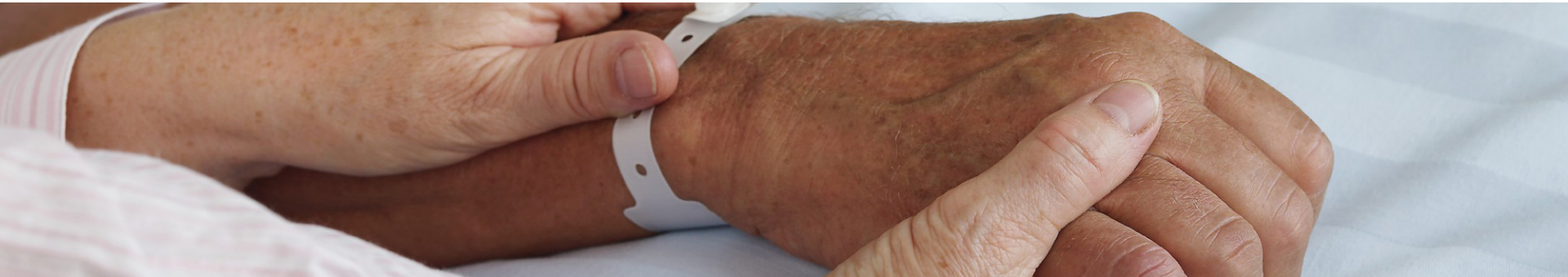
The Global Language of Business

Identification on the primary packaging level – for patient safety

Stream I – November 5th, 15.30-17.00

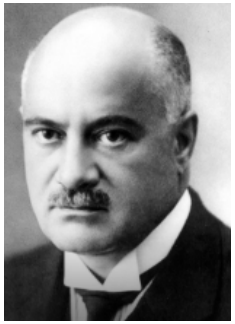
Identification on the primary packaging level – for patient safety

Sébastien Langlois-Berthelot



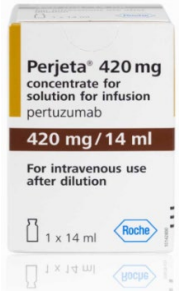
About Roche

A pioneer in Healthcare



- Founded in 1896 by Fritz Hoffmann-La Roche in Basel, Switzerland
- 1897 onwards Roche starts to expand worldwide
- 1968 Roche enters Diagnostics Market

TODAY – ROCHE CREATES INNOVATIVE MEDICINES AND DIAGNOSTIC TEST THAT HELP MILLIONS OF PATIENTS GLOBALLY

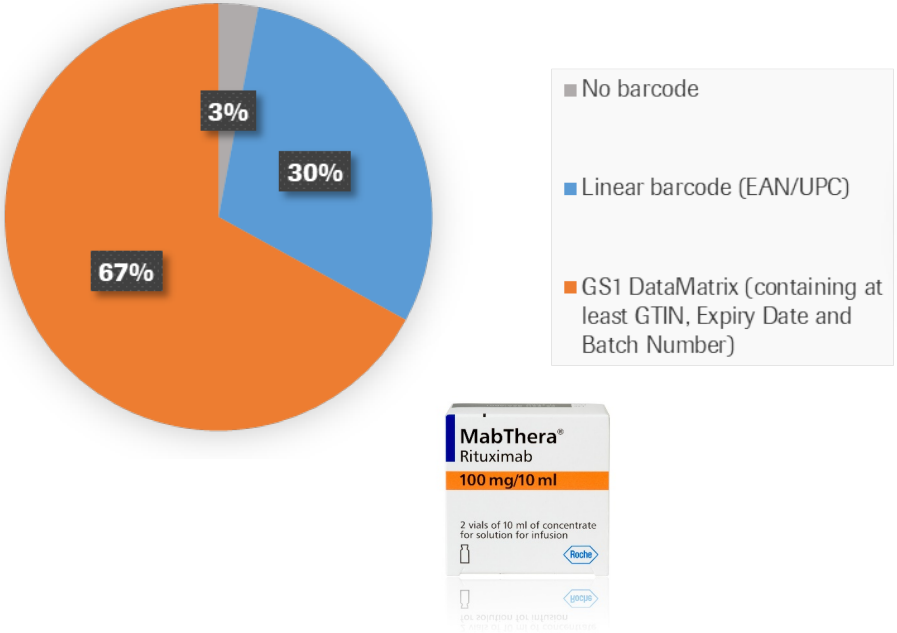


- Largest Biotech Company
- Frontrunner in Personalized Healthcare
- Global Leader in Cancer Treatments

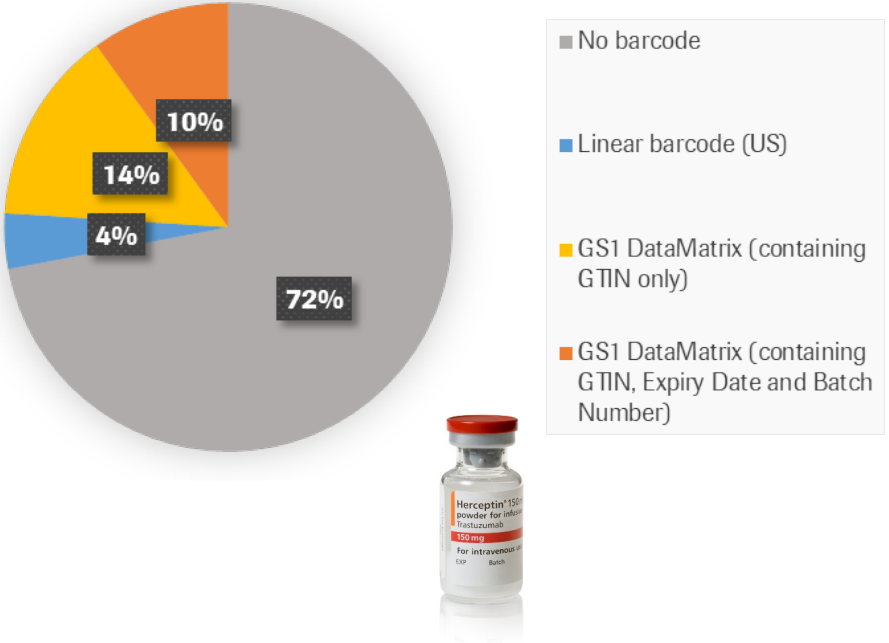
Barcode Implementation on Roche Pharmaceutical Products

