Panel – Patient safety beyond borders

Chairperson: Prof Dr. Terence Stephenson, Chair, General Medical Council, U.K.

Dr. Anne Snowdon, World Health Innovation Network, Scientific Director & CEO, SCAN Health, Canada

Mr. David Berridge, Deputy Medical Director, Leeds Teaching Hospitals NHS Trust, UK

Ms. Dr. Juliette Hommes, MD, University Medical Center of Maastricht (MUMC), The Netherlands

Passionate about patient safety

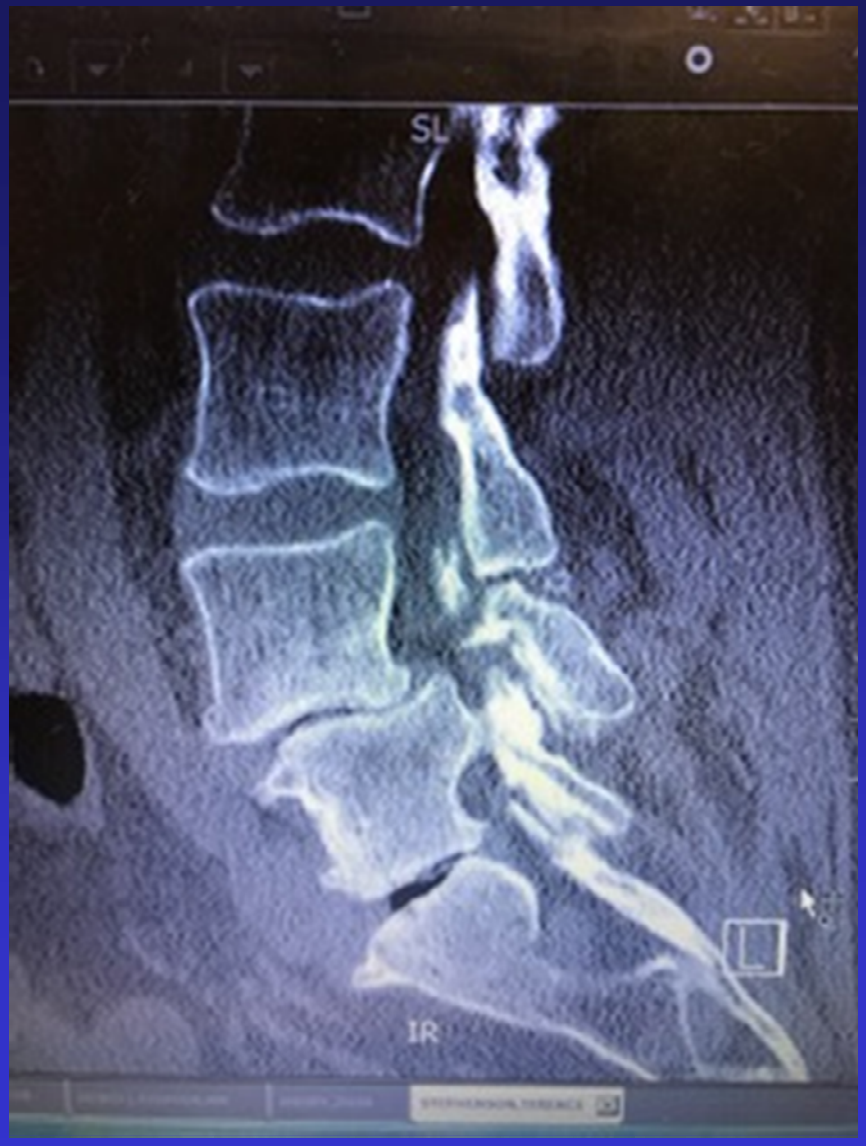
General Medical Council

Professor Terence Stephenson

DM, FRCPCH, FRCP, FRACP, FRCPI, FRCS, FHKAP, FRCGP, FRCA, FCAI, FRCSEd, FRCOG

Chair, General Medical Council

Working with doctors Working for patients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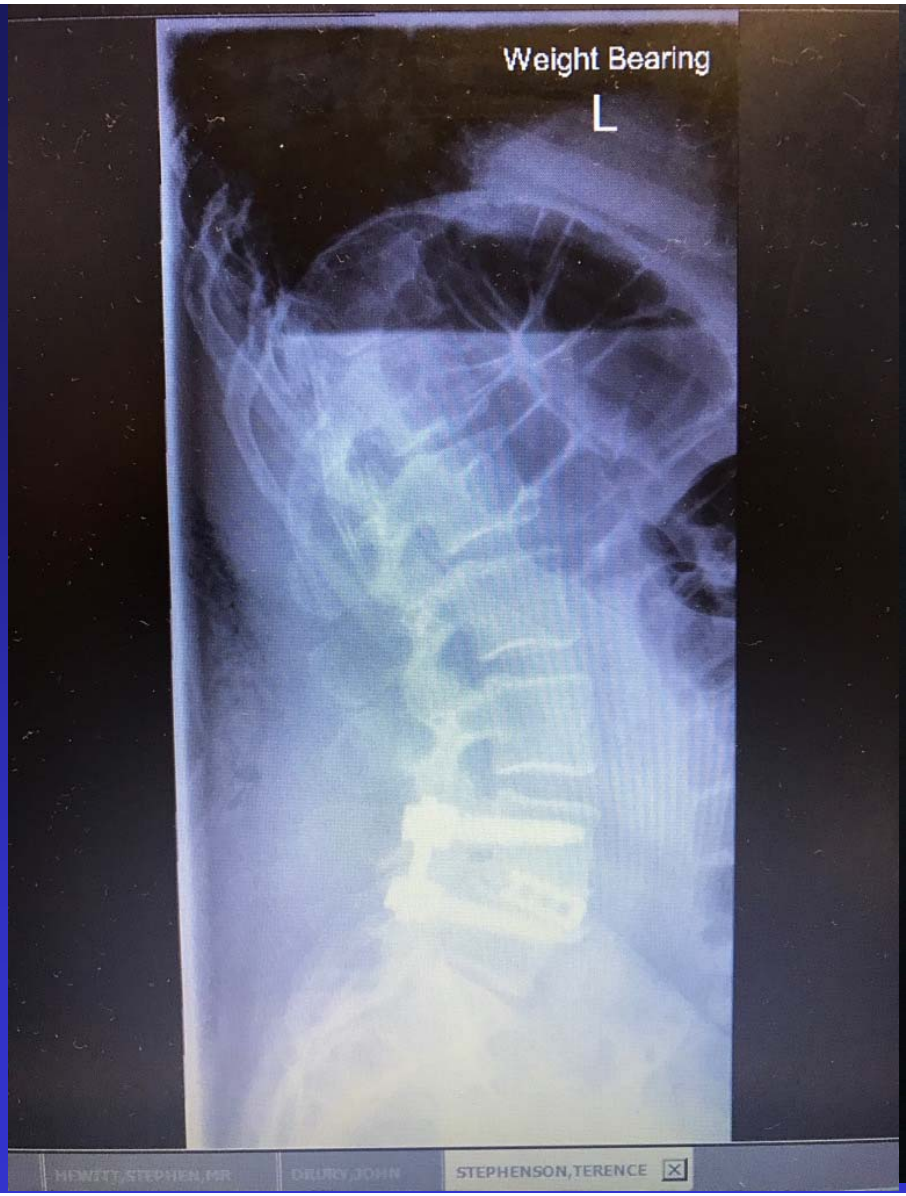
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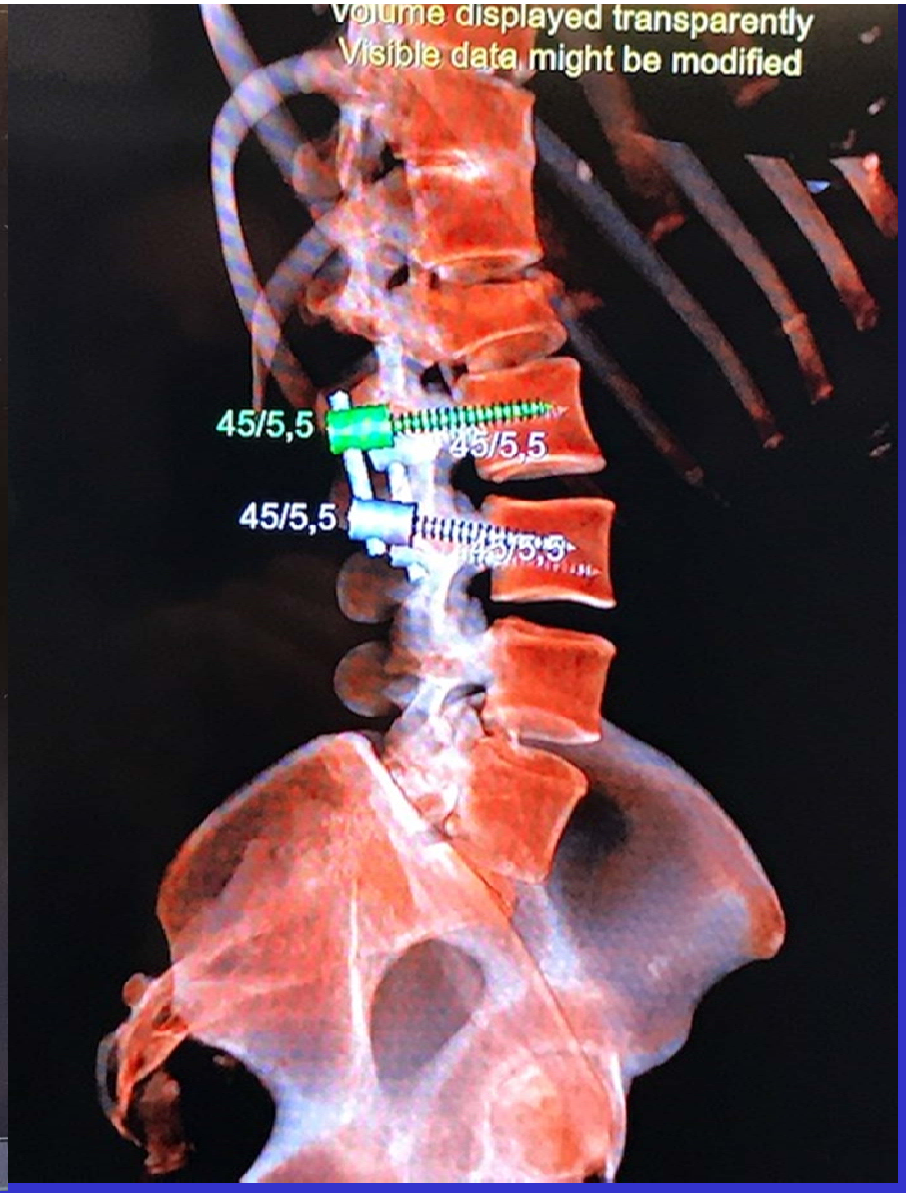
DRURY,JOHN
STEPHENSON,TERENCE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Is the NHS safe?

- Of the top 20 risk factors for all deaths, adverse in-hospital healthcare events come eleventh – above alcohol, drugs, violence and road traffic accidents.

- In the NHS each year there are: 624 million prescriptions, 300 million GP visits, 13 million OPD visits, 5.3 million admissions, 2.9 million emergency ambulance calls, and an estimated 900,000 adverse events.

- Every week – two wrong site surgeries and two operations with kit wrongly left inside. NEVER EVENTS 2016/17= 400
- Wrong site/retained foreign body/wrong implant = 79%; Medication error causing harm = 12%

- Adverse events (unintended injury caused by medical management rather than disease) lead to an additional three million NHS bed days. Costing at least £1 billion a year.


STARBUCKS
COFFEE
RB TAXIS
RB TAXIS


Wet hands with water
Apply enough soap to cover all hand surfaces
Rub hands palm to palm
right palm over left dorsum with interlaced fingers and vice versa
palm to palm with fingers interlaced
backs of fingers to opposing palms with fingers interlocked
rotational rubbing of left thumb clasped in right palm and vice versa
rotational rubbing, backwards and forwards with clasped fingers of right hand in left palm and vice versa
Rinse hands with water
dry thoroughly with a single use towel
use towel to turn off faucet
...and your hands are safe.


LCTING THE RIGHT INFUSION PUMP


2. 11. 2000

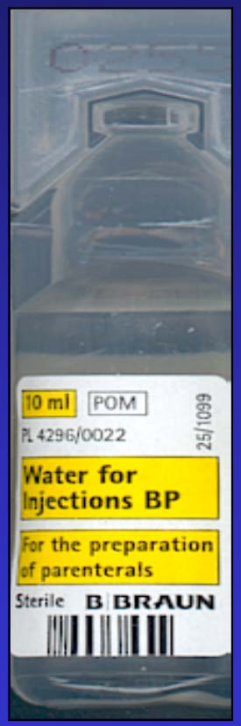
Baby Abbie Humphries abducted 1997

Legislation standardising the use of patient wristbands, and the information they contain, came into force in July 2008.

