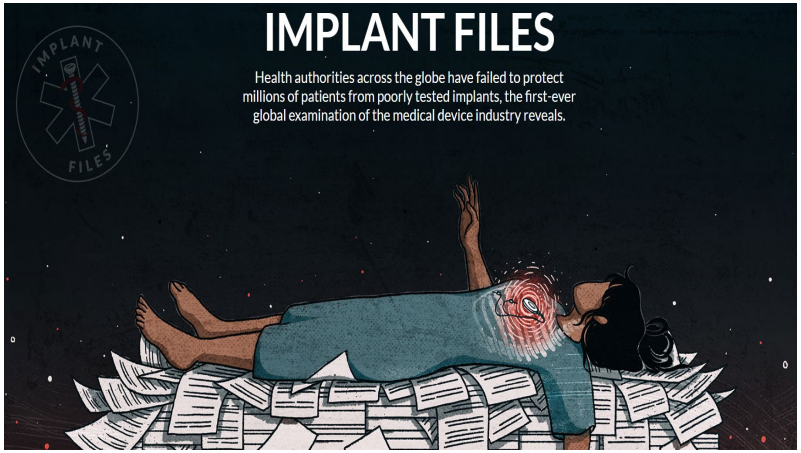
CPRD NIBSC MHRA

Key topics

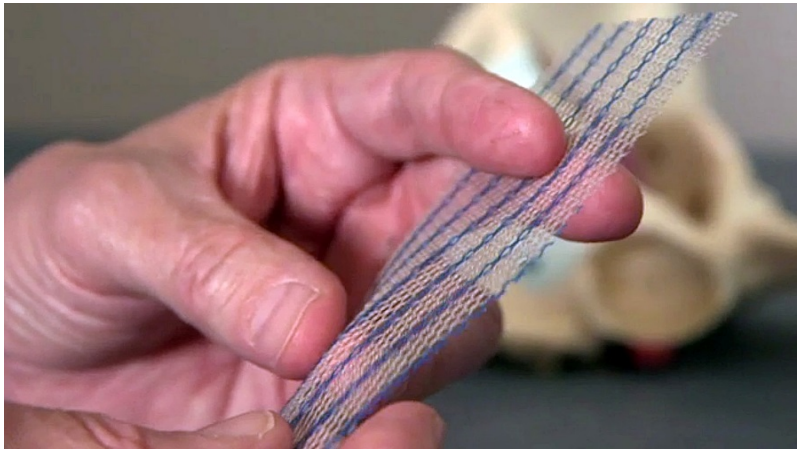
Why are implant registries important?

What is needed to set up registries that are accessible and allow full traceability?

How does GS1 fit / what can be the added value of GS1?


IMPLANT FILES
Health authorities across the globe have failed to protect millions of patients from poorly tested implants, the first-ever global examination of the medical device industry reveals.
IMPLANT FILES


The Guardian



thebmj

BMJ 2018;363:k5010 doi: 10.1136/bmj.k5010 (Published 26 November 2018)

NEWS

Check for updates

Surgeons call for compulsory registers of all new medical devices

Rebecca Coombes *head of news and views*

The BMJ

The government must act urgently to reform the lax regulation system governing medical devices, including a compulsory registry of all new implants, says the Royal College of Surgeons.

The call comes after a global investigation by journalists from 36 countries, including *The BMJ*, BBC *Panorama*, and the *Guardian*, into the medical device industry, which unearthed thousands of documents to reveal rising numbers of malfunctions and injuries.

The government said that it would work with the UK regulator to see what changes were required.

The investigation also provides new evidence of devices being implanted in humans after tests only in pigs or after small scale studies of just tens of patients. The lack of transparency and available data means that the scale of problems remains hidden from doctors and patients. Unlike with drugs, many devices are introduced rapidly onto the market without clinical trial data or centrally held evidence.

The president of the Royal College of Surgeons, Derek Alderson, said, "Government needs to address this urgently. There needs to be compulsory registration of every new device and implant that goes into a patient in the UK.

She called on the government to create a "Nordic style" no fault based compensation scheme, funded by manufacturers, for people injured by defective medical devices.

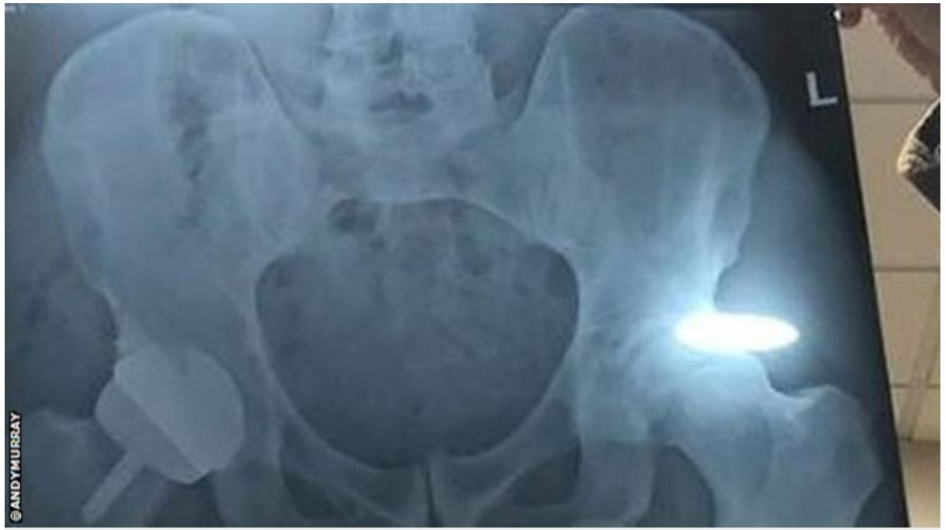
"The medical device industry revenue is in the billions, yet it is the patients who bear the burden of the risk when, in the rush to get a product to market, a device is not fully and properly tested," she said. "It should not be necessary for campaigning patients and lawyers to have to drag deep pocketed multinational device and pharma manufacturers through the courts to get any form of redress."

The Department of Health and Social Care for England said that the safety of patients was "our highest priority."

A spokesperson said, "The MHRA [Medicines and Healthcare Products Regulatory Agency] has a robust process in place to support the regulation of new medical devices, and we expect them to follow up any safety concerns swiftly and with patient care in mind. We will work with the regulator to see what future changes may be required."

The MHRA said that patient safety was "at the core what we do." Graeme Tunbridge, its group manager for devices regulatory affairs, told *The BMJ* and BBC *Panorama* in an

Derek Alderson – RCS President – *"there needs to be compulsory registration of every new device and implant that goes into a patient in the UK".*



Murray posted this picture on Instagram of his hip following surgery

How long will Andy Murray's hip replacement last?

Complex question.

Dependent upon a number of independent factors

- Design and durability of the implant
- Surgical technique – skill of the surgeon / instructions for use
- Activity after the procedure

How long does a hip replacement last? A systematic review and meta-analysis of case series and national registry reports with more than 15 years of follow-up

Jonathan T Evans, Jonathan P Evans, Robert W Walker, Ashley W Blom, Michael R Whitehouse, Adrian Sayers**

Summary

Background Total hip replacement is a common and highly effective operation. All hip replacements would eventually fail if in situ long enough and it is important that patients understand when this might happen. We aimed to answer the question: how long does a hip replacement last?

Methods We did a systematic review and meta-analysis with a search of MEDLINE and Embase from the start of records to Sept 12, 2017. We included articles reporting 15-year survival of primary, conventional total hip replacement constructs in patients with osteoarthritis. We extracted survival and implant data and used all-cause construct survival as the primary outcome. We also reviewed reports of national joint replacement registries, and extracted data for a separate analysis. In the meta-analyses, we weighted each series and calculated a pooled survival estimate for each source of data. This study was registered with PROSPERO (CRD42018085642).

Findings We identified 140 eligible articles reporting 150 series, and included 44 of these series (13 212 total hip placements). National joint replacement registries from Australia and Finland provided data for 92 series (215 676 total hip replacements). The 25-year pooled survival of hip replacements from case series was 77·6% (95% CI 76·0–79·2) and from joint replacement registries was 57·9% (95% CI 57·1–58·7).

Interpretation Assuming that estimates from national registries are less likely to be biased, patients and surgeons can expect a hip replacement to last 25 years in around 58% of patients.

Lancet 2019; 393: 647–54

See Comment page 613

*Joint senior authors

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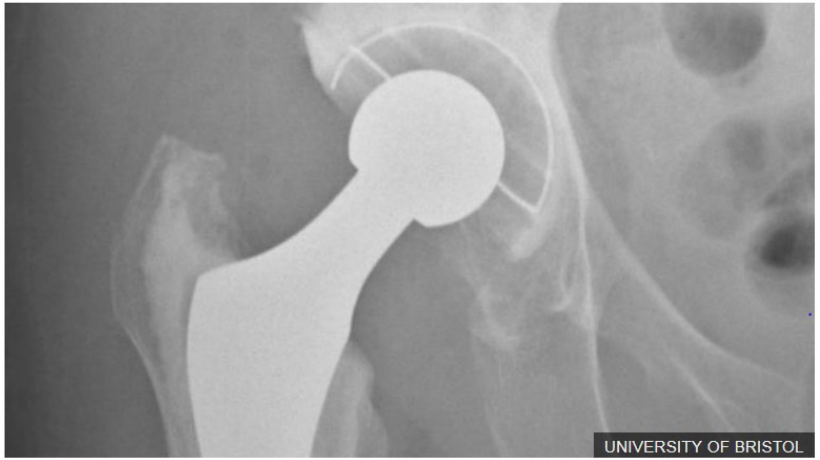
Health

Most hip and knee replacements 'last longer than thought'

By Philippa Roxby
Health reporter, BBC News

15 February 2019 Share



How long do they last?