Secondary vs. Primary Packaging

Barcodes on Secondary Packaging



Barcodes on Primary Packaging



Percentage of marketed Stock Keeping Units worldwide (March 2019)

Roche's Journey to Single Unit Barcodes

First Attempts to Meet Hospitals Needs (2011-2016)

GS1 DataMatrix with **GTIN only**

AMGROS Requirement in Denmark
(except for blisters)

Voluntary implementation for **all injectables in Switzerland**

Voluntary implementation for **infusion solution vials for all EU countries**
(centrally registered products)

Pictures for illustrative purposes only. Do not reflect the actual layout for the specific market.

Roche's Journey to Single Unit Barcodes

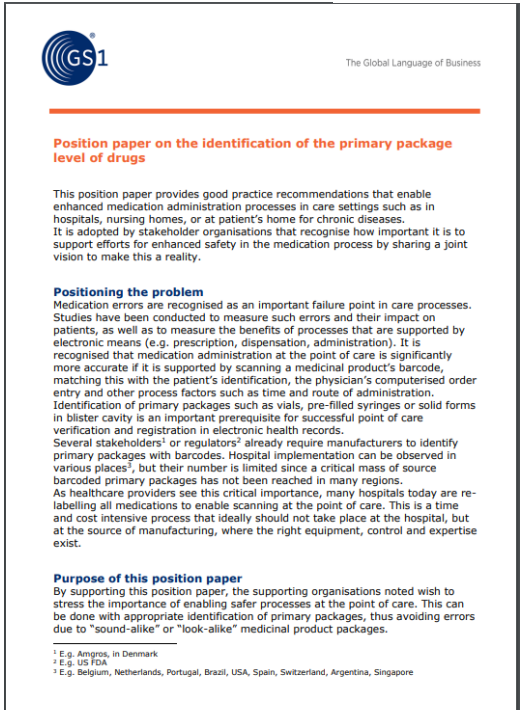
Moving to the next level (since 2017)

- Voluntary implementation of single unit coding **(GTIN + Expiry Date + Batch Number)** for **vials for selected products and markets**

- **Exploring technical possibilities** to implement on other types of containers (syringes, blisters)
- **Full implementation will take time!**

GS1 Position Paper on the identification of the primary package level of drugs (2017)

Endorsed by eahp european association of hospital pharmacists; efpia European Federation of Pharmaceutical Industries and Associations



GS1 The Global Language of Business

Position paper on the identification of the primary package level of drugs

This position paper provides good practice recommendations that enable enhanced medication administration processes in care settings such as in hospitals, nursing homes, or at patient's home for chronic diseases.
It is adopted by stakeholder organisations that recognise how important it is to support efforts for enhanced safety in the medication process by sharing a joint vision to make this a reality.

Positioning the problem

Medication errors are recognised as an important failure point in care processes. Studies have been conducted to measure such errors and their impact on patients, as well as to measure the benefits of processes that are supported by electronic means (e.g. prescription, dispensation, administration). It is recognised that medication administration at the point of care is significantly more accurate if it is supported by scanning a medicinal product's barcode, matching this with the patient's identification, the physician's computerised order entry and other process factors such as time and route of administration.
Identification of primary packages such as vials, pre-filled syringes or solid forms in blister cavity is an important prerequisite for successful point of care verification and registration in electronic health records.
Several stakeholders[1] or regulators[2] already require manufacturers to identify primary packages with barcodes. Hospital implementation can be observed in various places[3], but their number is limited since a critical mass of source barcoded primary packages has not been reached in many regions.
As healthcare providers see this critical importance, many hospitals today are re-labelling all medications to enable scanning at the point of care. This is a time and cost intensive process that ideally should not take place at the hospital, but at the source of manufacturing, where the right equipment, control and expertise exist.

Purpose of this position paper

By supporting this position paper, the supporting organisations noted wish to stress the importance of enabling safer processes at the point of care. This can be done with appropriate identification of primary packages, thus avoiding errors due to "sound-alike" or "look-alike" medicinal product packages.

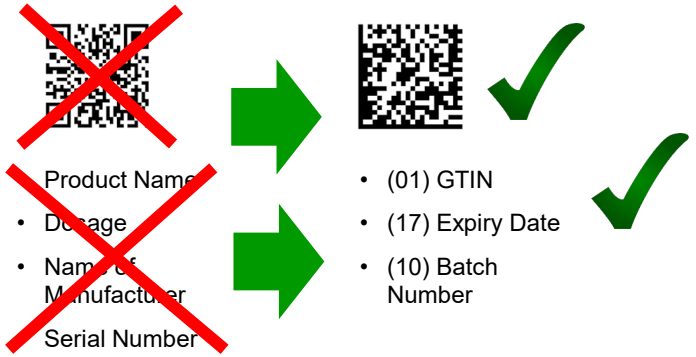
[1] E.g. Amgros, in Denmark
[2] E.g. US FDA
[3] E.g. Belgium, Netherlands, Portugal, Brazil, USA, Spain, Switzerland, Argentina, Singapore

Primary Packaging for Pharmaceuticals is often small

Space for barcode is limited: let's make the best use of it!