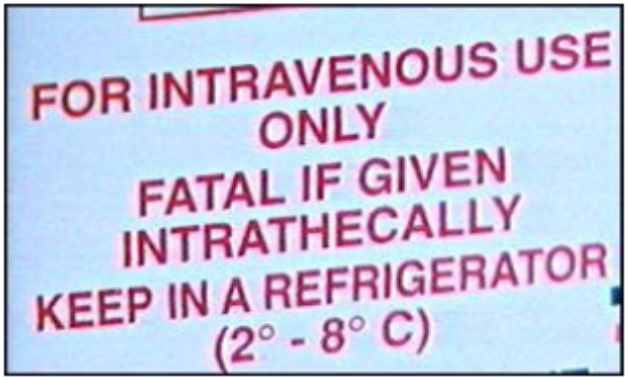
Known as the *NPSA Safer Practice Notice No.24*, all NHS organisations in England and Wales that use patient wristbands adhere to this new legislation and the standards that it sets.

Advisor to the National Patient Safety Agency, 2003-2006:
barcoding allows tracking of patient, product and place

Problems with identification of intravenous injections at an emergency

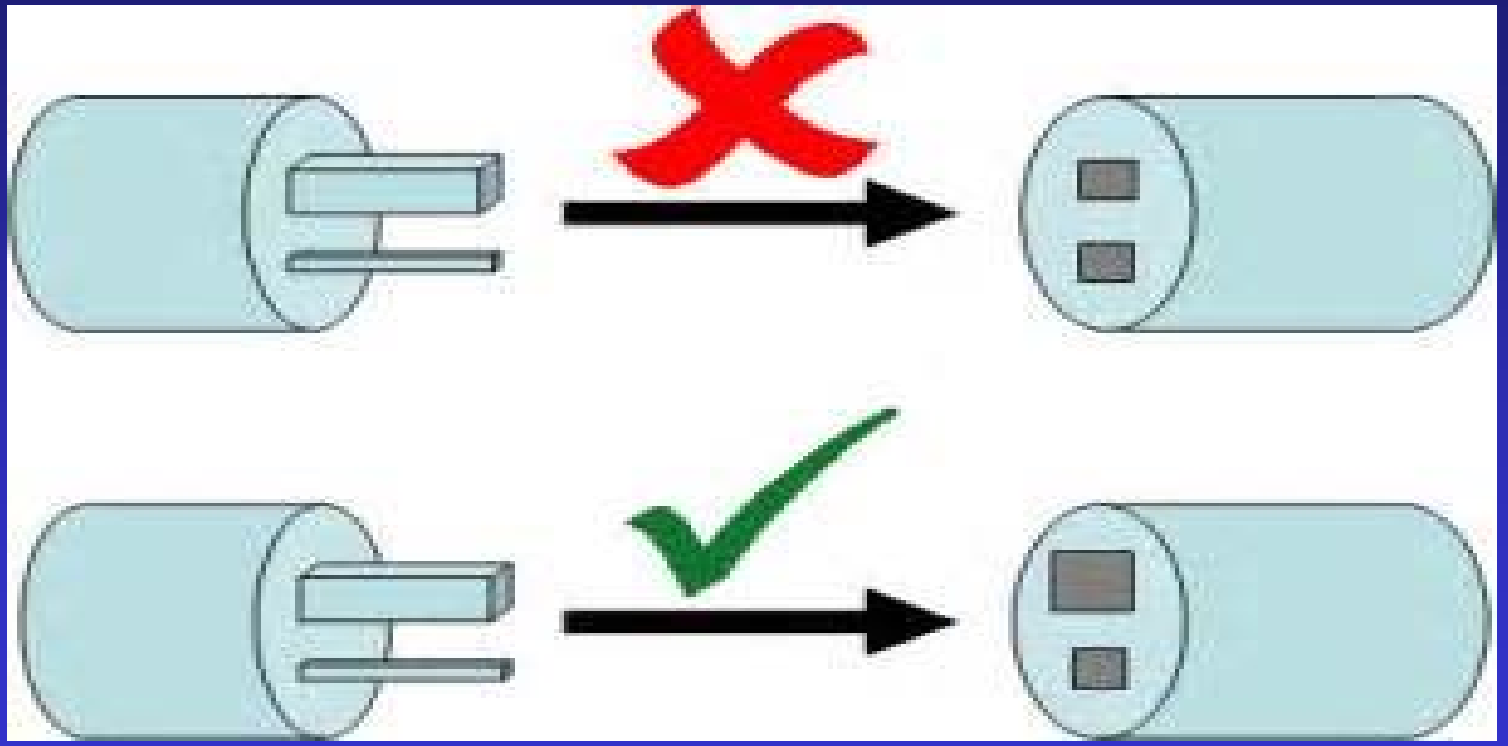


Death of Wayne Jowett (2000)



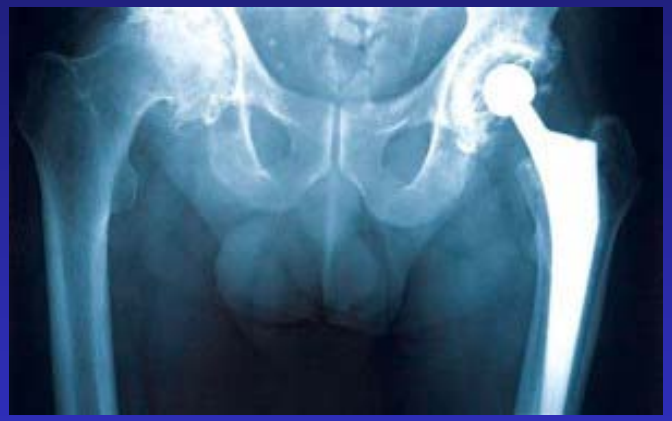
- Leukaemia patient in remission
- Queens Medical Centre Nottingham
- Cytotoxic IV vincristine given IT
- Immediate efforts to flush out drug
- Paralysis and respiratory failure
- Died 1 month later

POKA-YOKE OR MISTAKE PROOFING



2010 MHRA safety alert: metal-on-metal hip replacements

2010 MHRA safety alert: PIP silicone implants



Review of Medical Devices for the Medicines & Healthcare products Regulatory Authority (MHRA), Jan 2014


Source of calcium
Vegetarian
Bottle & Cap
alamy stock photo


© Alamy

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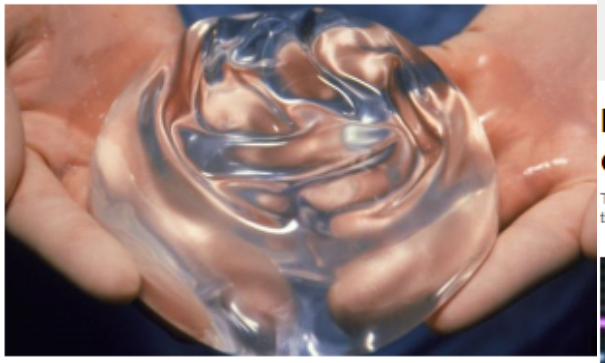
Health

Breast implants and other medical items get safety barcodes

29 December 2016 | Health



Barcodes are being printed on breast implants and other medical items for patient safety reasons.

The Department of Health initiative is to avoid future scandals like the **PIP breast implant scare of 2010**.

Problems arose tracing nearly 50,000 British women who had been fitted with the faulty silicone implants.

The new system is intended to record every medicine and implant given to patients by scanning the product packet and the patient's identity wristband.

Health Secretary Jeremy Hunt said: "This can actually save lives for the NHS."

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NHS trials barcode system to reduce mistakes during treatments

The Health Secretary hopes the technology could one day help reduce the 150 avoidable deaths that happen every week in the NHS.

The barcodes would be attached to everything - including equipment, doctors and patients

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News

Barcoding breast implants and hip replacements 'could save NHS £1bn'

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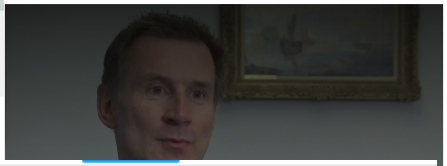

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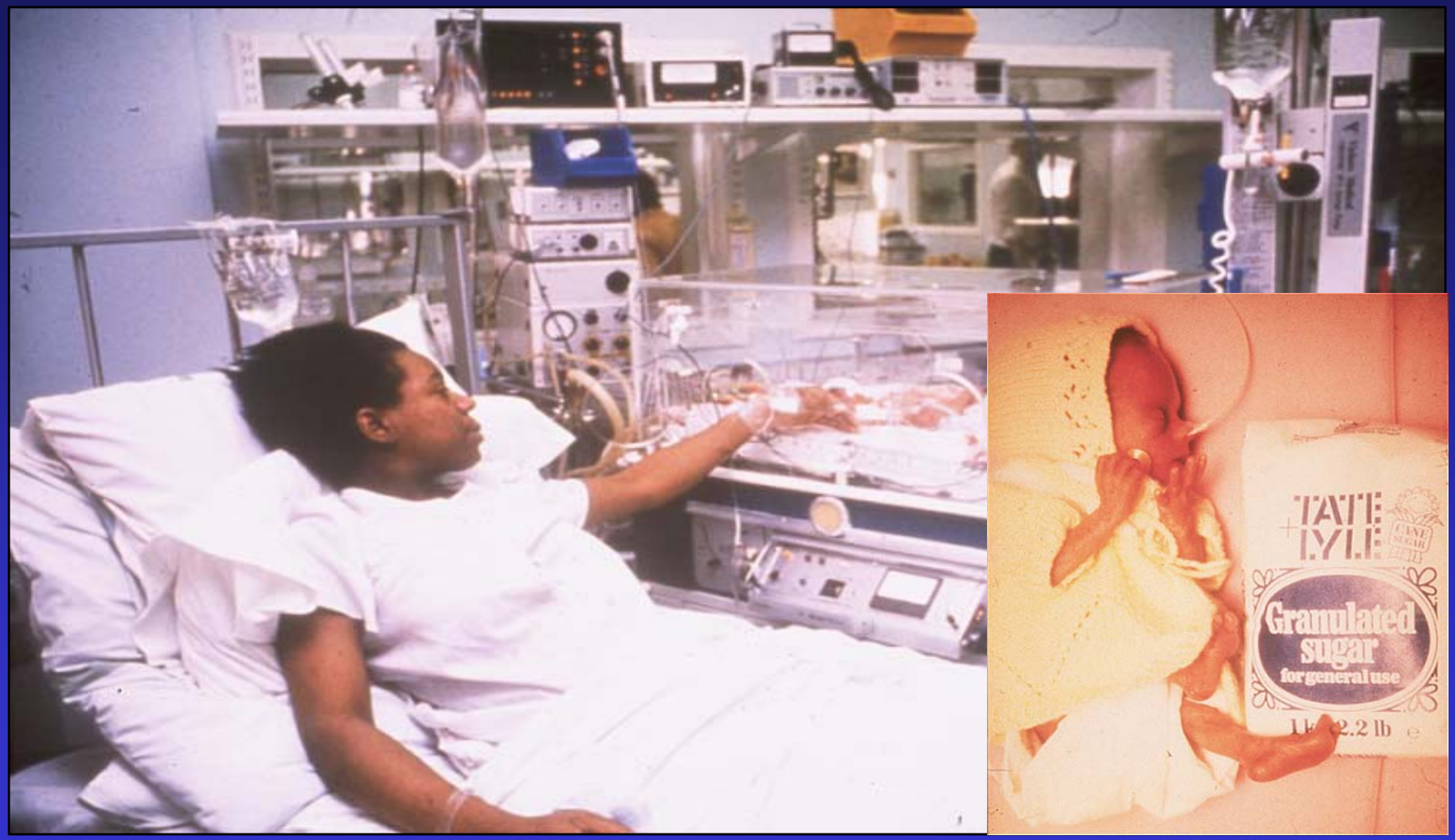
Breast implants are being given barcodes by the NHS in an attempt to 'revolutionise' patient safety by being able to track them in case they are faulty

- The Department of Health will give every surgical item a barcode to track it
- Products are scanned alongside a patient's wristband to match them together
- It is hoped the £12 million system will help to prevent any possible human errors
- Early results from 6 pilot NHS hospitals suggest it has the potential to save lives
- And it may also help the health service save up to £1 billion over the next 7 years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LYLE
Granulated
sugar
for general use

PERSONAL VIEW

To boldly go from "computer says no" to an iNHS

It's IT, Jim, but not as we know it, reports **Terence Stephenson**

Captain's log. Stardate May 2013
0830-0930: Consultant led handover as per Francis.[1] The cases are projected by the trainee, Dr McCoy, on to the screen of the NHS Enterprise. Mr Chekov says, "Let's just take a quick look at the chest x ray." Bones has to come out of the current program, decline several on-screen queries, open a new program, and re-enter his username and password—only to be told that the x ray software won't open unless he begins again and closes the word processing program. Three minutes have elapsed, and we have 60 minutes to discuss 20 cases. We give up, noting the excellent radiologist's report but missing a valuable teaching opportunity. Thank goodness we didn't have to access anything as complicated as the tricorder or switch the phasers to stun.
0930: Consultant led ward round[2] starts on ward A. The first patient has sickle cell disease and a fever and has been seen by another NHS hospital more than a year ago.
0945: The general practitioner and St