Hip replacements: 89% lasted 15 years, 70% lasted 20 years, 58% lasted 25 years

Total knee replacements: 93% lasted 15 years, 90% lasted 20 years, 82% lasted 25 years

Partial knee replacements: 77% lasted 15 years, 72% lasted 20 years, 70% lasted 25 years

MHRA’s use of registry data

Information from the National Joint Registry (NJR) is frequently used by the MHRA as a post market surveillance tool to detect poorly performing orthopaedic devices.

Analysis of data from the NJR was pivotal to MHRA being the first regulator worldwide to publish safety information for clinicians about the risk of soft tissue reactions to metal wear debris in patients implanted with metal-on-metal (MoM) hip replacements (Medical Device Alert MDA/2010/033).

USA TODAY

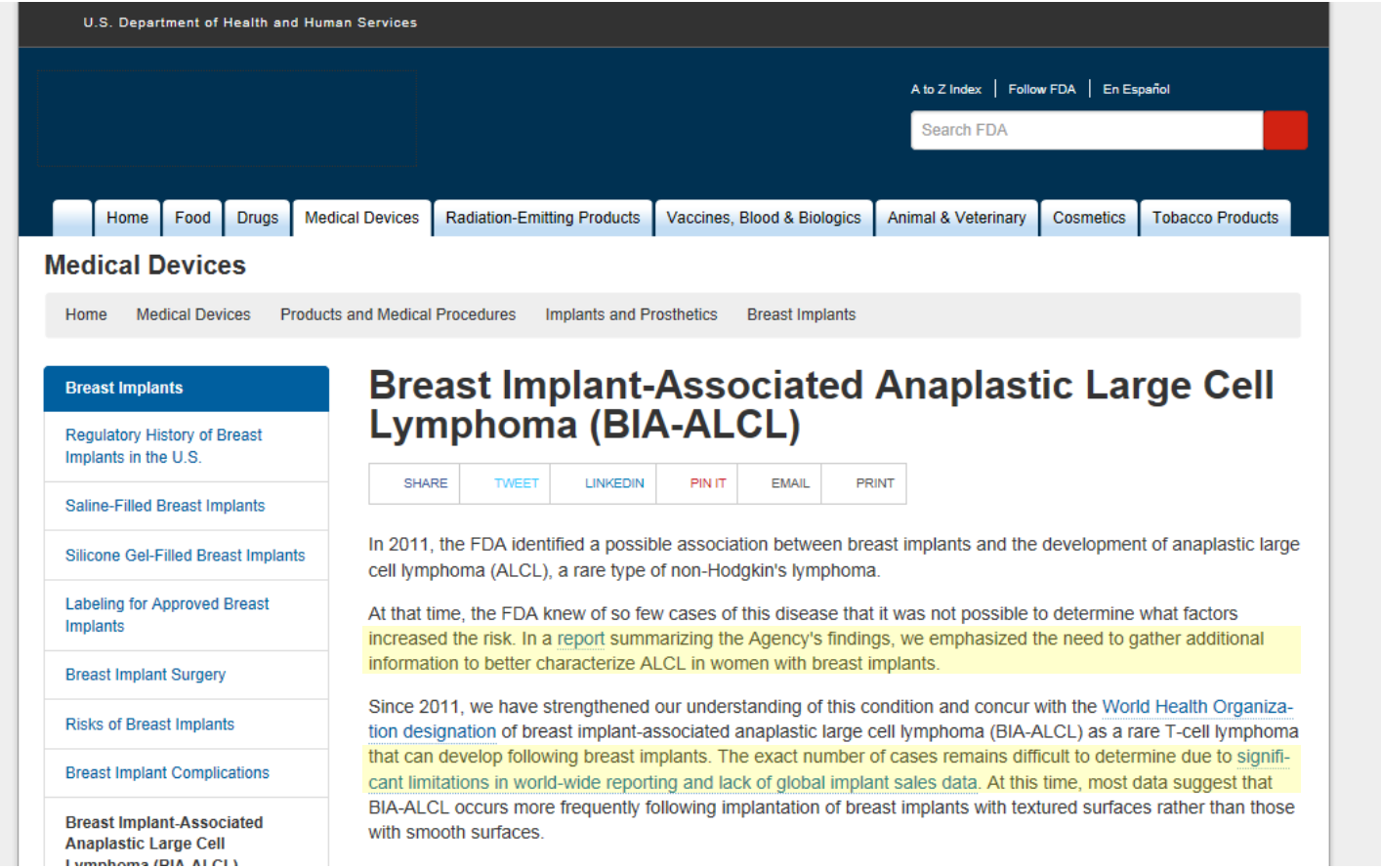
A rare cancer is linked to breast implants and it has killed at least 9 people, FDA warns

Ryan W. Miller | USA TODAY
Published 7:08 AM EST Feb 8, 2019

Breast implant-associated anaplastic large cell lymphoma.
BranislavP, Getty Images/iStockphoto

A rare cancer linked to breast implants has killed at least nine patients since 2010, federal health officials warned this week .

Of the 660 reports of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) received in the past decade, 457 unique cases of have now been confirmed, the U.S.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Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)
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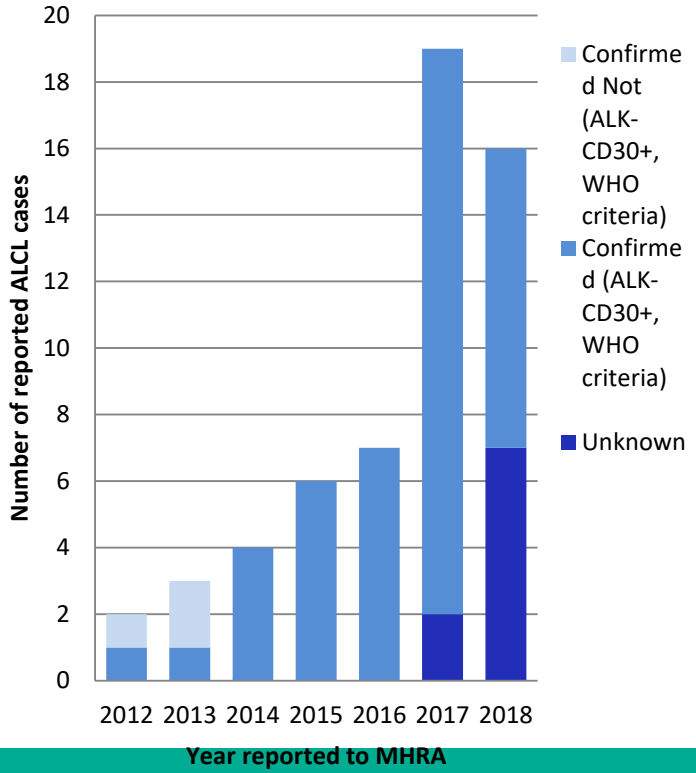
In 2011, the FDA identified a possible association between breast implants and the development of anaplastic large cell lymphoma (ALCL), a rare type of non-Hodgkin's lymphoma.
At that time, the FDA knew of so few cases of this disease that it was not possible to determine what factors increased the risk. In a report summarizing the Agency's findings, we emphasized the need to gather additional information to better characterize ALCL in women with breast implants.
Since 2011, we have strengthened our understanding of this condition and concur with the World Health Organization designation of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) as a rare T-cell lymphoma that can develop following breast implants. The exact number of cases remains difficult to determine due to significant limitations in world-wide reporting and lack of global implant sales data. At this time, most data suggest that BIA-ALCL occurs more frequently following implantation of breast implants with textured surfaces rather than those with smooth surfaces.

BIA-ALCL cases reported to MHRA (UK)



Cumulative total @ September 2018 = 57 cases including 3 deaths

- 45 Confirmed BIA-ALCL
- 4 Confirmed not BIA-ALCL
- 8 Unknown

Updated Sep 2018

Examples of questions relating to BIA-ALCL that implant registries can help to answer

What is the incidence of BIA-ALCL?

How long after device implantation does BIA-ALCL occur?

Are textured implants more likely to be associated with BIA-ALCL than smooth implants?

Are devices made by one particular manufacturer more likely to be associated with ALCL cases?

BAPRAS
British Association of Plastic Reconstructive and Aesthetic Surgeons

icobra™

International Collaboration of Breast Device Registry Activities

26 November 2018

A statement on breast implant safety

Breast implants are amongst the most used and most highly studied implantable medical devices in the world. Important lessons were learned from historical incidents which have resulted in improvements in the international regulatory system and the widespread introduction of national breast implant registries.

The establishment of effective national breast device registries combined with international collaboration has the ability to significantly improve health outcomes for patients with implantable breast devices globally.