Key Recommendations for a successful implementation

- ✓ Leverage Global Standards: **DataMatrix** instead of QR code!
- ✓ Leverage **Global Trade Item Number (GTIN)** as globally unique product identification key to point to further product data in databases!



Take Home Messages

- Advocate for the use of **GS1 standards** and refer to **ISO 16791**, which mentions primary pack identification

- Make use of the **GS1 Position Paper on the Identification of the Primary Package Level of Drugs**, which has been endorsed by EFPIA (European Association of Pharmaceutical Manufacturers) and EAHP (European Association of Hospital Pharmacists) as a basis for requirements

- Need to **engage with health authorities** to increase awareness on the importance of point of care scanning, and help us solving the dilemma between barcode, text and font size on labels and blisters

- More and more leading hospitals worldwide introduce barcode requirements for **tender orders**. This is a strong incentive for manufacturers, provided **requirements are consistent and harmonized**

Link to the Position Paper: http://www.gs1.org/sites/default/files/docs/healthcare/position-papers/single_unit_position_paper_final300617.pdf

Doing now what patients need next

shpa Specialty Practice

Identification on the primary packaging level – for patient safety

Maryanne Molenaar

Closed Loop Electronic Medication Management

The use of technology in the medication management process, from ordering through to administration.

Aims to minimise manual selection, inputs and transcription, to reduce human effort and some risks of human error.

Why is CLEMM important?

Closed Loop Electronic Medication Management

How we are achieving CLEMM in Australia

- Royal Children's Hospital, Melbourne, VIC
  - In-house barcodes
- Princess Alexandra Hospital, Brisbane, QLD
  - GTINs
- Alfred Health, Melbourne, VIC
  - GTINs
- St Stephen's Uniting Care, Hervey Bay, QLD
  - Unit Dose Packaging

shpa

Closing the loop of medication management in hospitals to improve patient safety with barcoding technology on unit dose packaging

POSITION STATEMENT

Introduction

The medication safety benefits for patients of hospitals using electronic medication management systems are well documented as is also that most of these benefits are in the reduced number of errors of administration if closed loop medication management is incorporated into the electronic medication management system. To this end, a small number of Australian hospitals have endeavoured to implement closed loop medication management by adding barcodes to the unit dose of the medication to be administered; however, this is not sustainable for most Australian hospitals. This position statement addresses the issues faced by Australian hospitals in the absence of a standard for barcoding medications at the unit dose level and makes recommendations for such a standard.

shpa Specialty Practice

Further Information

maryanne.molenaar@easternhealth.org.au

https://www.shpa.org.au/sites/default/files/uploaded-content/website-content/Fact-sheets-position-statements/position_statement_-_unit_dose_packaging.pdf

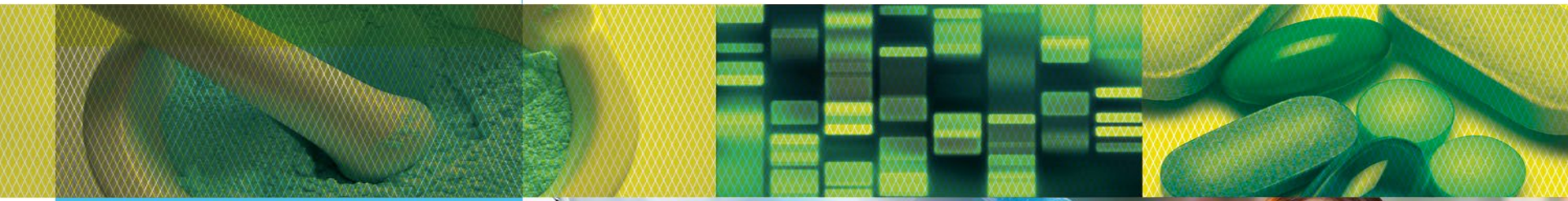
International Pharmaceutical Federation

Patient safety in the hospital

Robert J. Moss, hospital pharmacist, FFIP

President FIP Hospital Pharmacy Section

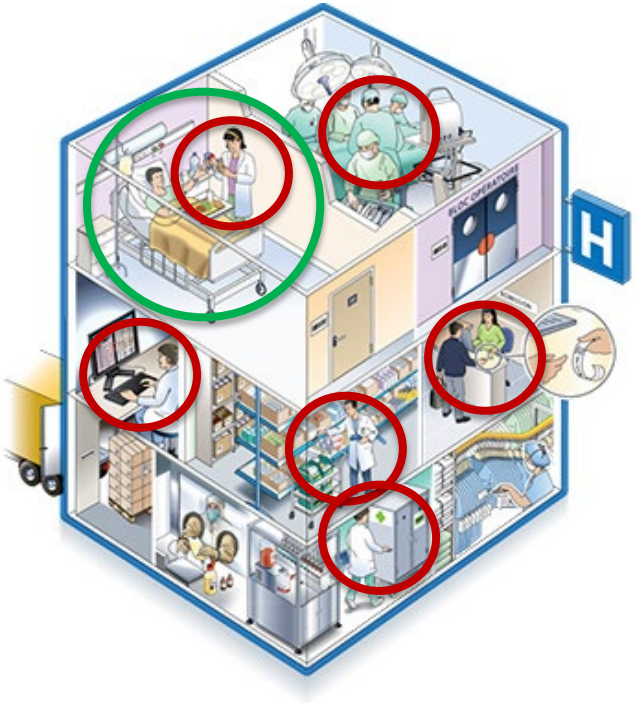
36th Global GS1 Healthcare Conference , November 5th, 2019