Thank goodness we didn't have to access anything as complicated as the tricorder or switch the phasers to stun

Safety—General practices have been using e-prescribing and e-records for 30 years. Why are systems which avoid errors of calculation, drug interactions, and illegible prescribing not routine in hospitals? Drug errors are a common cause of negligence claims; as many as a quarter of all settled negligence claims are because of drug prescribing errors.[3]
"Outside-in" design—We need an end to 10 minute computer start-ups, clunking through multiple screens, and
passwords that have to be char
We need user friendly interface
with jobbing doctors in mind.
functionality that is rarely requ
enemy of rapid, intuitive use. S
there seems to be no one who
zoom button on the x ray view
but everyone can find it on Goo
Efficient—There is a problem in
someone, but, because you hav
In the meantime, the phone is
when the person you've paged

BMJ 2013;346:f4028 doi: 10.1136/bmj.f4028 (Published 24 June 2013)

VIEWS & REVIEWS

PERSONAL VIEW

To boldly go from "computer says no" to an iNHS

It's IT, Jim, but not as we know it, says **Terence Stephenson**, with some suggestions for improvements

Terence Stephenson *professor and chair, Academy of Medical Royal Colleges, London EC1V 0DB, UK*

Captain's log. Stardate May 2013

0830-0930: Consultant led handover as per Francis.[1] The cases are projected by the trainee, Dr McCoy, on to the

1030: The nurse gives the antibiotics intravenously as prescribed but, through an easily avoidable decimal point error, the dose is only a tenth of the therapeutic dose and so is inadequate against the patient's septicaemia. Unfortunately,

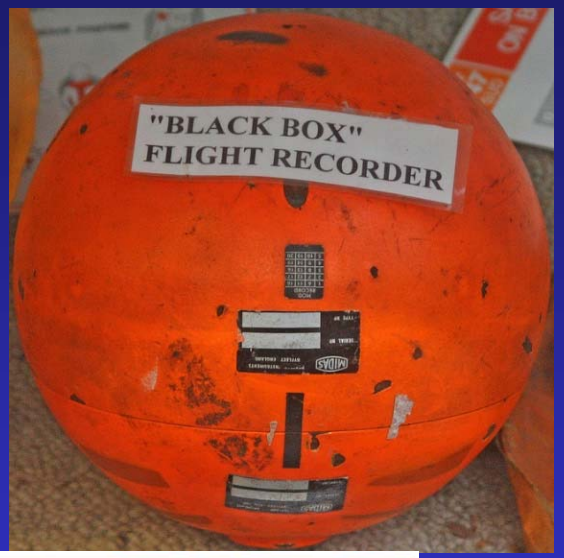
Chair of the Strategic Clinical Reference Group of the National Information Board

Reducing the % – worthwhile?

If 99.9% were good enough…

- Major plane crash every 3 days
- 12 babies given to wrong parents every day
- 37,000 ATM errors every hour

Institute for Healthcare Improvement
(data relate to US population)



Thank you

The Global Language of Business

Exploring the Journey of Supply Chain Transformation in Three Global Health Systems

Dr. Anne Snowdon, BScN, MSc, PhD, FAAN,
World Health Innovation Network, Scientific Director & CEO, SCAN Health, Canada

17 October 2017

Framing the Research

- **Medical Error** is now the third leading cause of death in USA, Canada, and the UK.
- **System Level Measurement** of patient outcomes linked to product use and care procedures does not exist; system infrastructure to support safety is under developed in the health sector.
- **Empirical Evidence of the Impact** of Supply Chain Implementation in Health Systems is very limited.
- **Goal**: To Create Empirical Evidence of the Health System Level Impact of Implementing GS1 Global Standards.

Canada: Alberta Health System

Alberta Health System Supply Chain Strategy

Alberta Health Services (AHS) is Canada's first fully integrated health system with a current budget of approximately $21 billion, serving 4.2 million people. Health receives 39% of provincial budget - $15 billion.

1) Implementation of Enterprise Resource Management Program (ERP);
2) Price harmonization, clinical engagement, and new procurement strategy;
3) The creation of a province-wide product item master and adverse event reporting system;
4) Integration of supply chain into programs and teams

Key Driver: Never Events that resulted in patient deaths in Dialysis

Price Harmonization and New (Centralized) Procurement

- Consolidation of 10 regions followed by implementation of a province-wide ERP system
- All contracts across the province consolidated, pricing standardized to lowest priced contract
  $80,000,000 savings (one time)
- Province-wide, online adverse event reporting system

Province-wide Item Master and Data Infrastructure

- Consolidated every product inventory list across the province from over 30 different inventories = 300,000 items in the item master initially, when “cleaned” now includes 100,000 product items with UDI, organized into functional categories.

- GS1 Standards were adopted province wide and built into all RFP’s.

- To validate the data, the team worked with vendors to meet integrity standards, product data was then uploaded into a UDI portal.

Integration of the Supply Chain Strategy

Clinician Engagement:

Supply chain staff are embedded in the Clinical program teams:

- Provide data on utilization, product cost, patient outcomes, and value to inform clinician team decisions
- Solicit feedback on new products, contracts, and implementation strategies
- Fully understand team needs and support team decisions

Alberta Health System Supply Chain “by the Numbers”

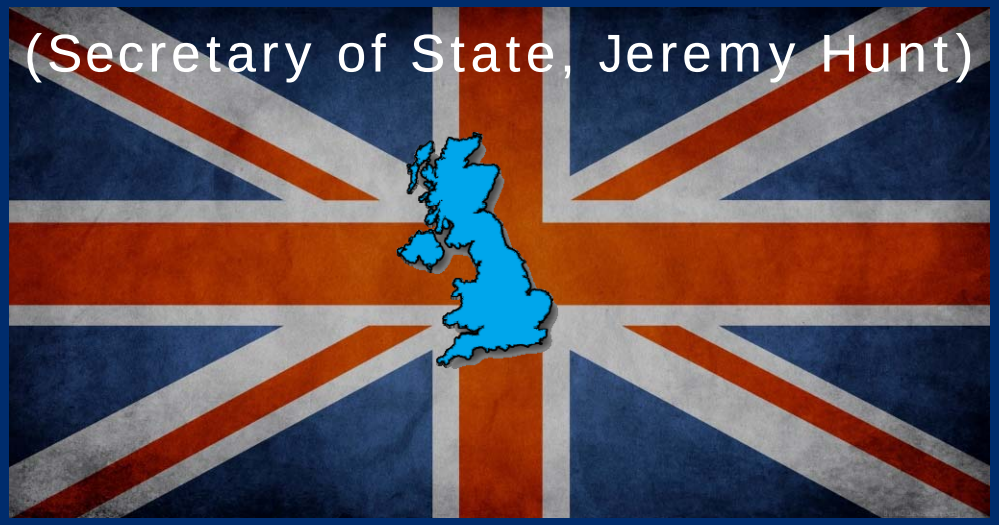
- CPSM Operating budget (2016/17): $78 million
- Staff: 881.5 FTE serving 354 sites across the province
- Annual Budget for Transformation Work: $3 million
  - (includes Data Management & Reporting Team, System and Process Transformation Specialists for Continuous Improvement and Project Managers)

Return on Investment: 7:1
(Inventory Savings Only, to Date)

Year	Costs (CPSM Team, IT Infrastructure)	Savings
2009/10	$26,000,000.00 (Oracle install) (Note: this included accounts payable, costing, and supply chain) $3,000,000.00 (CPSM labour)	$29,200,000.00 $80,000,000.00 (pricing standardization)
2010/11	$3,000,000.00 (CPSM labour)	$79,500,000.00
2011/12	$3,000,000.00 (CPSM labour)	$50,000,000.00
2012/13 (Q3)	$3,000,000.00 (CPSM labour)	$22,800,000.00
Total	**$38,000,000.00**	**$261,500,000.00**

NHS: “The World’s First Learning Organization”

(Secretary of State, Jeremy Hunt)



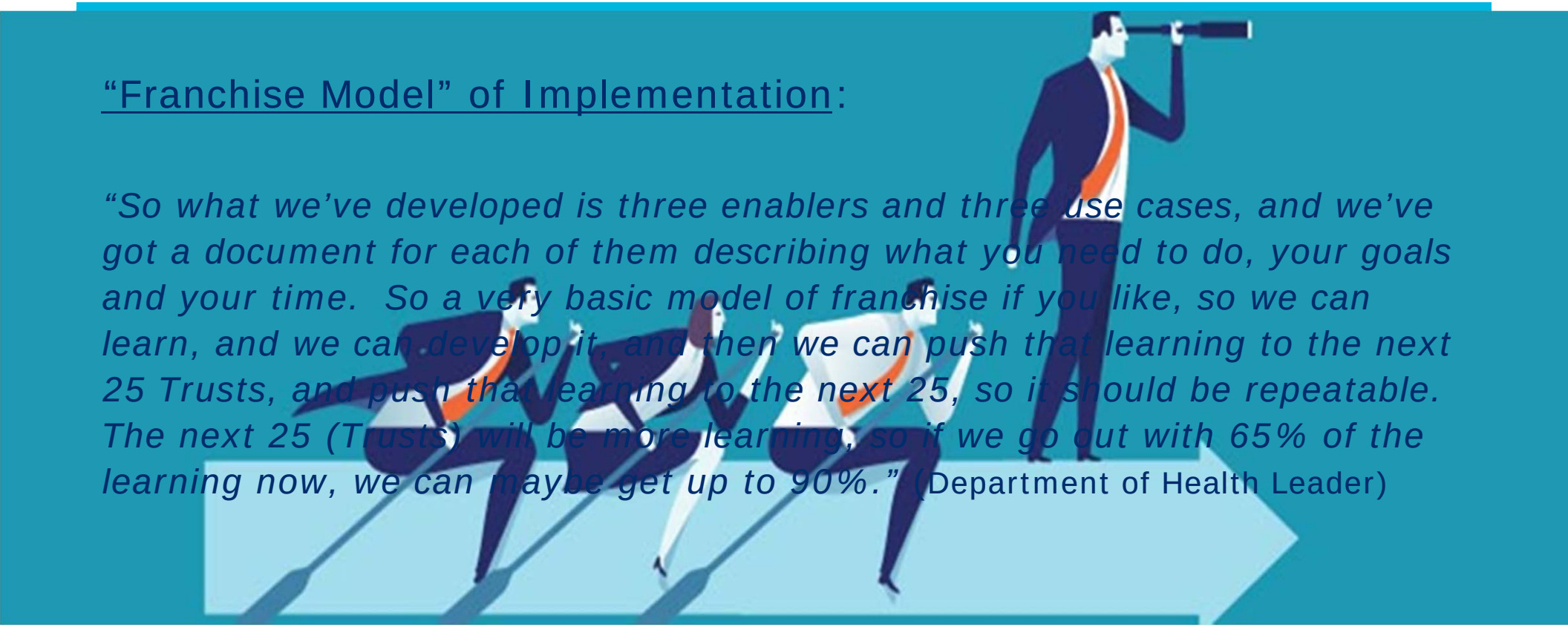
NHS

”There’s a denominator as well as a numerator. The numerator is the number of things that go wrong, the denominator is the phenomenal amount of work the NHS undertakes in a year.” (Dept. of Health Leader)

Key Drivers:

- Safety: Adverse events in hospitals are more prevalent than other leading causes of death: traffic accidents, alcohol-related, and common types of death in the top 20 UK risk factors,
- Horsemeat scandal and breast implant recall
- Efficiency, and Transparency across the System to Support Learning

Strategy: "Franchise Model for System Learning"



"Franchise Model" of Implementation:

"So what we've developed is three enablers and three use cases, and we've got a document for each of them describing what you need to do, your goals and your time. So a very basic model of franchise if you like, so we can learn, and we can develop it, and then we can push that learning to the next 25 Trusts, and push that learning to the next 25, so it should be repeatable. The next 25 (Trusts) will be more learning, so if we go out with 65% of the learning now, we can maybe get up to 90%." (Department of Health Leader)

Patient Safety: “We’ve got the Whole Picture”

“What we do on the ward is we identify where the adverse event occurred, I’ve got the context of the patient, I know the staff, I’ll scan that code and it prompts them to collect the information, every one of those transactions has a time stamp, so we’ve got the ability to start pulling out reports, so straight away we’ve got the whole picture.” (NHS Team Leader)

Clinician Perspective:

“The real big plus for me as the clinician is I want to know where my patient is 24/7, 365, where they’ve been, what they’ve had done, all of that, by whom, I want all of that information to be automatically uploaded onto their electronic discharge note. And we should be able to do that and we can’t.” (NHS Clinician Leader)

Inventory Optimization: “Knowing Exactly What We Are Buying and What We Paid For”

Inventory Transparency to Support System Engagement:

- *“We’re going to know exactly what we’re buying, and in what volumes, and what we’re paying, and we’ll benchmark it based on the others, and then we can start working collaboratively, we’ll get better value.”* *(NHS Trust Leader)*

- *“We figured that in the NHS hospital system, we think it’s 1.5 billion Pounds worth of inventory savings.”* *(Department of Health Leader)*