Value of registries

Registries have the demonstrated ability to be a key part of healthcare quality assurance systems by providing information about both device safety/performance and variability of clinical practice that is:

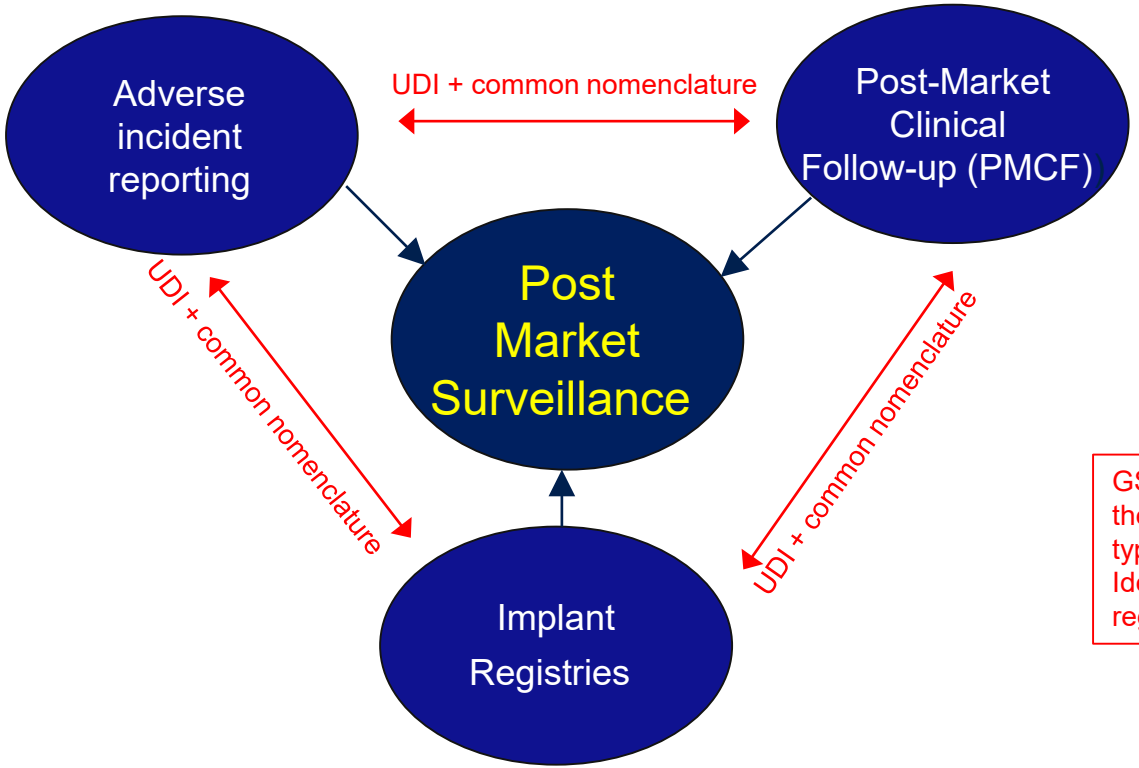
- comparative
- transparent; and
- tailored

to the needs of patients, medical device regulators, other healthcare regulators and healthcare professionals/institutions.

Registry information can be of significant value to:

- **patients** - safety of the devices / clinical practice of the healthcare professionals and institutions
- **healthcare regulators(such as MHRA)** - to inform regulatory decision-making - device safety and performance
- **manufacturers** - monitoring of the safety and performance of their devices throughout their lifecycle
- **healthcare professionals and professional institutions**
  - clinicians about their clinical performance in comparison with their peers
  - professional bodies - in support of clinical audit
  - decision making about choice of devices

Integration of key elements of post-market surveillance



GS1 GTINs are one of the most widely used types of Unique Device Identifiers (UDI) for regulatory applications

Key requirements for effective registries – MHRA's perspective

In order to be effective, it is vital that registries, should have:

- clearly defined aims and objectives which are accepted by key stakeholders
- sustainable long-term funding
- governance structures which ensure data confidentiality, transparency and appropriate reporting / feedback to key stakeholders

Eight qualifiers that define the impact, value and sustainability of a registry – regulatory perspective

- Includes sufficient device information (unique device identification)
- Is part of a health care delivery quality improvement system or is evolving into one
- Has established mechanisms to bring about beneficial change in health care delivery
- Is embedded in the healthcare delivery system. Data collected as part of care delivery - collection integrated with work flow of clinical teams
- Provides actionable information to decision makers in a relevant and timely manner
- Should be transparent (governance structure, data access and analytic processes)
- Information can be linked with other data sources
- Can serve as infrastructure for seamless integration of evidence throughout the device life cycle

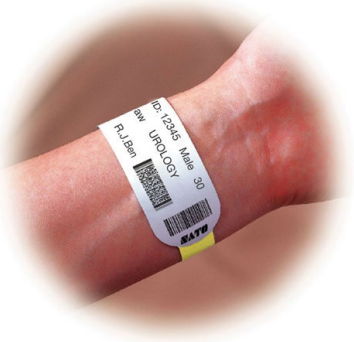
IMDRF International Medical Device Regulators Forum

Integration of data collection

Registries should be embedded in the health care delivery system with data collection being integrated with work flow of clinical teams using (for example) scanning technologies. The feasibility of this approach has been successfully demonstrated in England by the ***Scan4Safety*** initiative.

Using scanning approach will help to improve patient safety – implant tracking and surveillance

+ convergence with registries / real world data collection



- Implant / patient track-&-trace
- Post-market safety monitoring

More accurate and convenient registry and real world data collection


who
what
where
how
when
why

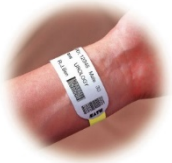
GS1 *core enablers* can support registry data collection

Deliverables– Initial Core Enablers

Location Identification

- Implementing **GLNs**, a global standard for location identification

Unique Location Identification



Patient Identification

- Wristbands **GSRN** compliant can be scanned by patient systems

Unique Patient Identification

Catalogue Management

- All relevant processes use the **GTIN** as the primary product identifier

Unique Device Identification

SCAN4SAFETY

MHRA supports the development of registries

MHRA supports the development of a comprehensive system of medical device registries (with particular focus on implantable devices) in support of patient safety.

This would be in line with new European regulations for medical devices* (coming into effect in May 2020) which:

- encourage the establishment of registries (Article 108); and
- introduce the use of Unique Device Identifiers and their capture within healthcare records (Article 27).

**European Medical Device Regulation (EU) 2017/745*

Thank you.

andy.crosbie@mhra.gov.uk

The Global Language of Business

35th Global GS1 Healthcare Conference, Noordwijk, the Netherlands

Dr. Hinne A. Rakhorst, Medisch Spectrum Twente Enschede,
Chair Dutch Association of Plastic Surgeons, The Netherlands

March 27, 2019

DBIR
DUTCH BREAST IMPLANT REGISTRY

icobra™

DICA
DUTCH INSTITUTE FOR CLINICAL AUDITING

Implant registries

A work floor perspective

Hinne Rakhorst
Babette Becherer, Marc Mureau, Juliette Hommes, Xavier Keuter, Annelotte van Bommel, Danny Young Afat, Marije Hoornweg
All plastic surgeons in the Netherlands

Disclosures

None other than voluntary professional board work

No connections to industry

Thank you

Who knows someone with breast implants?

Estimate
1:30 adult Dutch women

Approximately the same as hip athroplasties

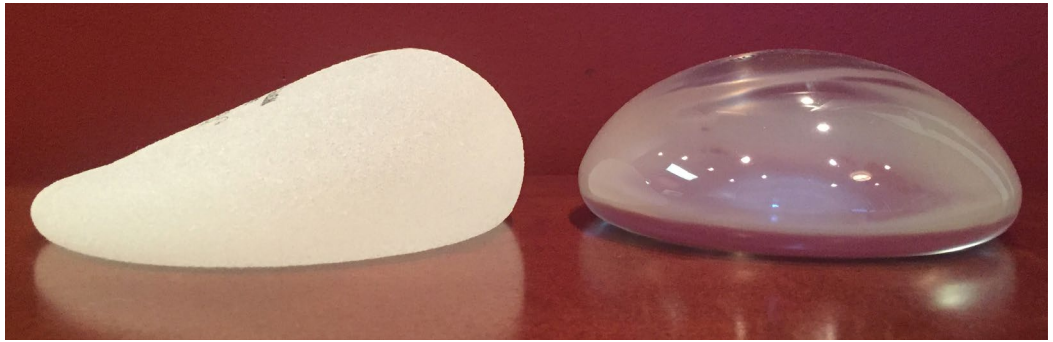
70% vs 30%

Esthetic vs Reconstructive

Many types, few variables

Texture;	Smooth vs macrotextured vs microtexture vs nanotexture
Shape;	Round vs Anatomical
Fill;	Saline fill vs silicone vs methylcelullose vs air
Coating;	Silicone vs polyurethane coating
Duration;	Temporary (tissue expander) vs Permanent

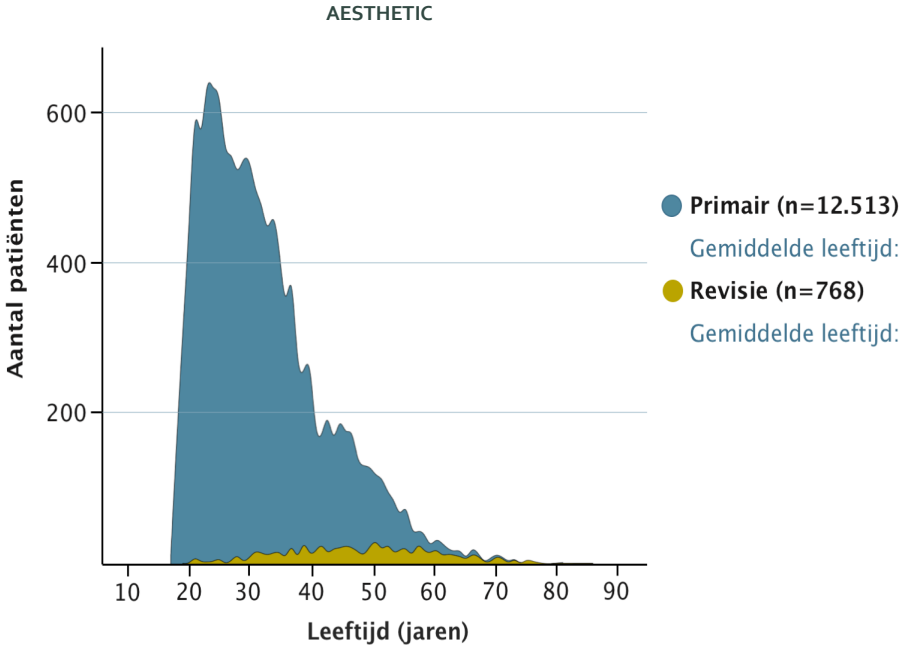
Large international variation in preference