ADVANCING PHARMACY WORLDWIDE

Patient journey

Healthcare



Healthcare

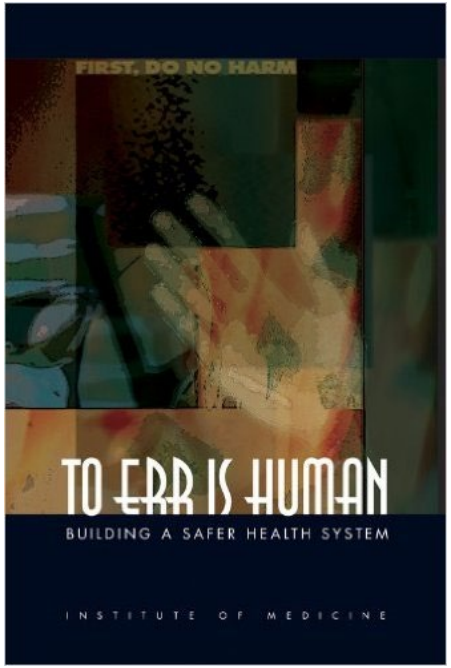
μὴ βλάπτειν

Primum non nocere

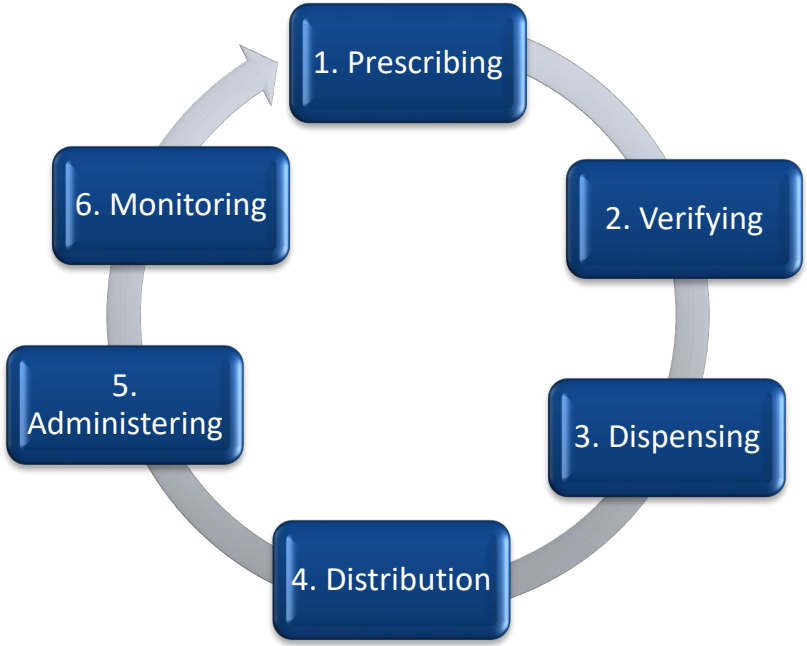
First do no harm

Patient safety

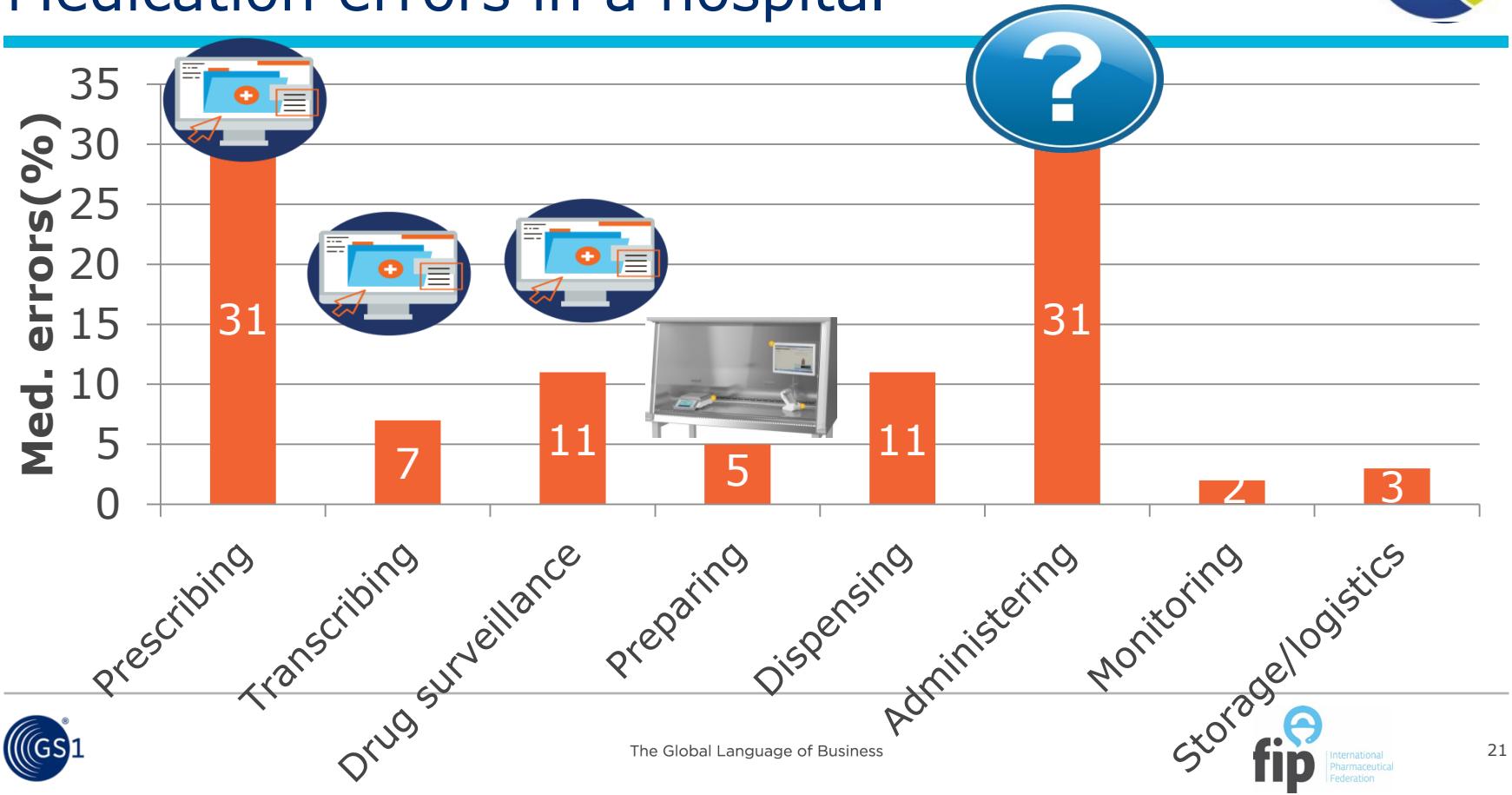
1999
Institute of Medicine (IOM) released the report, "To Err is Human: Building a Safer Health System"