Integration of Supply Chain Processes into Clinical Programs: Transition from "Adversaries" to "Collaborators"

Culture of Teamwork:

*"When I first came we'd sit in procurement and not go down, may occasionally speak on a phone or an **email was safer**… now clinicians come and sit next to us, they know who we are, we feel comfortable and we actually understand, and they do also, that we can make a difference."*
(NHS Procurement Leader)

Creating Evidence:

*"The first thing when you show a group of clinicians what the results are, they will say, '**we don't believe you**, we don't believe the data', …What the GS1 project does, is it starts to build the argument… it doesn't mean that all variation is wrong, it just starts to build the argument."*
(NHS Clinician)

Speaking the Same Language:

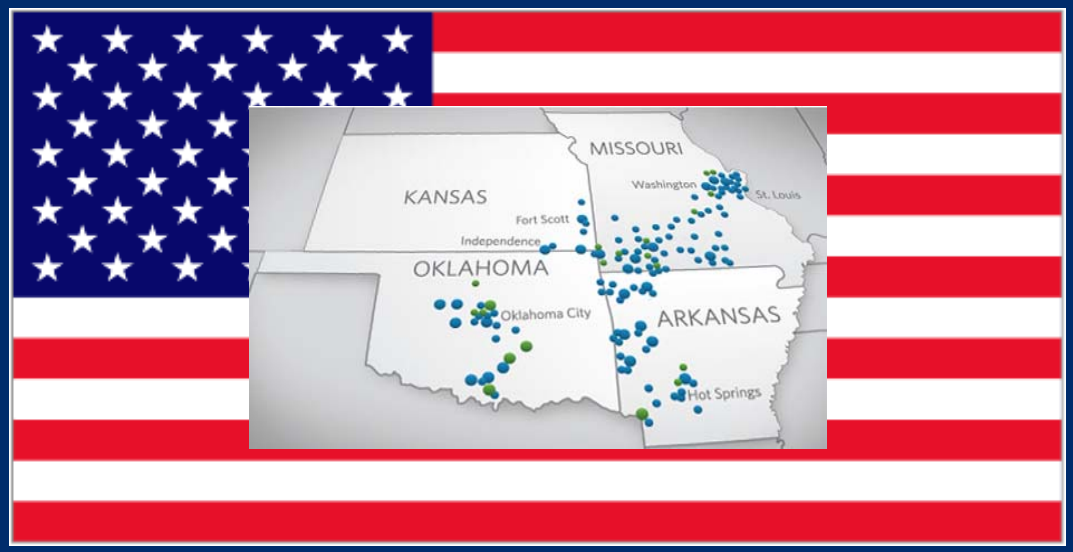
*"This is equivalent to the **cost of six nurses per year**… if you are happy with it please use it, if not, then tell us why… I had just two heated emails, that's how we changed 900 consultants… and we did it and I think it has been a very good."*
(NHS Procurement Leader)

Scan 4 Safety ROI: 4:1

(Inventory Savings Only, to Date)

- £4.4m actual savings; savings expected by March 2018 = £9m (Dept. of Health)
- 4:1 ROI expected by year 3, annualized savings which only includes inventory waste reduction, additional savings emerging in clinician time saved; patient safety outcomes not yet accounted for.
- Patient care and patient safety Improvement:
  - *Surgical teams now alerted if expired or recalled stock*
  - *93% of implantable devices accurately tracked to patient*
  - *Significant Clinician Time released back to patient care*
  - *Product recalls now performed in under an hour*
  - *Tracking Provider expertise relative to patient need and quality of care*

USA: Mercy Health System



Mercy Demographics

35

Facilities

259

OR Rooms

210,000

Periop Procedures

FY

July - June

$2,093,276,868

Perioperative Revenue

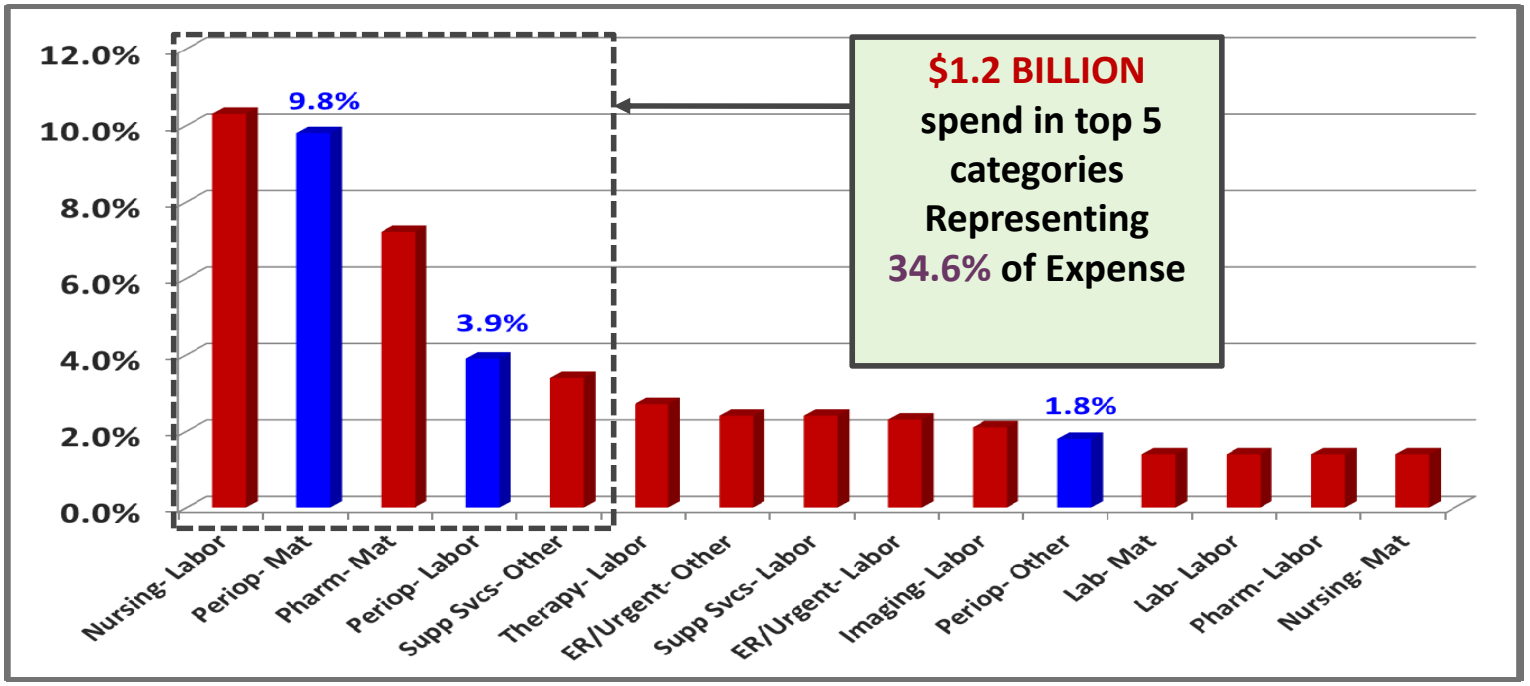
$351,487,571

Perioperative Spend

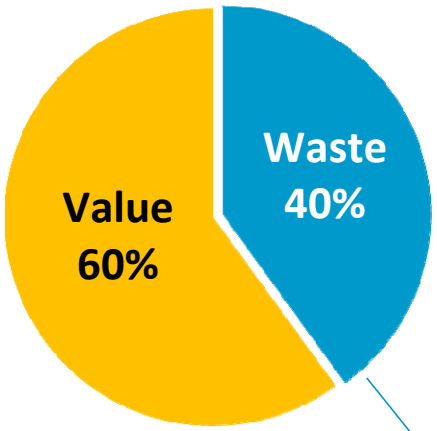
$1,741,789,297

Periop Contributing Margin

REALITY: Mercy Expense Breakout (Top 15)



REALITY: Waste Dominates Our Industry

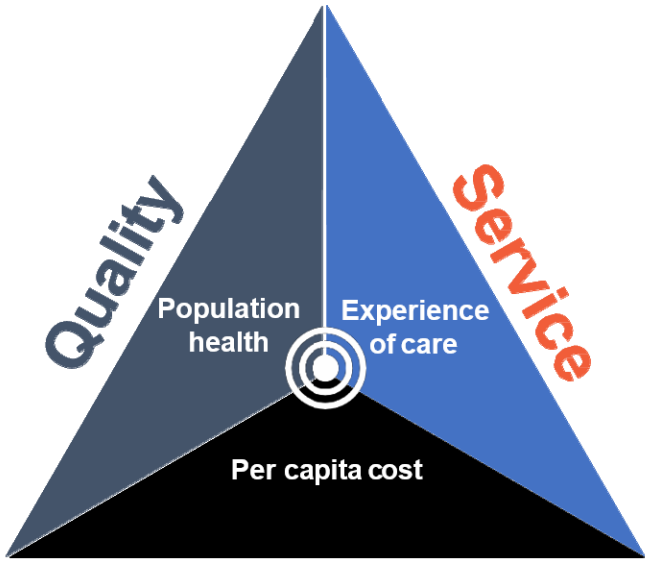


Source: Sg2

Medicare Waste	Examples
Unnecessary Care	• Preference based care without evidence of value • Defensive care • Excess or use of unproven technology
Inefficiency	• Over utilization of testing • Over utilization of ICU • Staff mix mis-match • Lack of equipment leveraging
Provider Error	• Extended LOS due to error • Readmission due to error • Added cost to treat error
Lack of Care Coordination	• Duplicate testing • Inappropriate treatment because relevant history or previous treatment is not accessed • Use of ED for non-emergent conditions because primary care services are not available • Adverse drug reactions that occur when a record of a patient's current medications is unavailable
Avoidable Conditions	• Timely access to quality outpatient care thereby avoiding hospitalizations • Care Management
Other	• Fraud and abuse

Goal: Achieve the Triple Aim by Leveraging UDI

- Patient safety
  - Expiry & recall
- Reduce risk
- Comparative effectiveness

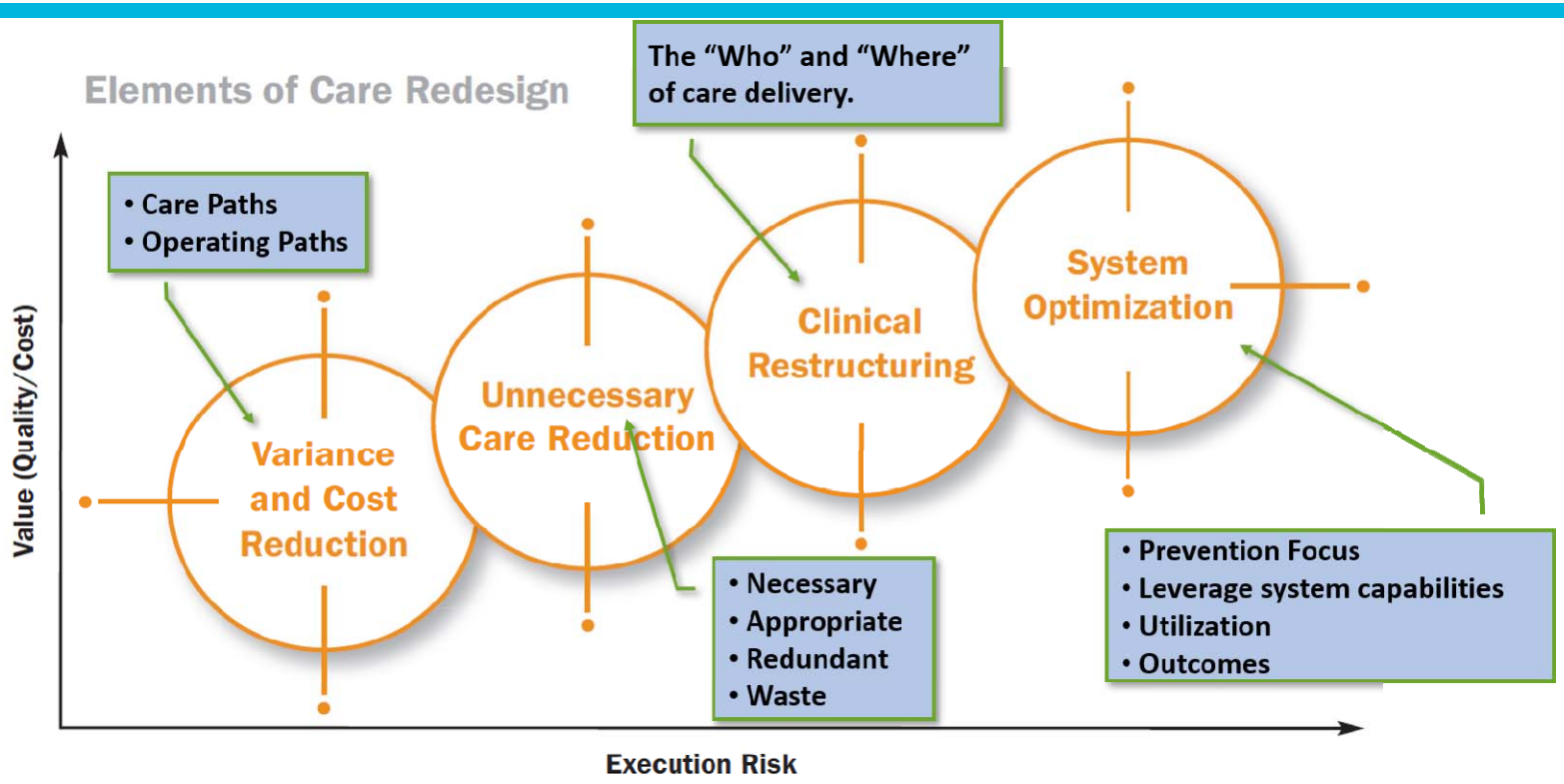


Financial

- Cost per case
- Charge capture

- Minimize distractions
- Improve clinical workflow
- Improve clinical satisfaction
- Standardization