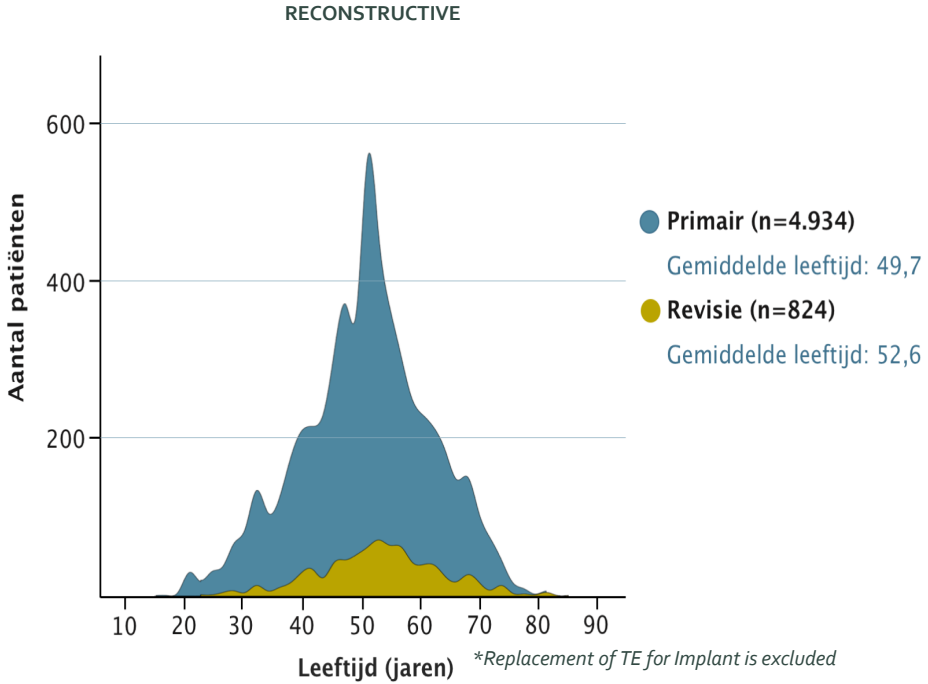


Breast implants are safe implants, class III

Breast implants have adverse events

Breast implants often need revision surgery





*Replacement of TE for Implant is excluded

what happens in (social) media

ICIJ | Implant Files ▾ Leak to us Support us Follow ICIJ

FDA Kept Hundreds of Thousands of Breast Implant Incidents Hidden From Public

The U.S. Food and Drug Administration held a public hearing into breast implant safety.

By SASHA CHAVKIN / March 25, 2019

Breast implants have serious adverse events uproar in society

so what to tell ;
The exception?
The rule?

2019

ANSM france,

FDA USA

Lets stick to the evidence
in respect to 3% of all women

What is the evidence?

What is the risk?

Risk;

$$\frac{\text{Numerator}}{\text{Denominator}}$$

$$\frac{\text{Number of cases}}{\text{Total number of women that have implants}}$$

Challenge

$$\frac{\approx \text{Rough estimate number of cases}}{\approx \text{Rough estimate number of women that have implants}}$$

Challenge

$$\frac{\approx \text{Rough estimate number of cases}}{\approx \text{Rough estimate number of women with } \mathbf{types\ of} \text{ implants}}$$

Solution come when we know about;
Numbers
Types

So register these data

Conclusion of all scientists and governments

- Need more data
- More transparency
- Need registries

Basic implant registry;

L.I.R. (NL)

EUDAMED
EUROPEAN DATABANK ON MEDICAL DEVICES

=

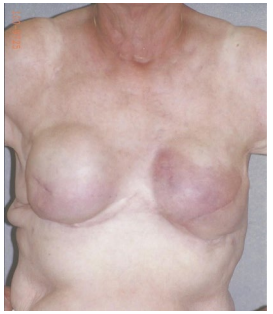
+

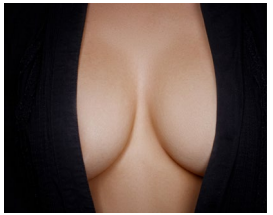
Clinical registries;

=

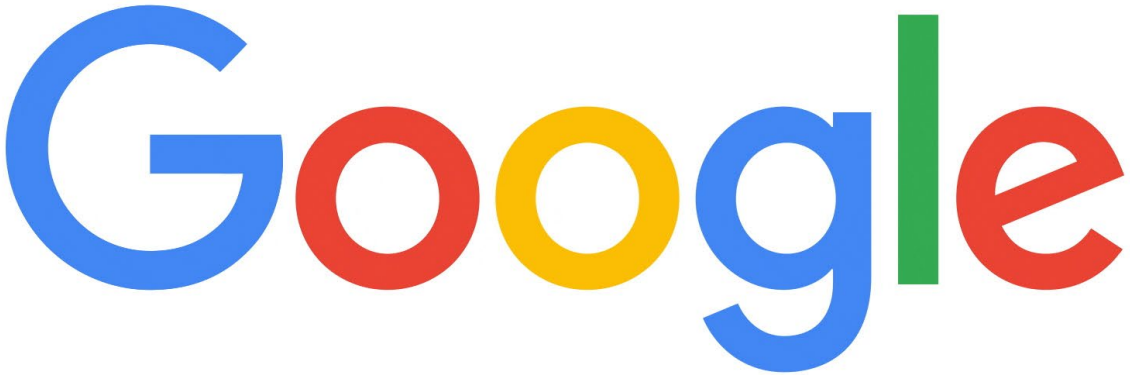
+

+





What do you think I do all day?



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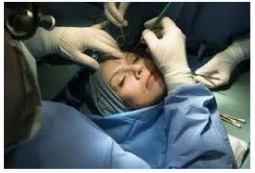
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Plastic surgeons offering revolutionary ...
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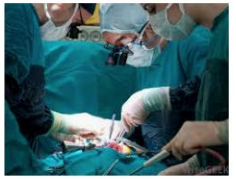
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Cosmetic surgery can be an 'aggression ...
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Choosing The Right Plastic Surgeon ...
divalikes.com


Surgery - Wikipedia
en.wikipedia.org


Careers in Plastic Surgeons' Offices ...
work.chron.com


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The 20 Richest Plastic Surgeons in the ...
moneyinc.com


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What does a Plastic Surgery Nurse do ...
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Plastic Surgery
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How To Find Cheap Plastic Surgery and ...
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news.com.au


Dr Stafford Broumand's Medical Missio...
plasticsurgeonsnyc.com


Kylie Jenner's Plastic Surgery — Spent ...
medium.com

My surgical working day

Registration time

Surgery

- 1-8 patients
- Surgery is great
- ‘turn over time’ is 5 minutes
  - Write surgical report
  - Write discharge letter
  - Pills
  - Call family
  - focus on next case, read notes
  - Say hi to next patient
  - Mark up next patient

  - ~~Have coffee~~
  - ~~EXTRA TIME~~

Need to register data

Need to register data
Big data

Need to register data
Big data
NO TIME!

Dutch Breast Implant Registry DBIR

Clinical registry

Start 2015

National

All patients

All procedures

Data

Patient;

name

Age

History?

other diseases

Surgery

L / R / L + R

Cosmetic/reconstructive

New or exchange

Implant

Shape

Texture

Fill

Patient characteristics

Unique patientnumber, clinic*

What is the ASA classification before operation*

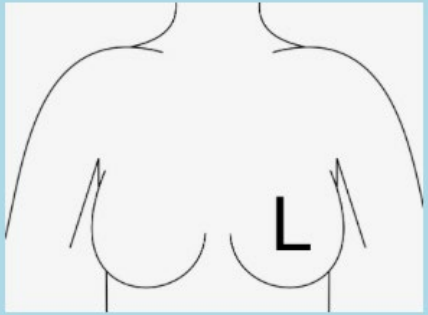
- A normal healthy patient.
- A patient with a mild systemic disease.
- A patient with a severe systemic disease that limits activity but is not incapacitating.
- A patient with an incapacitating systemic disease that is a constant threat to life.
- A moribund patient not expected to survive 24 hours with or without operation.
- ASA unknown

Nicotine abuse*

- Yes
- No
- Not known

Height in centimeters*

Weight in kilograms*



Side of operation*

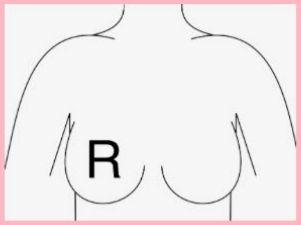
- Right
- Left

Indication of surgery*

- Cosmetic augmentation
- **Reconstruction post cancer**
- Reconstruction benign
- Congenital deformity
- Reconstruction post profylactic mastectomy

In case of revision, register indication and timing (if applicable) of primary surgery.