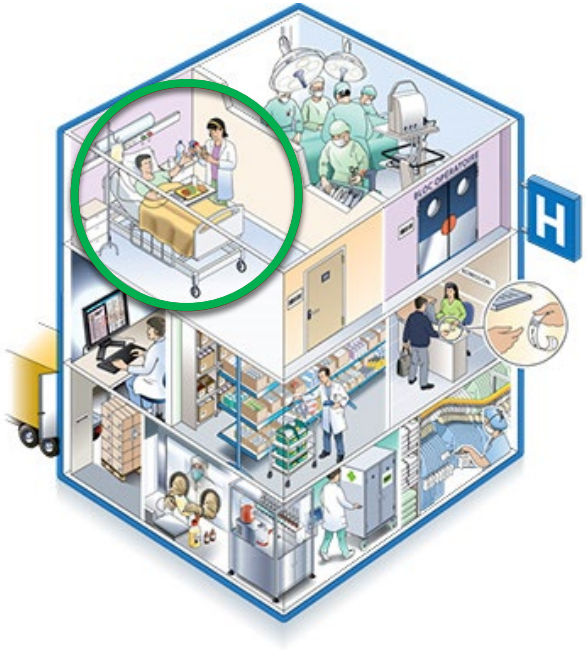
Medication in a hospital

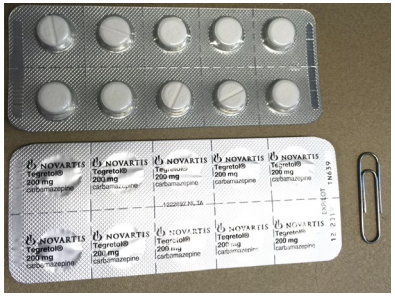


Medication errors in a hospital



Medication safety



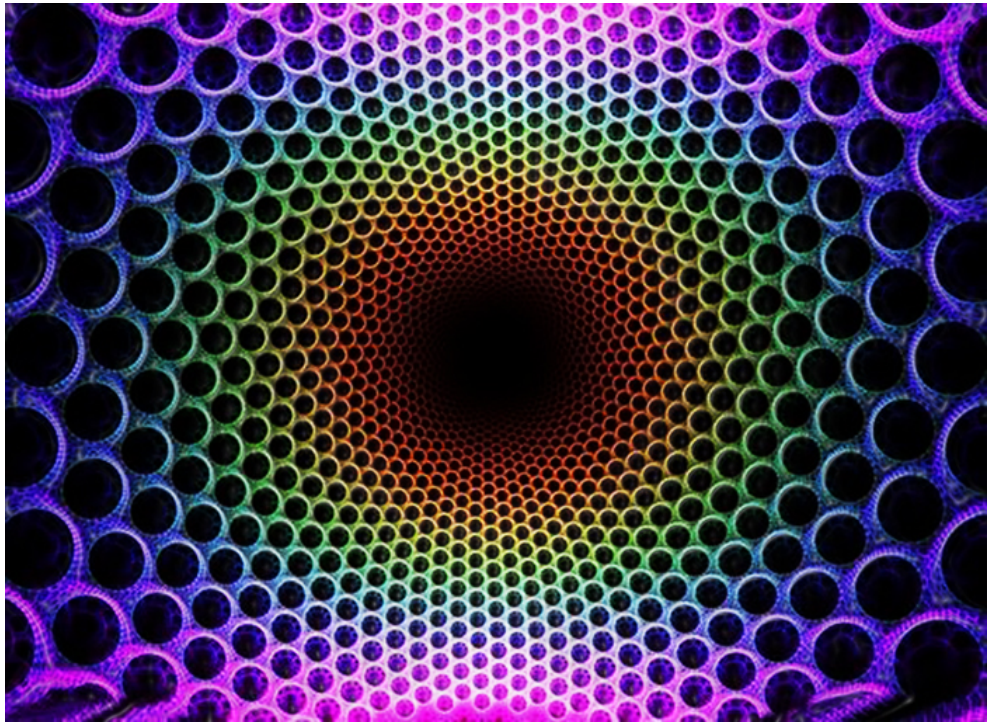


UNIT DOSE

- Identification
- Expiry date

- (01) GTIN
- (17) Expiry Date
- (10) Batch Number

Medication safety: the human factor



Medication safety: the human factor

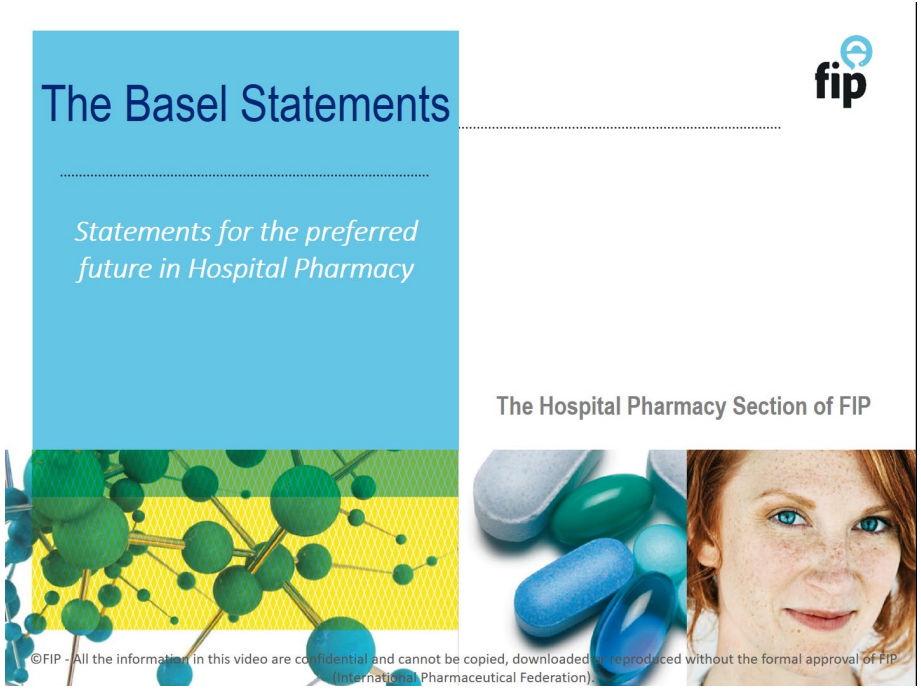
An itvgnoieatisn of an Elsginh Urinvetsiy dosecverid taht it dsoen't mtetar in wcihh oedrr the lteetrs are wteitrn in a wrod. The only itcnorapme is that the fsrit and the lsat lteetr are sdntniag at the rhgit ltcoioan.

Medication safety: the human factor

Medication safety

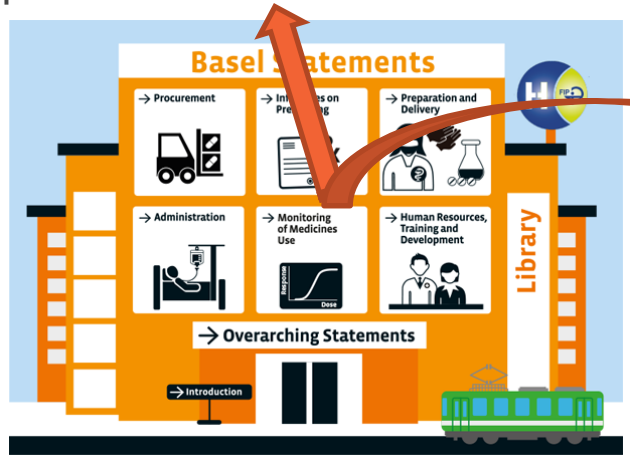
Medication safety

Medication safety



Medication safety