HOW: A High-Level Vision



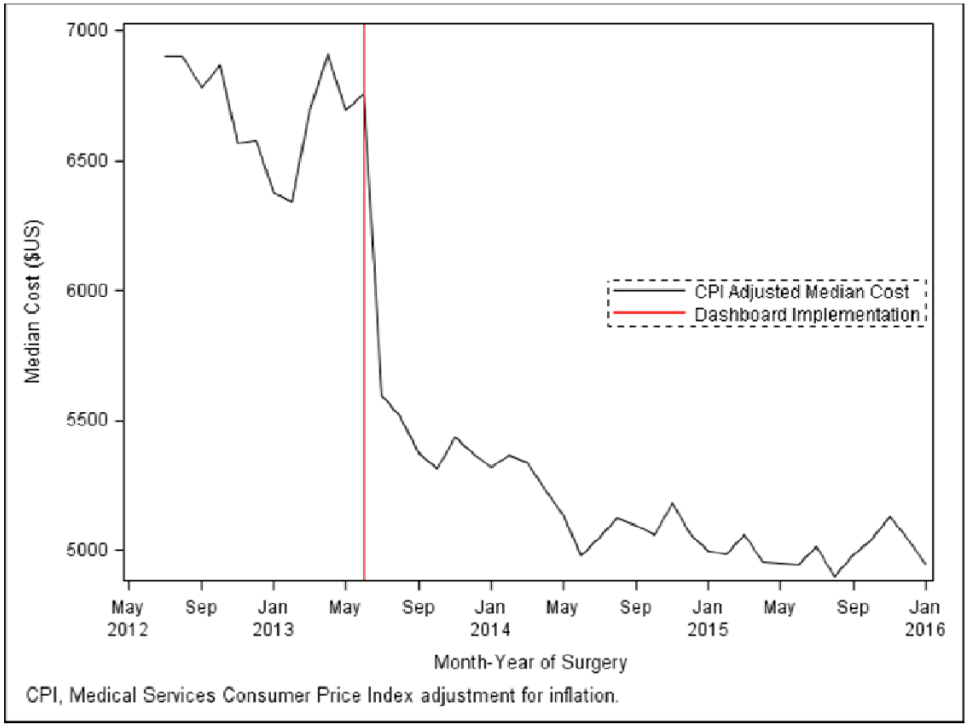
Source: Sg2, 2013

CLINICAL ACCELERATION: Perioperative Results Total Knee Arthroplasty

Total Knee Arthroplasty

CPI Adjusted Intraoperative Supply Cost Per Case

May 2012-Jan 2016 (n=11,834)



e.g., Walmart contract for negotiated cost per case

Defining Success Through Resource Management

Savings to date $55,048,737, only 3/35 hospitals

Emerging Findings Across Three Countries

Patient Safety is a Key Driver of the Strategy: recall and traceability are common areas of focus, no measures of patient safety outcomes to date, safety outcome cost savings not yet captured.

Inventory Savings are substantial. Ranges from **1:4 to 1:8 ROI** on inventory savings alone – system may be able to "self fund" the strategy as savings are recurrent. Savings due to Patient Safety are not yet accounted for and is anticipated to increase the ROI.

Integration of Supply Chain Team with Clinical Program teams engages clinicians in a key decision-making role, aligns procurement of products with clinical decisions for safety, cost, and standardization - emerging as a key condition for success.

Emerging Findings Across Three Countries

“Rate Limiting Step:” accuracy and integrity of product data is slow to emerge as supplier implementation of GS1 standards and “clean” product data continues to emerge.

- Global alignment of product information – a “minimal required data set” - may accelerate industry progress.
- Multiple and different ”registries” and data bases emerging, alignment globally could enable and hasten progress.

System Transparency: supply chain integration across systems is emerging as a **Strategic Operational Management Framework.**

- Creates needed transparency of the value that health systems are delivering; foundational to driving quality and safety across global systems.
- Emerging evidence as a platform for innovation.

“Change does not roll in on the wheels of inevitability, but comes through continuous struggle.” *Martin Luther King Jr.*

Thank you!

Anne W. Snowdon

snowdon@uwindsor.ca
www.scanhealth.ca

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SCANH
Supply Chain Advancement Network in Health

NHS
The Leeds Teaching Hospitals
NHS Trust

David Berridge

Deputy Chief Medical Officer
Medical Director – Operations
Consultant Vascular Surgeon

October 2017

SCAN4SAFETY

NHS
The Leeds Teaching Hospitals
NHS Trust

One Trust – Seven Hospitals

Leeds General Infirmary

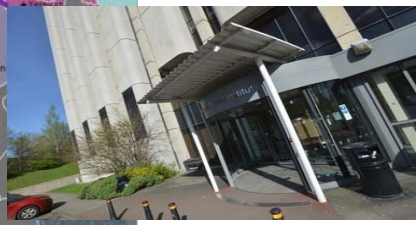
St. James's University Hospital

Leeds Children's Hospital

Seacroft Hospital

Wharfedale Hospital

Chapel Allerton Hospital



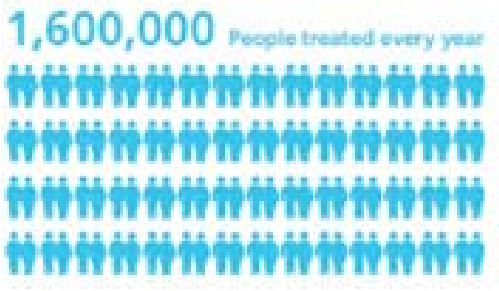
Leeds Dental Institute

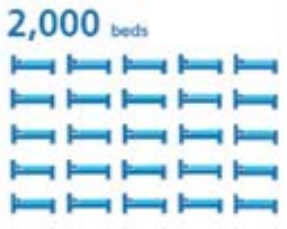
SCAN4SAFETY

NHS
The Leeds Teaching Hospitals
NHS Trust

About Leeds Teaching Hospitals NHS Trust

- Over 1,100,000 Outpatients
- Over 263,000 A&E Attendances
- Over 117,000 Inpatients
- Over 108,000 Day Cases
- 9,844 Babies born





Over 17,000 staff

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Turnover

£1.17 billon

($1.83 billion)

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The Leeds Teaching Hospitals
NHS Trust

About Leeds Teaching Hospitals NHS Trust

Providing 120 specialist services

82 Adult Specialities 28 Paediatric Specialities

5 Pathology Services 5 Medicines Management and Pharmacy Services

175 Buildings

Covering **574,234m²** gross internal area which houses

114 wards

135 Departments & Clinical areas

And **69** Operating Theatres

Bar coding

22,017 Global Location Numbers

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NHS Trust

Specialist Services

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Patient identification

All inpatients and day case patients regardless of age have a GS1 compliant wristband

Once the printers have been delivered and installed all Patients attending through Accident and Emergency will have a GS1 Compliant wristband

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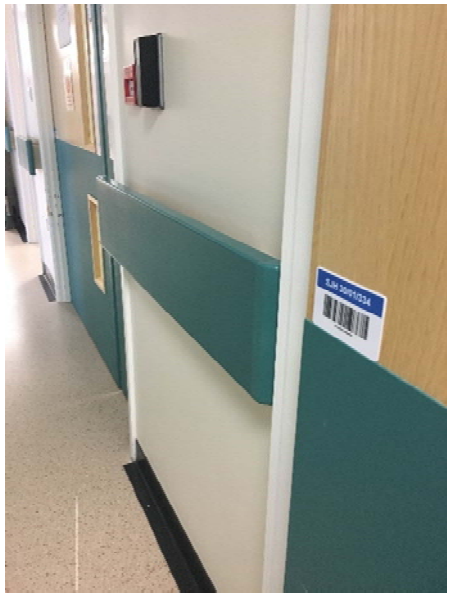
Global Location Numbers

Plaques issued for every room in use throughout the organisations (22,017 Rooms and Spaces)



GLN duplicated on the door for Supplies and Security Purposes

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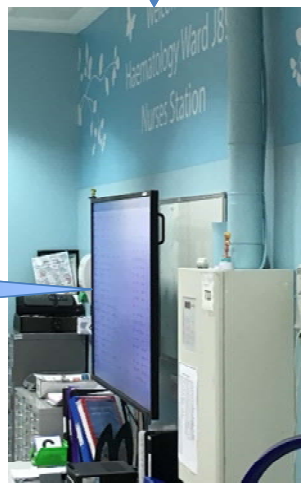
Global Location Numbers

First of the demonstrator sites to label down to bed space level and start unlocking the potential

Ward View: 91 (SJUH) St James's Institute of Oncology, Ward Code: J91

Action	Ward	Bed	Patient	Age	Scanned Location	Time Since Arrival	Consultant	Specialty	LOS	EDD	MFFD	Planning	EDID	Needed For Discharge / Transfer	Clinical Summary	eDAN	eMeds
	91 (SJUH)	1	RASPBERRY Robert	32y	Bed Area, J91 05-Oct-2017 06:53	18d 22h 18m	AA	General Medicine	19d			On Ward			This is some text to test carriage...	Pharmacy	
	91 (SJUH)	2	PLUM Henry	47y	Bed Area, J91 04-Oct-2017 02:32	4d 18h 27m	ADJ	Urology	5d			On Ward					
	91 (SJUH)	3	PEAR Pamela	37y	Bed Area, J91 06-Oct-2017 ...	8d 8h 15m	MRM	Anaesthetics	4d			On Ward				Pharmacy	
	91 (SJUH)	4	GRAPE Bella	57y	Xray, 06-Oct-2017 14:53	2d 3h 5m	ADJ	Urology	3d			On Ward					
	91 (SJUH)	5	BLUEBERRY George	32y	Bed Area, J91 06-Oct-2017 ...	30d 5h 22m	AA	General Medicine	31d			On Ward					
	91 (SJUH)	6	PINEAPPLE Peter	45y	Examination Room, Outpatients 06-Oct-2017 15:10	12d 8h 27m	MRM	Anaesthetics	13d			On Ward					
	91 (SJUH)	7	OLIVE Adrianne	37y	Bed Area, J91 06-Oct-2017 ...	16d 22h 18m	ADJ	Urology	19d			On Ward					
	91 (SJUH)	8	PEACH James	57y	Room 3, Endoscopy 06-Oct-2017 14:12	8d 23h 19m	JHB	General Medicine	9d			On Ward					
	91 (SJUH)	9	ORANGE David	32y	Bed Area, J91 06-Oct-2017	3d 8h 15m	JHB	General Medicine	4d			On Ward					



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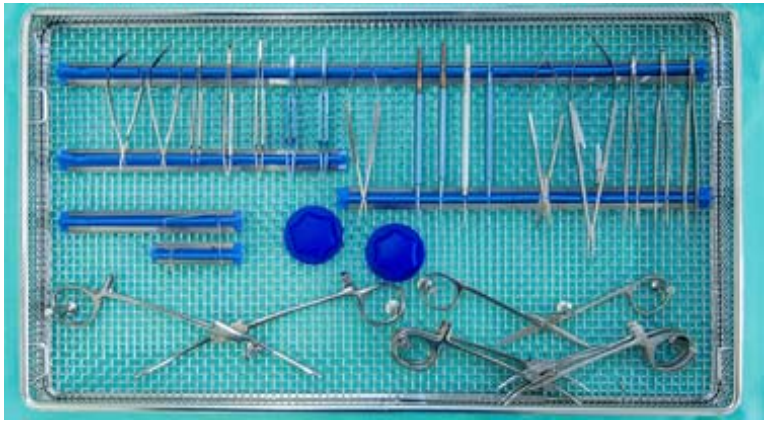
NHS Trust

Theatre Tray Rationalisation

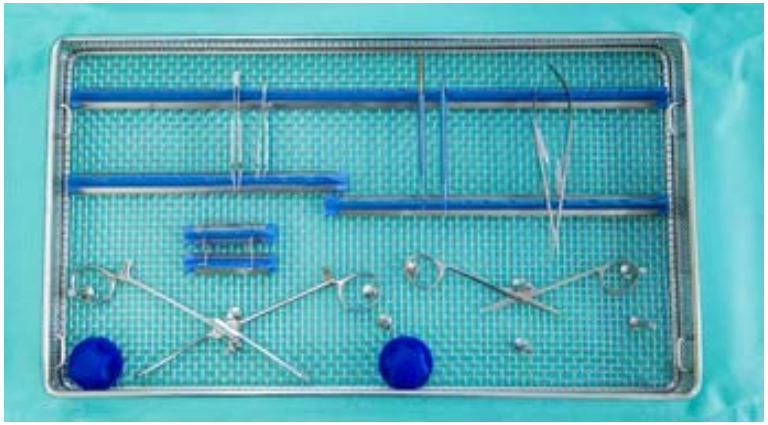


Savings	FYE 16/17	PYE 17/18	Total
Recurrent	£87,037.95	£7,026.54	£94,064.49
One off	£0	£39,500	£39,500

Theatre Tray Rationalisation Programme removed

£94,064.49 ($126,046.40)

per annum of sterilisation costs.