Timing initial reconstruction*



Texture*

- Textured
- Smooth

Coating*

- Silicone
- Polyurethane
- Other

Fill*

- Silicone
- Saline
- Hydrogel
- Other

Shape*

- Round
- Shaped / Anatomical

Weight/Volume of implant (cc or gr)*

Volgende sectie

Toevoegen device

Het maximum aantal records is al bereikt (1)

Results

DUTCH BREAST IMPLANT REGISTRY (DBIR) ANNUAL REPORT 2015 – 2017

DBIR

DUTCH BREAST IMPLANT REGISTRY

DICA

DUTCH INSTITUTE FOR CLINICAL AUDITING

NVPC

Nederlandse Vereniging voor Plastische Chirurgie handchirurgie, reconstructieve en esthetische chirurgie

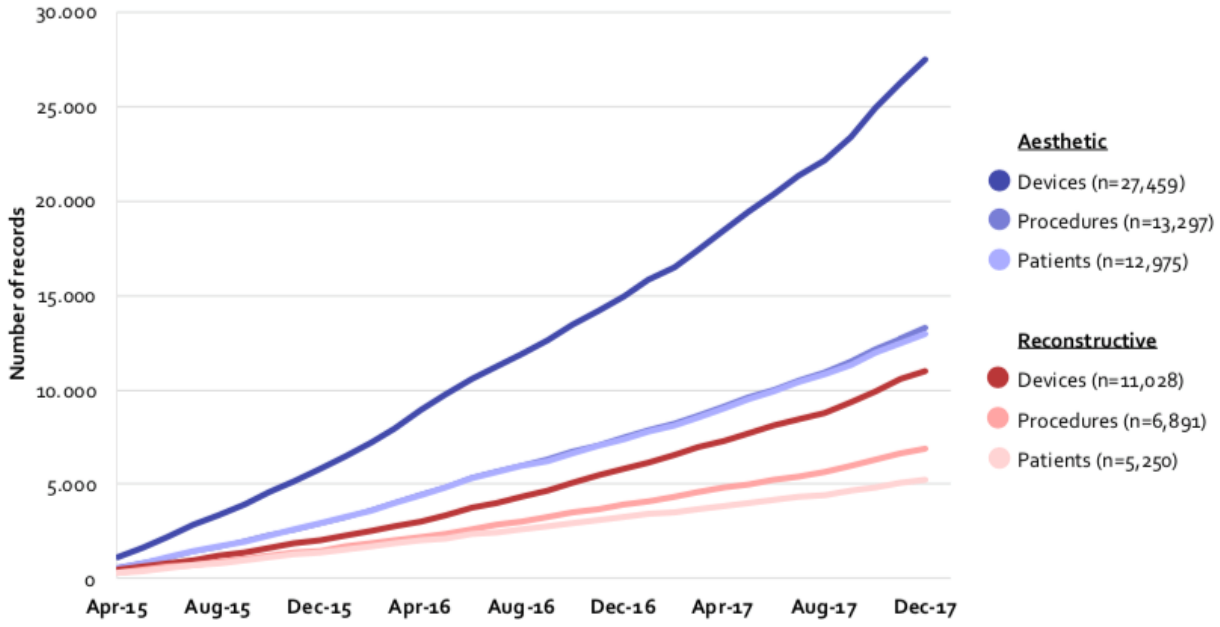
40.000 implants

(2015 – 2017)

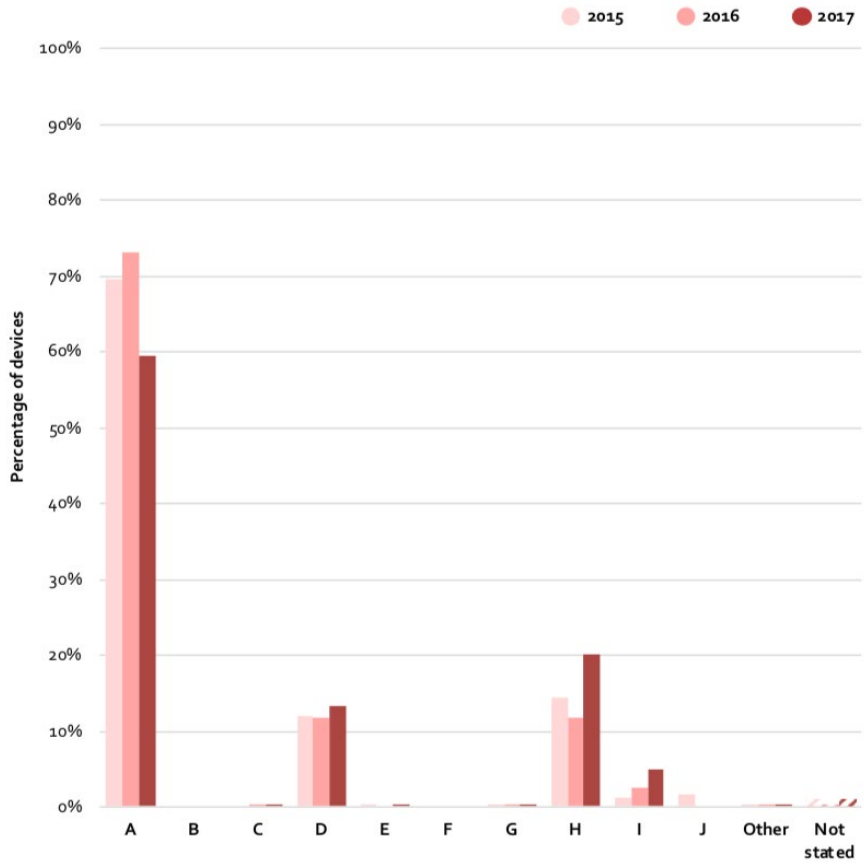
Total number of

- Patients ± 18.000
- Operations ± 20.000
- Implants ± 38.000

Figure 3. *Cumulative number of registered patients, procedures and devices (2015 – 2017)*



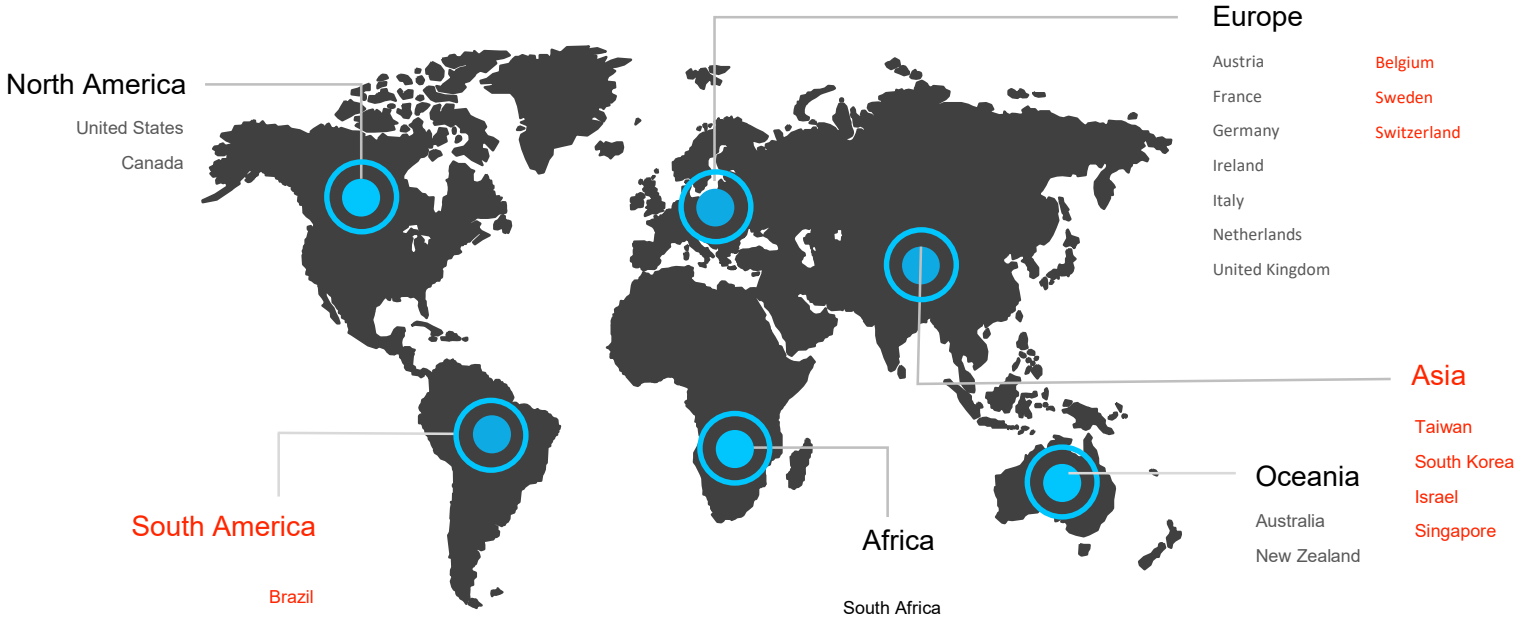
Vendor distribution




Arctic Ocean
Netherlands
Atlantic Ocean
Pacific Ocean
Pacific Ocean
Atlantic Ocean
Indian Ocean
Southern Ocean

International Collaboration of Breast Registry Activities

ICOBRA + partners/invitees



Inspectie Gezondheidszorg en Jeugd
Ministerie van Volksgezondheid, Welzijn en Sport