47. Hospital pharmacists should ensure the development of quality assurance strategies for medicines administration to detect errors and identify priorities for improvement

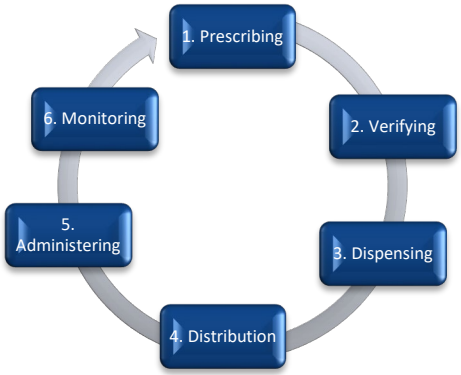


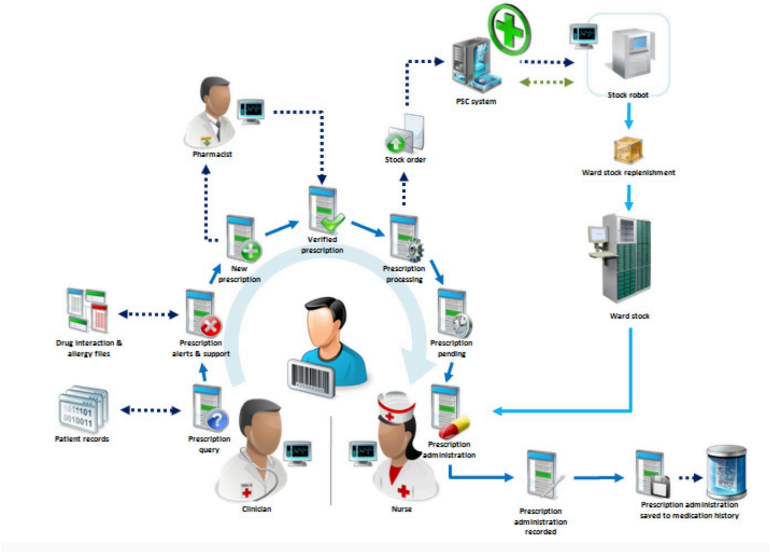
https://www.fip.org/basel-statements

48. The medicines administration process should be designed such that transcription steps between the original prescription and the medicines administration record are eliminated

Medication safety

Barcode Assisted Medication Administration





Medication safety

FDA workshop at the National Institutes of Health "Minimzing Medical Product Errors: A Systems Approach"

Drug manufacturers should make high leverage changes prior to marketing a product, including providing medications in unit dose packages and bar-coding their products.