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Cardiology - PLICS

- Activity takes place predominantly in the Cath Labs
- Approx £14m ($18.8) annual expenditure
- Approx £13m ($17.4) is on consumables that range from a few pounds to £16.5k ($22.1) each (TAVI's)
- Main cost drivers are consumables and Cath Lab minutes/procedure

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Initial Analysis – Cost vs Tariff

High volume non complex HRG
(EA54Z Percutaneous Standard Ablation)

- Assumed mean procedure time of 79 mins for costings
- Cost £1,821 ($2,440)
- Income £1,820 ($2,438)
- Loss 0.84p per patient

Actual Procedure Time (mean):133 minutes

Actual loss £808 ($1082) per patient

FYE: circa £153,300 ($205,020)

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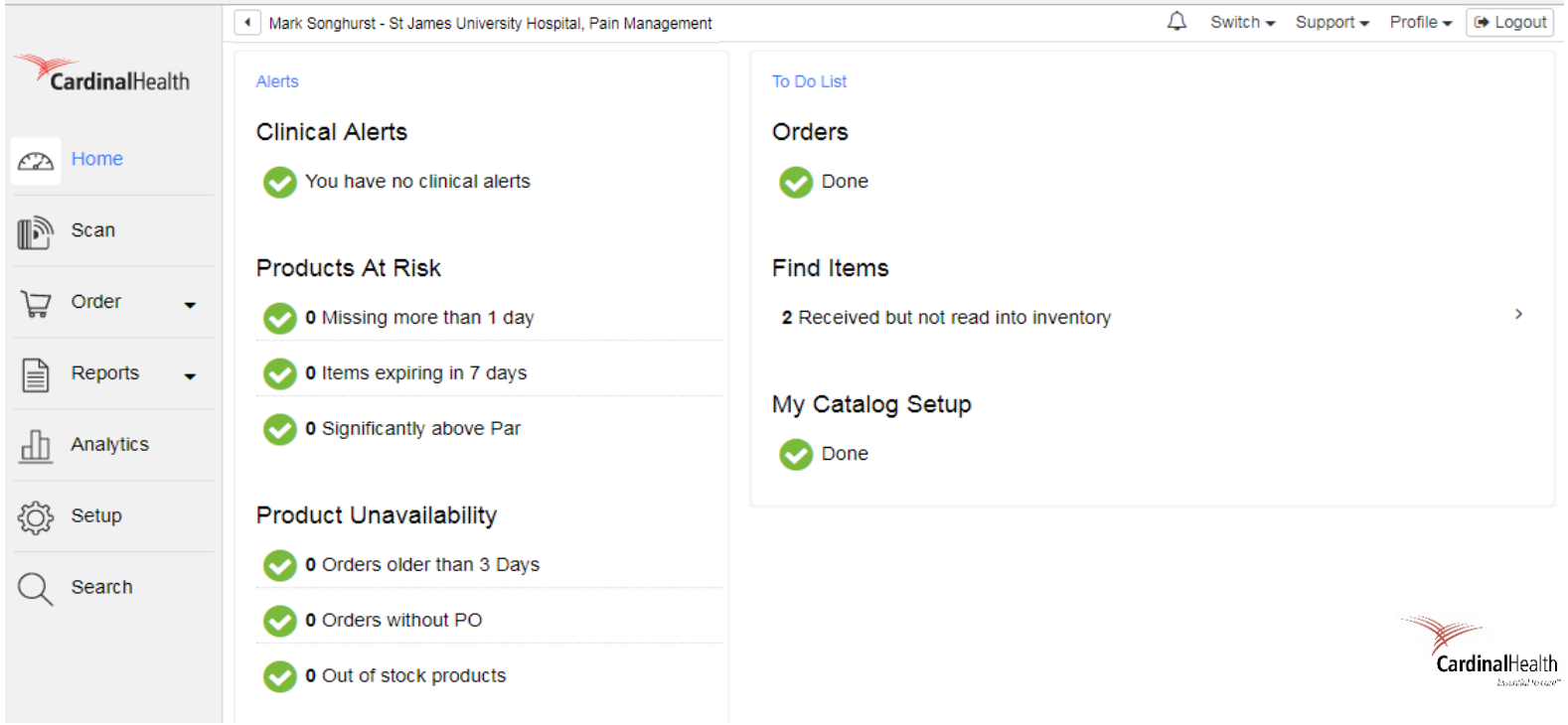
Cardinal CIMS Inventory Management



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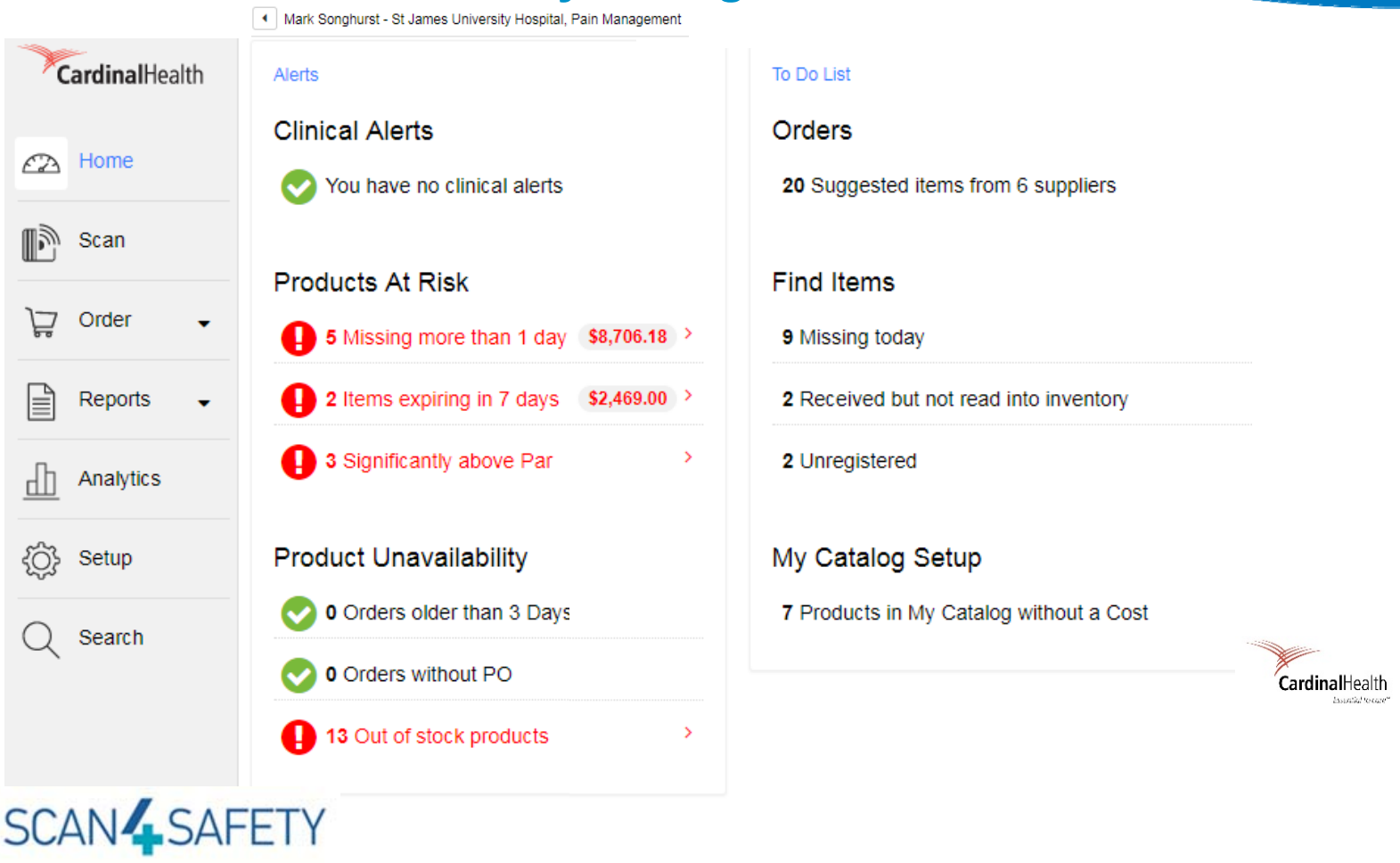
Cardinal CIMS Inventory Management



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Spend on Single Patient Use Tourniquets

Cost £0.39 ($0.53)

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Recurrent Saving £90,000 ($120,600) FYE

Cost £0.08 ($0.11)

Out of Date Stock from initial visit

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Ophthalmology Product Recall Test

Nursing Time (Old System)
Minimum of £173 ($232) and **8.33 hours**

Inventory Time (New System)
Maximum of £9 ($12) and **35 minutes**

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Benefits realised PCI Procedures

Leeds Carried out 4,180 PCI Procedures

September 2016 – August 2017

Process	Mean Time Taken	Mean Time Released	Annual Effect of time Released
Computer Scanning of Products	**6** min **23** sec		
Scan4Safety Handheld	**1** min **53** sec	**4** min **30** sec	**42 Days**

Monetary Equivalent at midpoint of Band 5 = **£4,095** ($5,487)

SCAN4SAFETY

Perfect Week – identifying potential

- Portering Service spent 12.82 man days on wasted tasks with an annual value of £39,698.41 ($53,195) over the 07:00 – 23:00 on seven days
- Implementing Scan4Safety could return 3.14 man days of the above time over a year this would return £9,723 ($13,029)

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Benefits realised

Area	Benefit	
Product Recall Staff Time	£84,411	($113,111)
Inventory Reduction	£812,000	($1,088,080)
Returned Stock	£141,536	($189,658)
Reduced Waste and Obsolescence	£357,356	($478,857)
Tray Rationalisation	£133,564	($178,976)
TOTAL	**£1,489,397**	**($1,995,792)**

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Every time!

@LTHScan4Safety (#BetterCareAsStandard)

lth.scan4safety@nhs.net

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Thank-you for your attention

The Global Language of Business

How GS1 meets breast implants

Ms. Dr. Juliette Hommes, MD, University Medical Centre of Maastricht (MUMC), The Netherlands

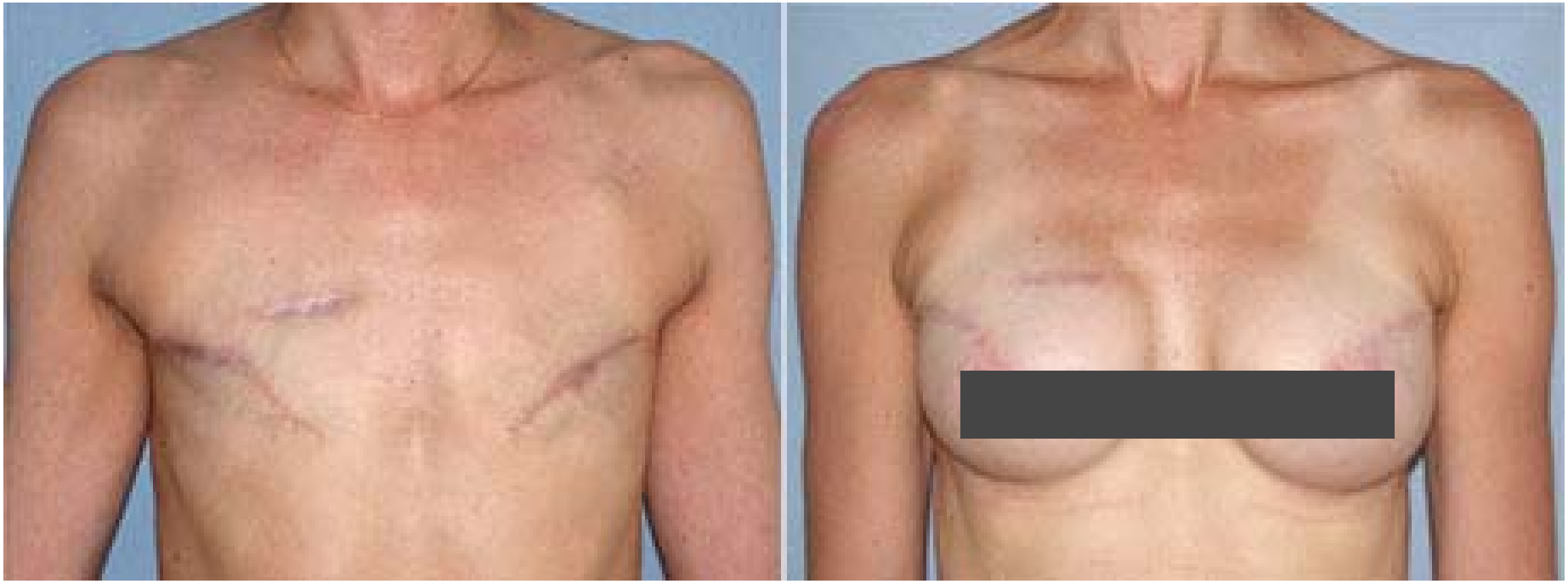
Pauline Spronk, Danny Young Afat, Manuel Harmsen, Marije Hoornweg, Xavier Keuter, Marc Mureau, Hinne Rakhorst

17 October 2017

How many persons do you know who carry breast implants?