MHRA
Regulating Medicines and Medical Devices

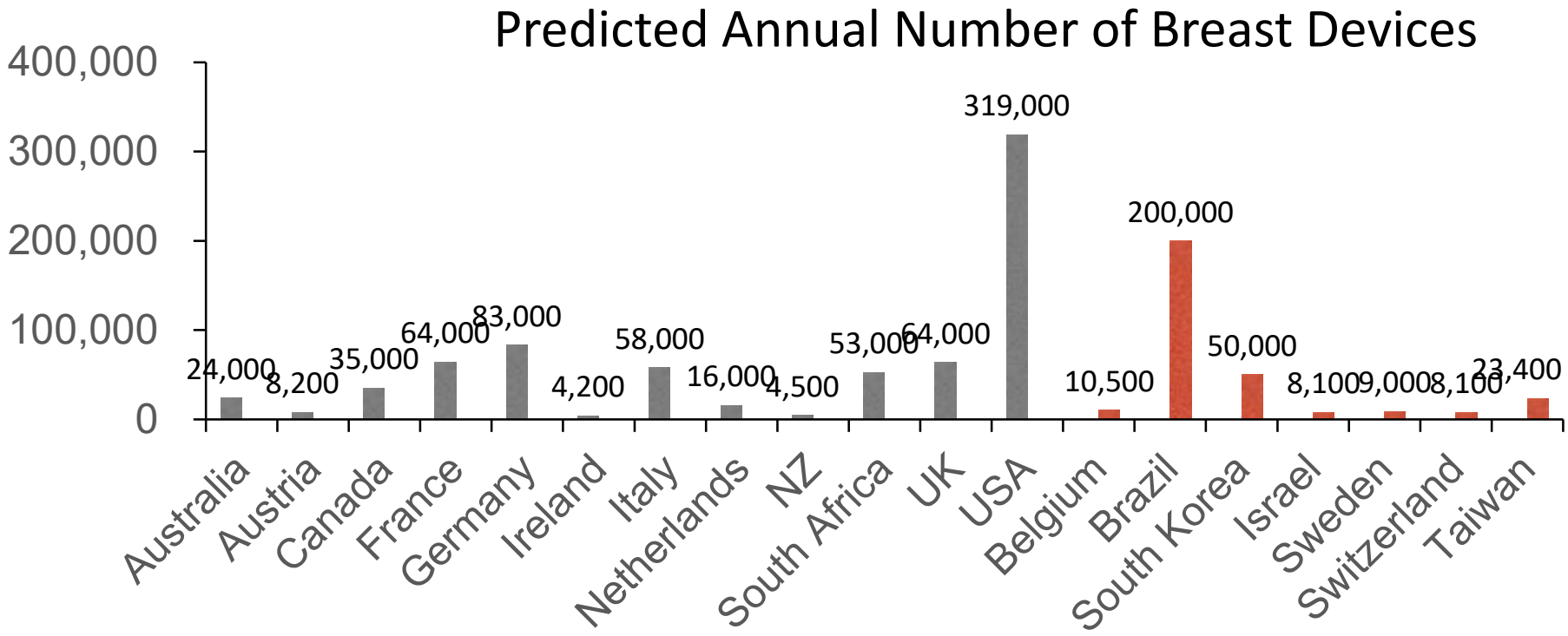
European Commission

Australian Government
Department of Health
Therapeutic Goods Administration

GS1

FDA

Total: 1,032,900



ICOBRA MINIMUM DATA SET; implant

- UDI; serial number/Lot
- Producer
- Texture
- Fill
- Shape
- Volume of implant

International professionals all want the same data
ICOBRA set of minimum datapoints

We have an international professional standard

DUTCH BREAST IMPLANT REGISTRY (DBIR)
ANNUAL REPORT 2015 – 2017

DBIR

DUTCH BREAST
IMPLANT REGISTRY

DICA
DUTCH INSTITUTE FOR CLINICAL AUDITING

NVPC
Nederlandse Vereniging voor Plastische Chirurgie
handchirurgie, reconstructieve en esthetische chirurgie

NHS Digital

Breast and Cosmetic Implant Registry

October 2016 to June 2018 Data Summary
(England, management information)

Published 15 November 2018

BRIMP-
BREAST IMPLANT REGISTER
ANNUAL REPORT 2017

140.000 implants up to 2017

Lessons learned;

- Reduce typo’s
- Reduce interpretation errors
- Reduce administative time
- Enhance re-use of already registered data
- Use IT
- Enhance reliability in tracing and output

What would help?

- A single indentifyer for an implant

What helps?

- UDI Unique device Identifyer

What did we do to make use of UDI?

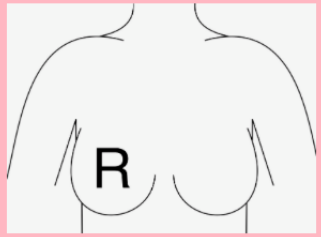
From the start;

- Ask industry for support
- Ask government for guidance

- Made it functional

Uw wijzigingen zijn opgeslagen

- Patiënt
- Registered surgeries
- -
  - Side of operation
  - Hospital/patient characteristics
  - **Right-Cosmetic augmentation**
    - Intervention
    - Operation techniques
    - Antiseptic precautions/drains
    - Devices
    - **Inserted-Permanent implant**
      - Device type
      - Device specific information
      - Device Manufacturer and barcode
      - Device indentification information
    - Status



Manufacturer*

Eurosilicone

Using GS1 barcode scanner?*

- No, enter details manually
- Yes

GS1 barcode. Code starts with (01)*

Volgende sectie

Toevoegen device

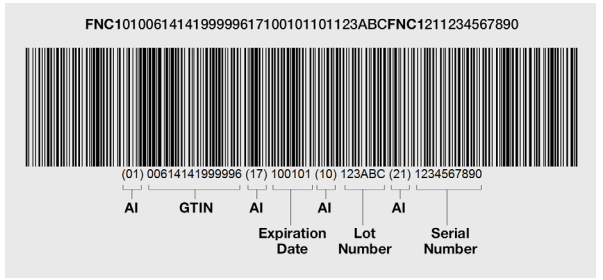
Het maximum aantal records is al bereikt (1)

DBIR

DUTCH BREAST
IMPLANT REGISTRY

General information:

- Registration of a patient is finished when all errors (!) have disappeared.
- Please visit the DICA website for instruction videos (section DBIR - Documenten).



Barcode functionality;

- Less typos
- Quicker entry
- More reliable output;
  - Manufacturer
  - Surgeons
  - Patients
  - society

Future

More automation


Unique Device Identifier

Key to

Fixed number of globally agreed device datapoints


GS1 GDSN

stakeholders

- Surgeons
- Patients
- Hospitals
- Industry
- governments

DBIR
DUTCH BREAST IMPLANT REGISTRY

icobra™

DICA
DUTCH INSTITUTE FOR CLINICAL AUDITING

Workfloor wants registries

Workfloor wants efficient data entry

Hinne Rakhorst
Babette Becherer, Marc Mureau, Juliette Hommes, Xavier Keuter, Annelotte van Bommel, Danny Young Afat, Marije Hoornweg
All plastic surgeons in the Netherlands

The Global Language of Business

Implant Registries

Impact and solutions for hospitals

Henrik Stilling, IT-Architect, Aarhus University Hospital, Central Denmark Region

GS1 Healthcare Conference, Netherlands, March 2019

Disclaimer

Any barcodes or pictures of devices that might relate to real-world products in this presentation is unintentional.

Any critique or problems discussed in this presentation caused by devices or in the process of identifying devices is in no way intended to be relatable to named manufacturers.

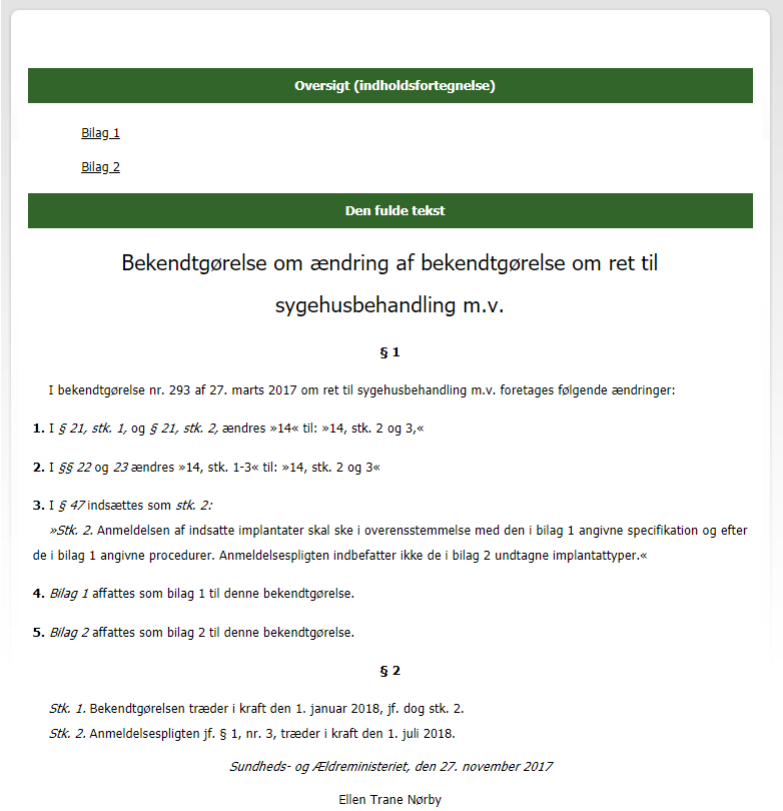
All illustrations are intended as unidentifiable examples. Pictures of personnel and operating rooms are staged for educational purposes and are the copyright of Central Denmark Region and may be distributed by GS1 and affiliates as a part of this presentation.

Henrik Stilling

Who am I?

- Central Denmark Region
- Lead architect for item identification and tracking
- Engineer by trade
  - Process management
  - Technology adaption
- Worked within health care industry since 2008
- Part of Danish national initiative on identification and traceability in healthcare

National Danish Implant Registry



Oversigt (indholdsfortegnelse)

Bilag 1

Bilag 2

Den fulde tekst

Bekendtgørelse om ændring af bekendtgørelse om ret til sygehusbehandling m.v.

§ 1

I bekendtgørelse nr. 293 af 27. marts 2017 om ret til sygehusbehandling m.v. foretages følgende ændringer:

1. I *§ 21, stk. 1,* og *§ 21, stk. 2,* ændres »14« til: »14, stk. 2 og 3,«

2. I *§§ 22* og *23* ændres »14, stk. 1-3« til: »14, stk. 2 og 3«

3. I *§ 47* indsættes som *stk. 2:*

»*Stk. 2.* Anmeldelsen af indsatte implantater skal ske i overensstemmelse med den i bilag 1 angivne specifikation og efter de i bilag 1 angivne procedurer. Anmeldelsespligten indbefatter ikke de i bilag 2 undtagne implantattyper.«

4. *Bilag 1* affattes som bilag 1 til denne bekendtgørelse.