1998 1999 2000 2001 2002 2003 2004

Medication safety

Report prepared by the Qual Coor Task F to the IOM report

Bar coding of medications and use of robotics in dispensing medications can ensure that the appropriate medication is provided to the appropriate patient at the appropriate time.

1998 1999 2000 2001 2002 2003 2004

Medication safety

National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) recommends the implementation of uniform bar code standards into the medication use process

ASHP Statement on Bar-Code-Enabled Medication Administration Technology

HIMSS-sponsored journal, (JHIM) touted BCMA to Health IT industry

Medication safety

"A safe and effective medication-distribution system that is consistent throughout the organization." As part of that mandate, the standard will *require unit-of-use packaging* "when the medication is available from the manufacturer in such packaging, or repackaging by pharmacy into unit-dose is feasible."

Joint Commission on Accreditation of Healthcare Organizations (JCAHO), proposed a new set of medication-use standards

FDA propose a new rule requiring bar codes on certain drug and biological product labels

Medication safety

Manufacturers, repackers, relabelers, and private label distributors of prescription and OTC drugs would be *subject to the bar code requirements*.
Applies to prescription drugs, biological products (other than blood, blood components, and devices regulated by the Centre for Biologics Evaluation and Research), and over-the-counter (OTC) drugs that are commonly used in hospitals.

FDA's final rule on bar code labelling

1998 1999 2000 2001 2002 2003 2004

Medication safety

BCMA: implementation

92.6% of **US** hospitals have **barcode-assisted medication administration** systems, **ASHP national survey of pharmacy practice in hospital settings: Prescribing and transcribing-2016**
Pedersen CA, Schneider PJ, Scheckelhoff DJ, Am J Health Syst Pharm. 2017 Sep 1;74(17):1336-1352

1999 2004 2009 2014 2019 2024

BCMA: implementation

SCAN4SAFETY
Patient. Product. Place. Process.

GS1 Healthcare Reference Book 2019-2020

Stories of successful implementations of GS1 standards

1999 2004 2009 2014 2019 2024

BCMA: repackaging

FDA workshop at the National Institutes of Health "Minimzing Medical Product Errors: A Systems Approach"

FDA's final rule on bar code labelling

1999 2004 2009 2014 2019 2024

BCMA: implementation

?? % of **non-US** hospitals have **barcode-assisted medication administration** systems

- **JCI accreditation**
- **Individual activities**
- **National programs?**

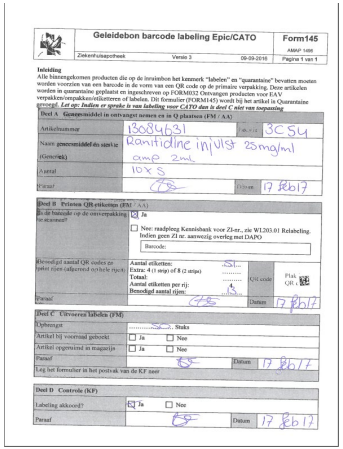
1999 2004 2009 2014 2019 2024

BCMA: repackaging

Slide kindly provided by P. Helmons, St Jansdal

1999 2004 2009 2014 2019 2024

BCMA: repackaging



Geleidebon barcode labeling Epic/CATO

Form145

Slide kindly provided by P. Helmons, St Jansdal

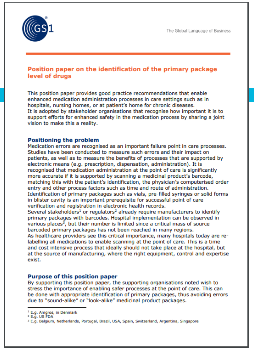
1999 2004 2009 2014 2019 2024

Medication safety

Medication safety

FDA workshop at the National Institutes of Health "Minimzing Medical Product Errors: A Systems Approach"

FDA's final rule on bar code labelling


The Global Language of Business

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[1] E.g. Amgros, in Denmark
[2] E.g. US FDA
[3] E.g. Belgium, Netherlands, Portugal, Brazil, USA, Spain, Switzerland, Argentina, Singapore

GS1 Position Paper on the identification of the primary package level of drugs *(2017)*

Endorsed by eahp (european association of hospital pharmacists) and efpia (European Federation of Pharmaceutical Industries and Associations)

1999 | 2004 | 2009 | 2014 | 2019 | 2024

Medication safety

Additional tendering options to improve patient safety (e.g. primary package barcoding or avoiding soundalike/lookalike) or efficiency (e.g. aggregated barcoding for compliance with the Falsified Medicines Directive) can be incorporated in the procurement process

eahp
european association of hospital pharmacists

EAHP Position Paper on Procurement

Advocating for the involvement of hospital pharmacists in procurement

Medication safety

BCMA: publications

- Implementing BC
  with significant r
  administration er
  dose errors. **Effe**
  medication adr
  department me
  al, Acad Emerg M