Breast implants

Breast implants



Breast implants

Breast implants

Device

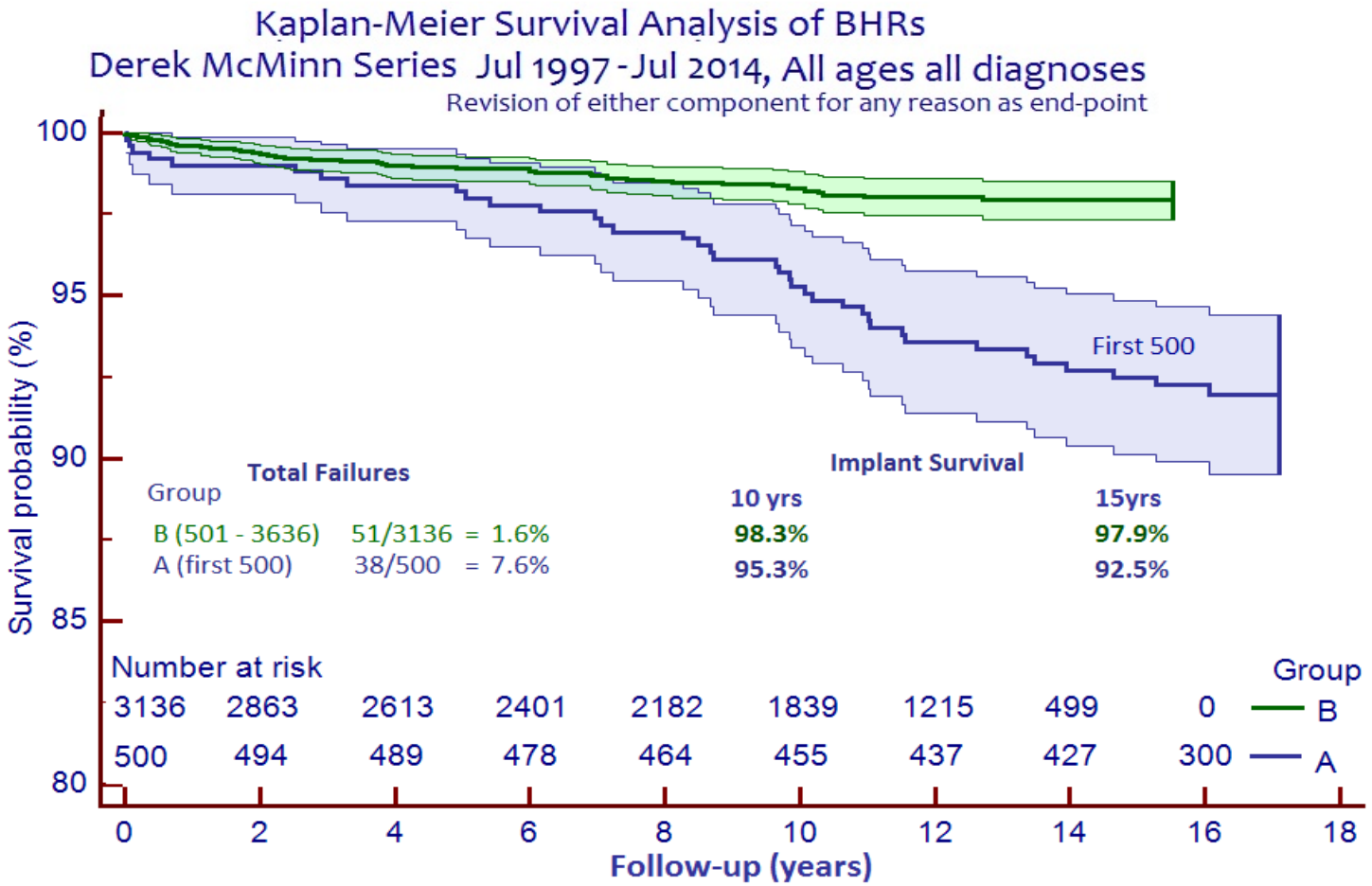
Patients

Surgeons

Hospitals

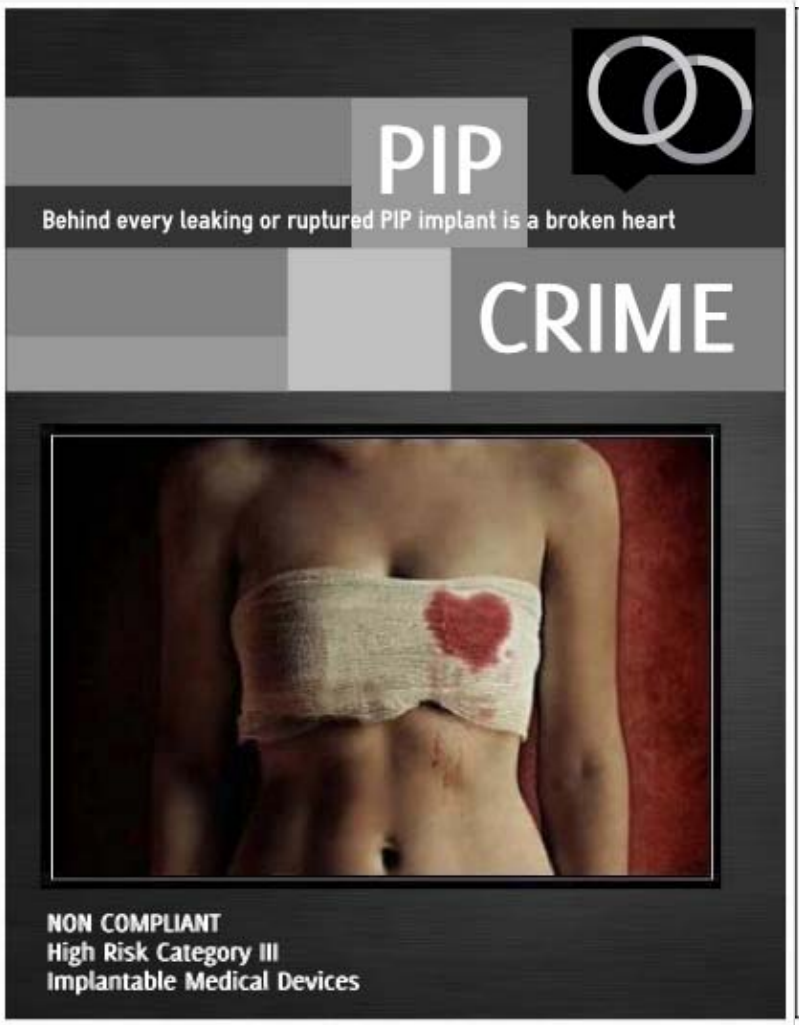
might directly influence complication rates.

Quality of evidence is weak



Problems?


Will your implants give you cancer?
Have you been hearing about
Breast Implant Associated Anaplastic
Large Cell Lymhoma (BIA-ALCL) on the news?



The New York Times

Business

SUNDAY, FEBRUARY 16, 1992

Dow Corning's Moral Evasions

By STEVEN FINK

The implant maker told the truth only after deception failed.

The Telegraph

Home Video News World Sport Business Money Comment Culture Travel Life
Politics Investigations Obits Education Science Earth Weather Health Royal Celebr

HOME » NEWS » HEALTH

Silimed silicone implants suspended over contamination fears

Silicone implants immediately suspended as an investigation is launched over contamination fears

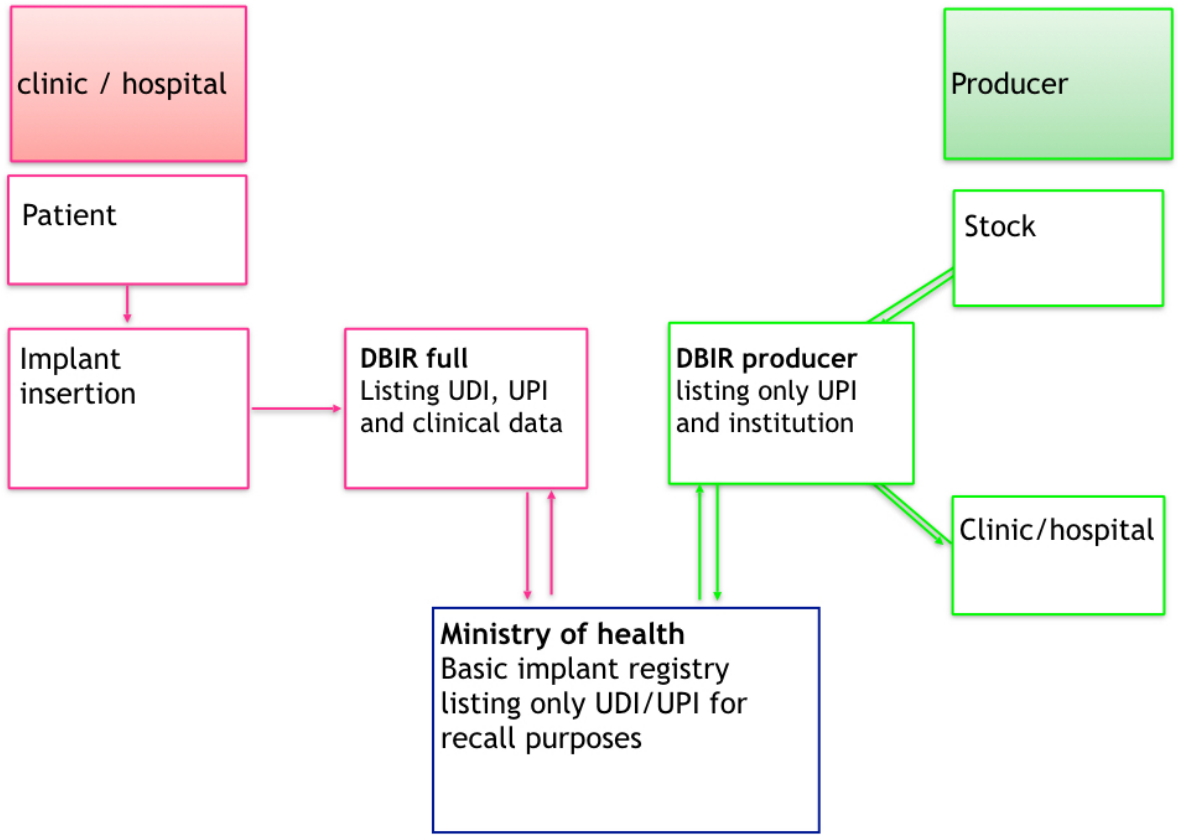
Lessons?