5. *Bilag 2* affattes som bilag 2 til denne bekendtgørelse.

§ 2

Stk. 1. Bekendtgørelsen træder i kraft den 1. januar 2018, jf. dog stk. 2.

Stk. 2. Anmeldelsespligten jf. § 1, nr. 3, træder i kraft den 1. juli 2018.

Sundheds- og Ældreministeriet, den 27. november 2017

Ellen Trane Nørby

Overview

- Mandatory for all use of surgical implants from 1st of July 2018 and onwards
- Register implantable devices to a given patient
  - CPR
  - GTIN
  - Device attributes
    - Batch/Lot/Serial
    - Manufacturing date/Expiry date
    - ...

Traceability, transparency and fulfilment

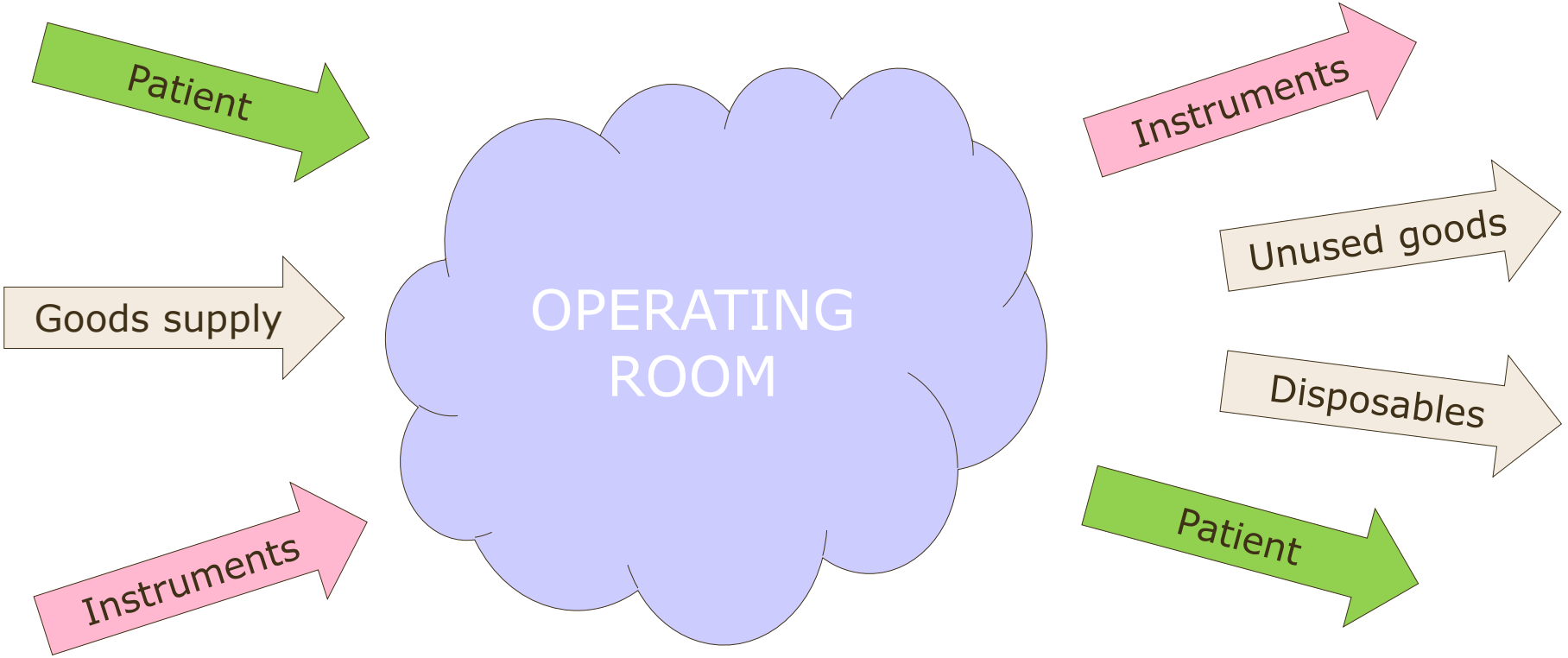
Clinical process

- Correct implant for the right patient
- Agility
- Flexibility
- Decision support
- Use before expiry date

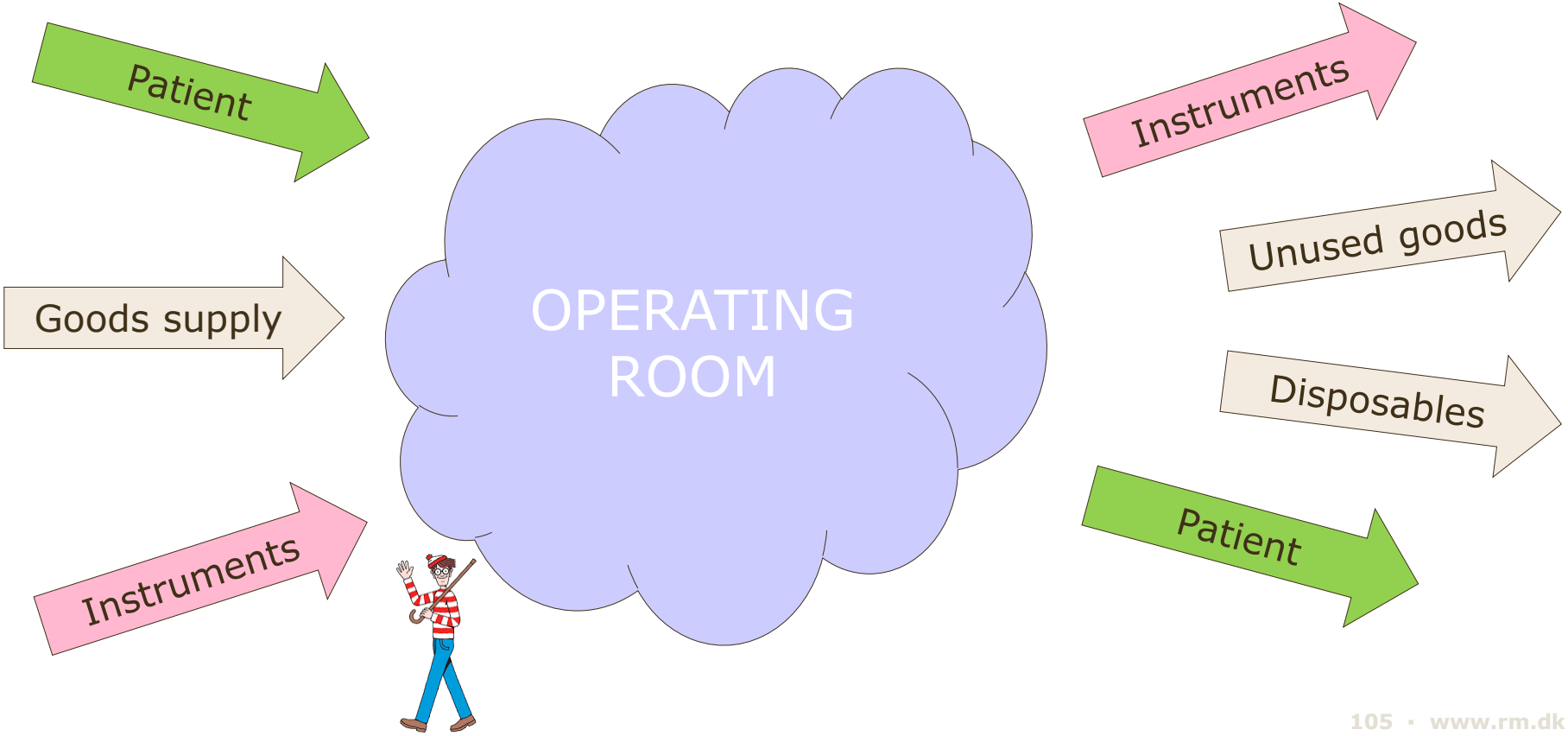
Supply chain

- Just in time
- Minimize storage
- Use before expiry date
- Optimal selection of implants