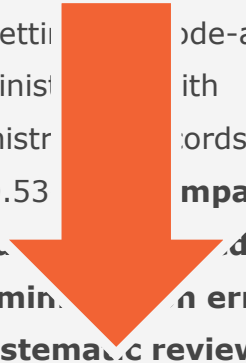
Implementation of BCMA-eMAR in two hospitals was associated with significant increases in total medication **barcode techn** **medication adı** **medication acc** Maddox RR, Flynn EA, Williams CK, Am J Health Syst Pharm. 2014 Feb 1;71(3):209-18

Onsite pharmacist dispensing and BCMA were associated with fewer **medication** errors and are important components of a **medication** safety strategy in CAHs. **Comparison of medication safety systems in critical access hospitals: Combined analysis of two studies** Cochran GL[1], Barrett RS[2], Horn SD, Am J Health Syst Pharm. 2016 Aug 1;73(15):1167-73

1999 2004 2009 2014 2019 2024

BCMA: reviews

Review and critically appraise interventions designed to reduce MAEs in the hospital setti ode-assisted medication adminis ith electronic administr ords (0.71, 95 % CI 0.53 **mpac interventions du medication admin n errors in hospitals: a systema c review** Keers et al, Drug Saf. 2014 May;37(5):317-32



- 30-50%

BCMA has the potential to reduce nontiming administration errors, transcription errors, and total **ion ematic y When Used er Entry and Automated Dispensing Devices (Shah et al,** Can J Hosp Pharm. 2016 Sep-Oct; 69(5): 394–402)

1999 2004 2009 2014 2019 2024

BCMA: reports

Barcodes on medication save 47 lives each year!

Trouw

HOME RELIGIE EN FILOSOFIE GROEN DEMOCRATIE SAMENLEVING CULTUUR OPINIE

47 dode patiënten per jaar minder door barcodes op medicijnen

HOME

Jos de Groot – 18:43, 5 april 2017

Een barcode op ziekenhuismedicijnen kan per jaar bijna vijftig dode patiënten voorkomen. Jaarlijks overlijden honderd mensen in Nederlandse ziekenhuizen na verkeerde medicijnen te hebben gekregen, waarvan de helft dus onnodig, blijkt uit onderzoek van het ministerie van Volksgezondheid.

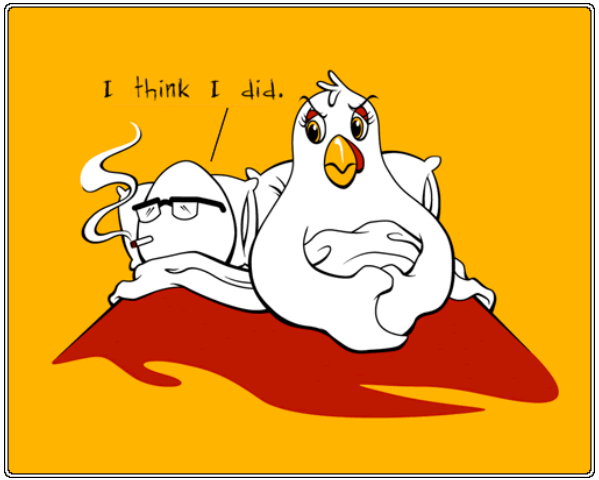
And:

- **250** cases of preventable harm
  - **10.000** additional days in the hospital
  - Total savings: **€21,4 million** euro
  - Current number of Dutch hospitals with BCMA or other computerized check: about 10 (11%)

https://www.rijksoverheid.nl/documenten/kamerstukken/2017/01/31/kamerbrief-over-barcodering-primaire-verpakking-geneesmiddelen (Dutch)

1999 2004 2009 2014 2019 2024

BCMA: primary pack barcoding



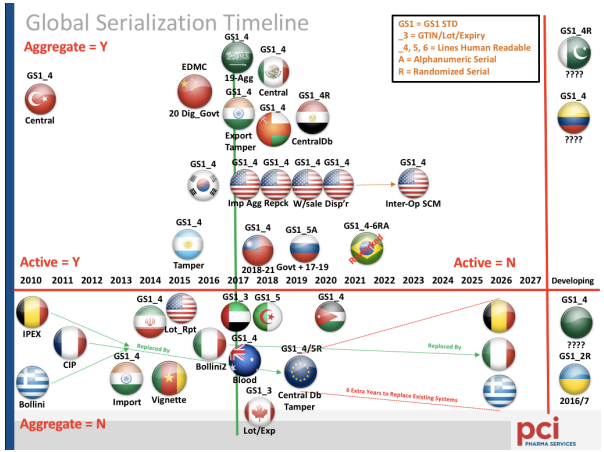
‘They’ are not ready

1999 2004 2009 2014 2019 2024

Serialisation

FDA's final rule on bar code labelling

Anti-SF serialisation



1999 2004 2009 2014 2019 2024

Serialisation

Patient safety

FDA's final rule on bar code labelling

1999 2004 2009 2014 2019 2024

Medication safety

Medication safety

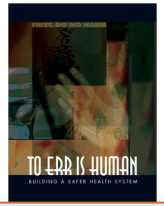
BCMA: implementation

non-US hospitals have **barcode-assisted medication administration** systems

- **Availability of primary pack barcoding using GS1 standards**

1999 2004 2009 2014 2019 2024

Medication safety: a common standard



FDA workshop at the National Institutes of Health "Minimzing Medical Product Errors: A Systems Approach"

1999 2004 2009 2014 2019 2024

Thank you for your attention

FIP Hospital Pharmacy Section

rob.moss@fip-hps.org