- Possible implant recall structure is mandatory
- Quality of care registry
- Implant quality registry

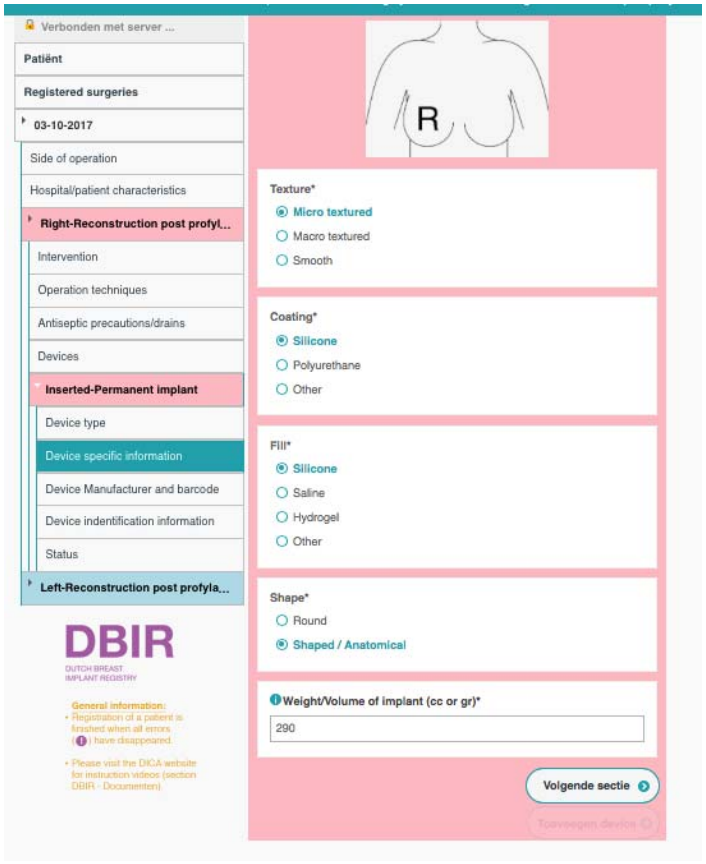
DBIR: Dutch Breast Implant Registry

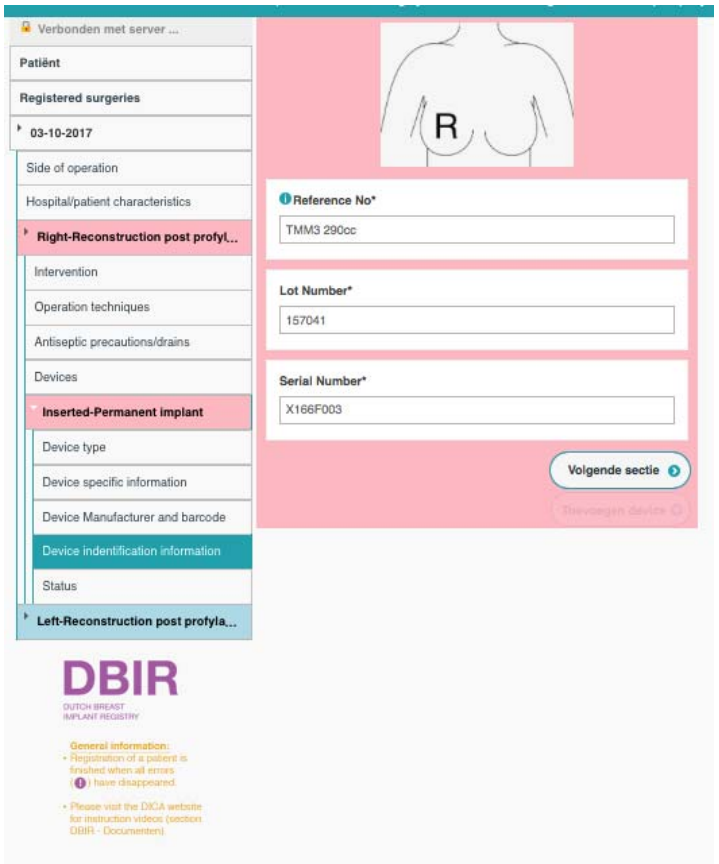
1. Recall

1. Quality assessment



Example


Verbonden met server ...
Patiënt
Registered surgeries
03-10-2017
Side of operation
Hospital/patient characteristics
Right-Reconstruction post profyl...
Intervention
Operation techniques
Antiseptic precautions/drains
Devices
Inserted-Permanent implant
Device type
Device specific information
Device Manufacturer and barcode
Device indentification information
Status
Left-Reconstruction post profyla...
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)
R
Texture*
Micro textured
Macro textured
Smooth
Coating*
Silicone
Polyurethane
Other
Fill*
Silicone
Saline
Hydrogel
Other
Shape*
Round
Shaped / Anatomical
Weight/Volume of implant (cc or gr)*
290
Volgende sectie
Toevoegen device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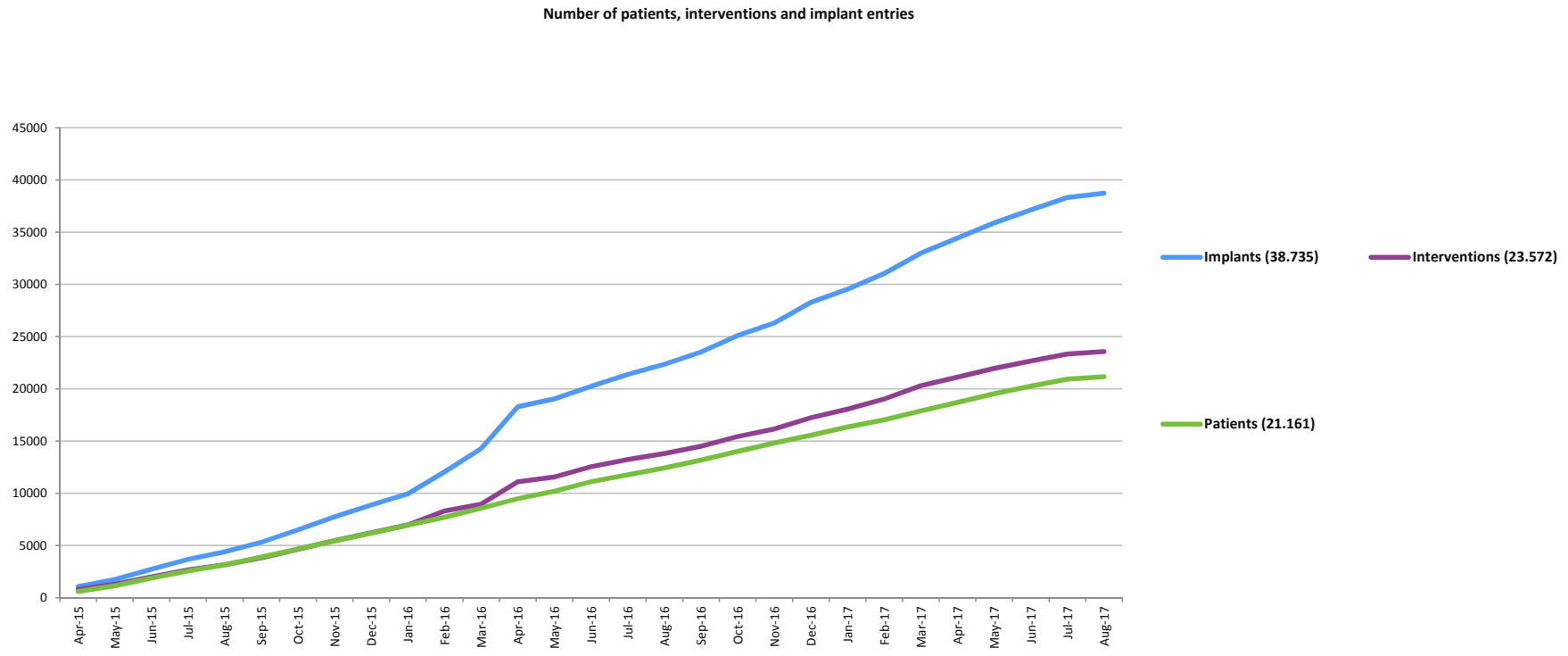
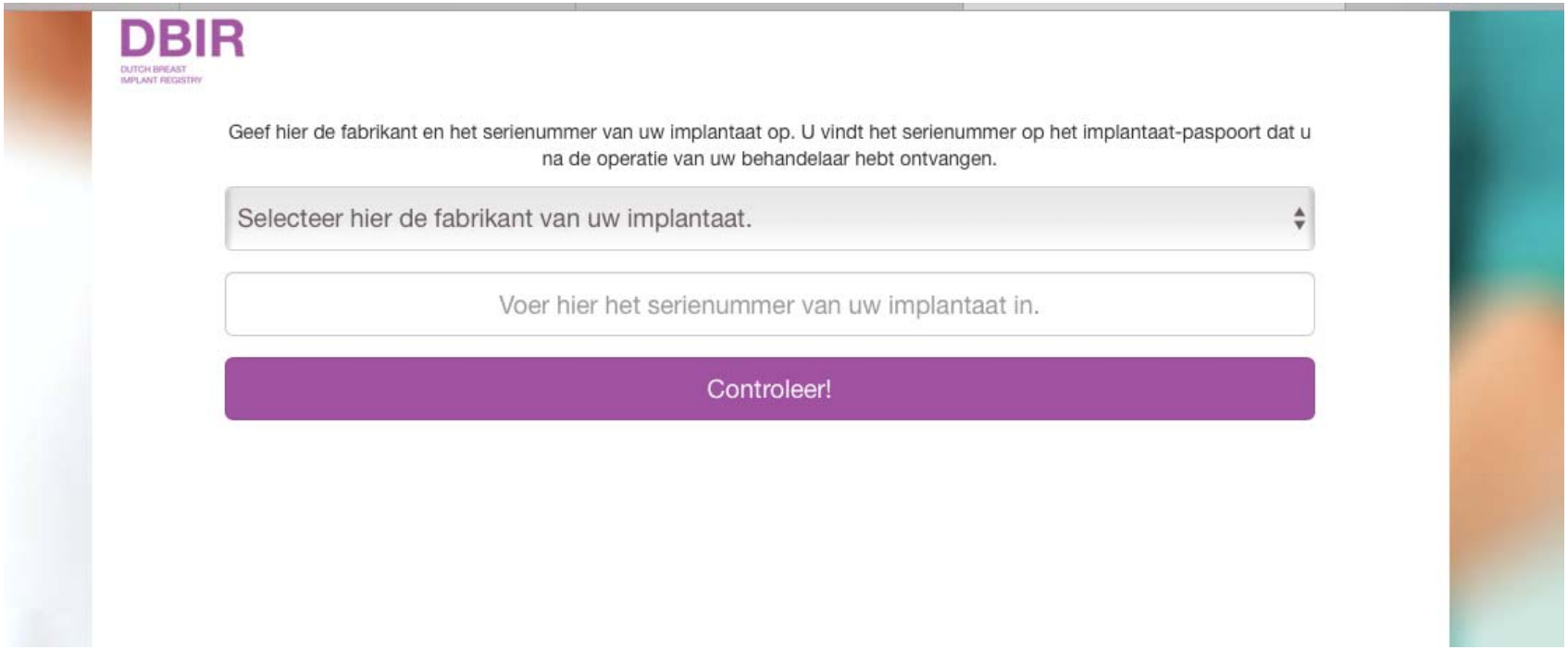
DUTCH BREAST IMPLANT REGISTRY
General information:
Registration of a patient is finished when all errors ( ) have disappeared.
Please visit the DICA website for instruction videos (section DBIR - Documenten)
R
Reference No*
TMM3 290cc
Lot Number*
157041
Serial Number*
X166F003
Volgende sectie
Toevoegen device

DBIR current status



Crisis

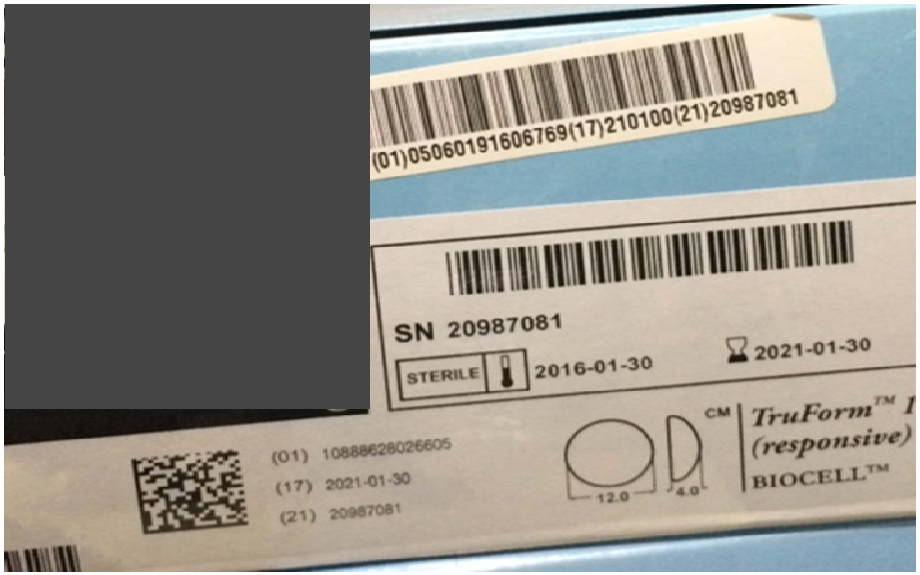
- In case of a crisis most patients have no problem



How is GS1 related?

Registry fails if information is incomplete or wrong

Problem: Product codes manually inserted



What do we need?

Better insights into the quality of care for patients with breast implants.

The quality of the data depend on you (industry & GS1).

Reduction of typo's
Reduction of time
Improvement reliability
Happier industry
Happier surgeons
Happier Hospitals

Happier and healthier patients

What do we need?

GS 1 coding system

- Scanning system (SN, LOT, expiry date)

Product data exchange through GS1 (GDSN)

- UDI linked to dimension, weight, silicone type, texture, fill

Globally aligned data to compare between countries

World wide one coding system

Why special?

- 1994 **UK -** NBIR / UKBIR
  - 1999 **DENMARK -** DRPSB
    - 2000; **NL**: DRIPS; ended prematurely due to withdrawal funding government
    - 2002 **USA -** TOPS
    - 2002 **USA -** NSQIP
    - 2002 **INTERNATIONAL** - IBIR
      - 2004 **AUSTRIA -** ABIR
        - 2011 **AUSTRALIA -** ABDR
          - 2012 **SWEDEN** - BRIMP
            - 2015 **NETHERLANDS** – DBIR
              - 2016 **UK** - BCIR

The future

Share implant data world wide

icobra

Questions

In case of questions, please mail me at

Juliette.hommes@mumc.nl

Patient Safety beyond borders

Panel discussion

In the past we have seen several initiatives for breast implant registries.
Why do you think this registry will succeed in more understanding of breast implant quality? What is the difference with past and other current registries?

Thank you very much for your attention