Setting the scene



Setting the scene



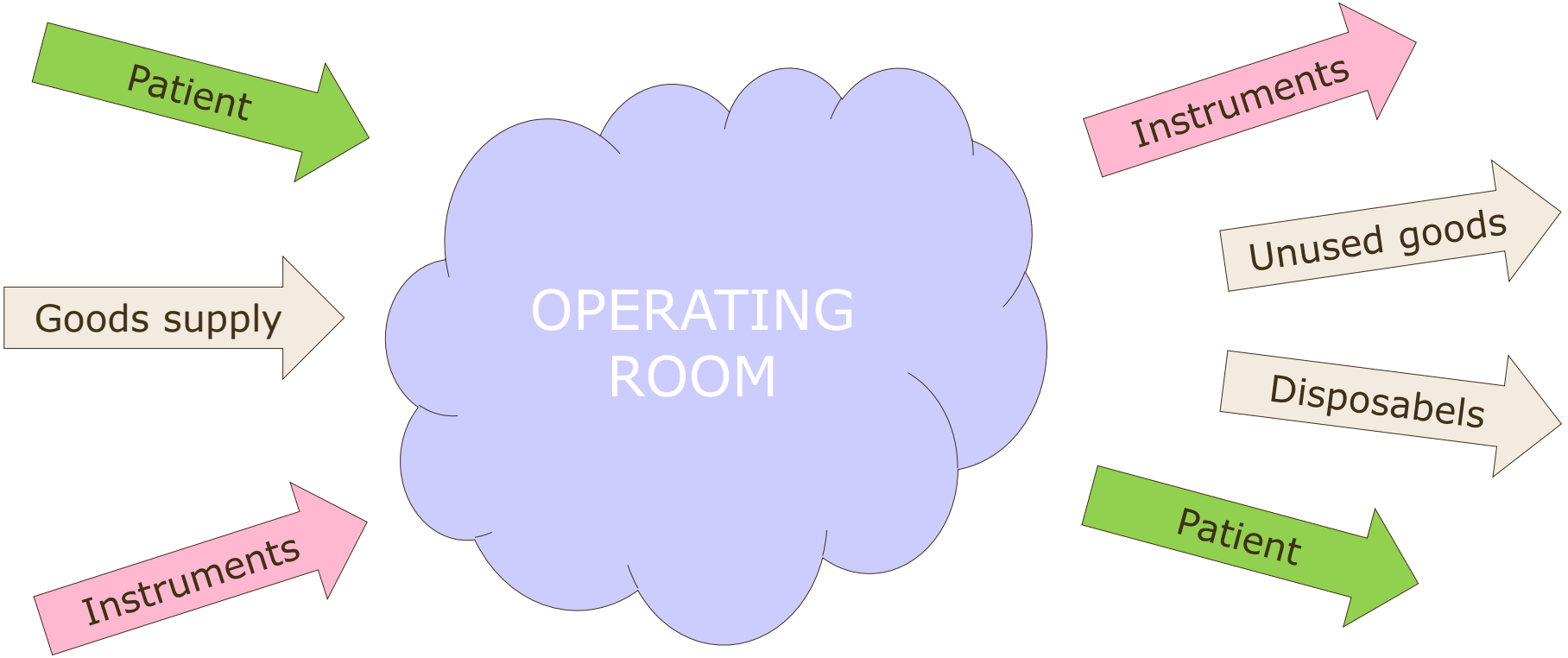
Realtime registration

Multi-platform hybrid registration

Multi-platform hybrid registration

...no two
surgical specialties
are the same!

Finding the information



Completeness, quality and optimization

Datasource

- GS1 Application Identifiers
- GTIN
- Expiry
- Batch
- Serial

Possibilities

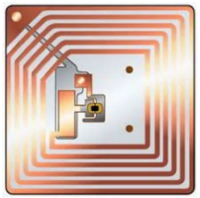
- Making the adequate choice
- Making the best choice
- Use before expiry date
- Use in order of expiry
- Know what drives your bottom line

Getting the data

Prefered

Usable

Exotic



Getting the data

Prefered

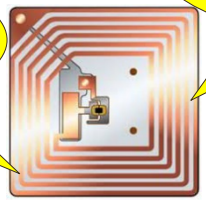
Single scan

Usable

Complex scan

Exotic

Low availability



Expensive scan

Registering correctly - requirements

- Define best practice
- “Closed loop scanning”
- Quality barcodes

Registering correctly - results

- 1 in 20 manual registrations contains errors
- Scanning is simple...
- Scanning the wrong data is even easier
- Real-time scanning is a driver and safety asset when used correctly
- Easy to implement but requires a high level of understanding to use

Next steps

- Further development
- Training
- Implant registries are not a goal in its own right
  - Clinical quality and safety
  - Overview and decision support
  - Have data available before use
  - Supply chain
- Why can’t we scan all available information?
- Now we’re registering – what about recalls?

The Global Language of Business

Using UDI to support Product Registry

35th Global GS1 Healthcare Conference, Noordwijk, the Netherlands

Blair Korman,
Senior Project Manager Supply Chain Visibility Johnson & Johnson Supply Chain

March 27th, 2019

Using UDI to support Product Registry

Blair Korman

GS1 Global Healthcare Conference
Noordwijk, Netherlands
27.March.2019

Johnson & Johnson

#Digital@JJSC

Presentation Overview

Introductions

UDI Landscape and Timelines

Aspects of UDI

Leveraging the UDI Data

Our Credo

Johnson & Johnson

We believe our first responsibility is to the patients, doctors and nurses, to mothers and fathers and all others who use our products and services. In meeting their needs, everything we do must be of high quality. We must constantly strive to provide value, reduce our costs and maintain reasonable prices. Customers' orders must be serviced promptly and accurately. Our business partners must have an opportunity to make a fair profit.

We are responsible to our employees who work with us throughout the world. We must provide an inclusive working environment where each person must be considered as an individual. We must respect their diversity and dignity, and recognise their merit. They must have a sense of security, fulfilment and purpose in their jobs. Compensation must be fair and adequate, and working conditions clean, orderly and safe. We must support the health and well-being of our employees, and help them fulfil both their family and other personal responsibilities. Employees must feel free to make suggestions and complaints. There must be equal opportunity for employment, development and advancement for those qualified. We must provide highly capable leaders, and their actions must be just and ethical.

We are responsible to the communities in which we live and work, and to the world community as well. We must help people to be healthier by supporting better access and care in more places around the world. We must be good citizens – by supporting good works and charities, improving health and education, and bearing our fair share of taxes. We must maintain in good order the property we are privileged to use, protecting the environment and natural resources.

Our final responsibility is to our stockholders. Business must make a sound profit. We must experiment with new ideas. Research must be carried on, innovative programmes developed, investments made for the future and mistakes paid for. New equipment must be purchased, new facilities provided and new products launched. Reserves must be created to provide for adverse times. When we operate according to these principles, the stockholders should realise a fair return.

Johnson & Johnson Portfolio

Consumer

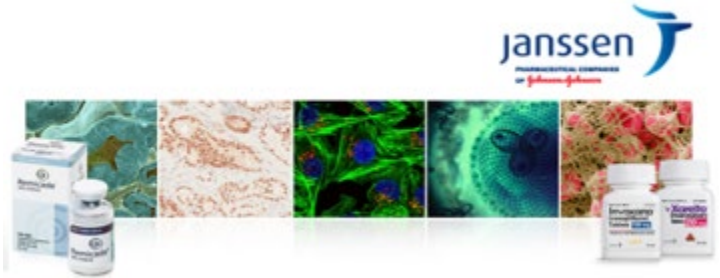
Baby Care • Body Care • Facial Skin Care • Sun Care • Feminine Personal Care • Allergy Care • Compromised Skin Care • Cough and Cold Care • Digestive Health • Oral Care • Pain Care

Medical Devices

Wound Closure & Surgical Devices • Minimally Invasive Surgery • Joint Replacement • Sterilization • Eye Health • Diabetes Care

Pharmaceuticals

Oncology • Infectious Diseases & Vaccines • Immunology • Cardiovascular & Metabolism • Neuroscience & Pain • Pulmonary Hypertension



UDI Global Data Access

US FDA	Access GUDID (https://accessgudid.nlm.nih.gov/) Data for all device classes available for J&J products
EU MDR	Public access database is planned via EUDAMED system Data submission to be uploaded by May 2020
UK NHS	Data access via GDSN must register with certified data pool Data for all device classes available for J&J products
Turkey	Data available in country via UTS product registry since July 2017 An aspect of UTS includes track & trace

UDI is expanding around the globe…….

Global UDI Activity

Regulations expected to impact 2019 activities

China

UDI Draft issued, likely includes data, labels, direct mark

Korea

UDI Draft issued, with limited details but includes UDI data, labels, direct mark, track & trace

Taiwan

No draft issued, but provided sample GUDID data

Brazil

UDI regulation published, impacts hip and knee implants (similar to Argentina)

Saudi Arabia

UDI Draft issued, based on IMDRF expected to include data (SAUDID), labels, and direct mark. Track & trace expected.

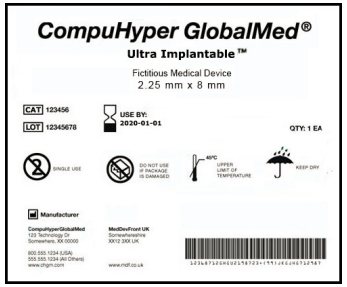
UDI Overview

Common components included in UDI regulations

EUDAMED
EUROPEAN DATABANK ON MEDICAL DEVICES

ACCESS GUDID
IDENTIFY YOUR MEDICAL DEVICE

Data Repositories



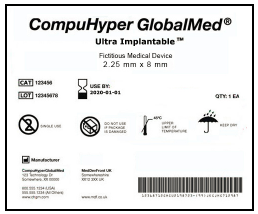
Label Requirements

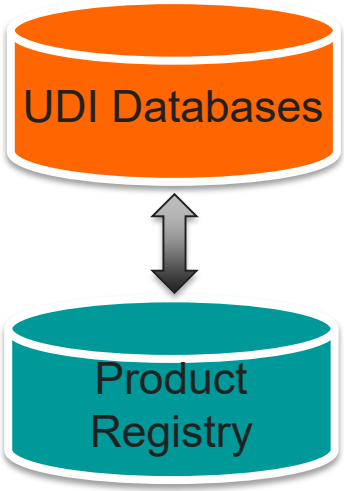
Direct Marking

What to Leverage in the UDI Data

- Unique Device Identifier → GTIN, HIBCC, other → The DI
- Other searchable criteria include catalog or reference number
- Monthly GUDID full downloads are available for all devices
- UDI Nomenclature provides searchability to like devices
- Source of truth for data and identifying new products

How to Leverage the UDI Data





Scan the UDI DI

Access UDI database and include in registry

Improve data methods

Thank you

#Digital@JJSC

Q & A : SLIDO

1. Go to slido.com
2. Enter #GS1HCNoordwijk
3. Select the panel **Implants registries**
4. Go to “Questions”
5. Make sure you enter your full name so that if the questions you’ve raised are not selected, the GS1 team can revert to you
6. Post your questions

The Global Language of Business

Implant Registries – impact for manufacturers, hospitals, governments and patients

Questions and wrap-up

35th Global GS1 Healthcare Conference, Noordwijk, the Netherlands

March 27th, 2019

The Global Language of Business

Thank you very much for your attention

March 27th, 2019