



Bedside scanning & medicines bar coding: the international picture

Ulrike Kreysa, Vice President GS1 Global Office

EAHP meeting at University hospital Leuven/Belgium, 14 October 2013





**Imagine
your child ...**



**... has an
accident.**



**Takes an
ambulance...**



**...to the
hospital.**



**They take
x-rays...**



**...and do
tests.**



**Maybe
perform
surgery.**



**There's all
sorts of
medicine...**



...all sorts.



**And it's
dispensed
by all sorts
of routes...**



...all sorts.



**But doctors
and nurses
are only
human.**

**And that means mistakes
can happen.**

**A problem at the
supermarket checkout
costs time and money.**

**A problem at the
supermarket checkout
costs time and money.**

**A problem at the hospital
can cost a **life**.**

**GS1 standards can help to
reduce medication errors.**



GS1 – an international standard organisation



Not-for-profit

111 Member Organisations

**Over one million user companies
(from SME to global companies)**

Member driven

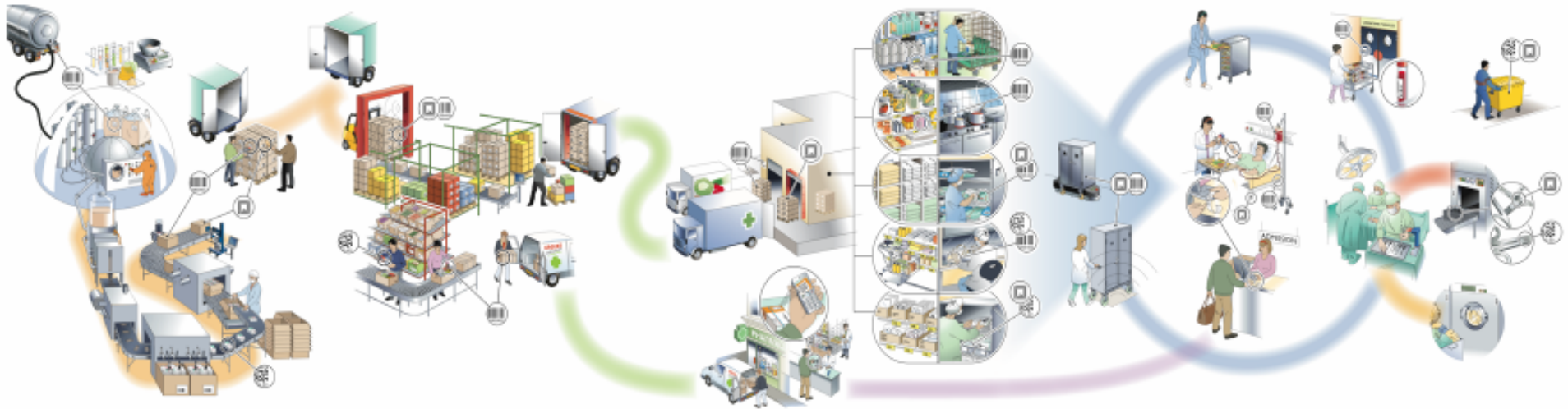
150 countries served; 20 different domains

2,500 people helping us

Over 6 billion transactions a day



GS1 Healthcare - a voluntary, global Healthcare User Group



To lead the healthcare sector to the successful development and implementation of **global standards** by bringing together **experts** in healthcare to enhance **patient safety** and **supply chain efficiencies**.



GS1 Healthcare User Group

Supply-side organisations engaging further





Leading healthcare organisations pave the way...

Buyer/Provider-side organisations going global



France



Germany



Netherlands



Macedonia



Hong Kong



Switzerland



Austria



Saudi Arabia



Germany



USA



Austria



USA



Ireland



Netherlands



France



USA



USA



GS1 Healthcare around the World

Members global user group

Manufacturers

- 3M
- Abbott Laboratories/Abbvie
- Alcon Labs
- Amgen
- Astra Zeneca
- B. Braun
- Baxter
- Bayer
- Becton Dickenson
- Cook Medical
- Covidien
- Edwards Lifescience
- F. Hoffmann-La Roche Ltd
- Fresenius
- GE Healthcare
- Genzyme
- GlaxoSmithKline
- Johnson & Johnson
- Medtronic
- Merck & Co.
- Pall Medical
- Pfizer
- Purdue Pharma
- Smiths Medical
- Takeda
- TEVA
- Zimmer

Solution provider

- Advanco
- Axway
- GHX
- Seidenader
- Excellis Health
- Tracelink
- Oracle

Distributors/Healthcare providers/ GPOs/T&L

- AmerisourceBergen (US)
- Cardinal Health (US)
- CH Aulnay sous Bois (France)
- Comparatio Health (Germany)
- DHL Exel Supply Chain (UK)
- Erasmus MC Rotterdam (NL)
- Filip Vtori (Macedonia)
- Hong Kong Hospital Authorities
- King FAISAL Specialist Hospital & Research Center (Saudi Arabia)
- McKesson (US)
- Novation (US)
- Orthopädisches Spital Speising Wien (Austria)
- Premier (US)
- St. James Hospital (Ireland)
- Marienhospital Herne (Germany)
- UMC Groningen (NL)
- UNI.HA (representing 17 French university hospitals)
- University Kentucky Healthcare (US)
- Wiener Krankenanstaltenverbund (Austria)

Non-voting members

- AHRMM
- Cladimed
- EDQM – Council of Europe
- FDA USA
- Instituto Brasileiro de Ética Concorrencial – ETCO
- Public Health Agency of Canada
- US DoD

Local participation

Manufacturers

- 3M
- Bayer
- Becton Dickinson
- Boehringer Ingelheim
- Coloplast
- Draeger Medical
- Genzyme
- Hospira
- Kimberly-Clark
- Novo Nordisk
- Purdue Pharma
- St. Jude Medical
- Stryker
- Teva Pharmaceuticals
- Terumo
- UCB
- Upsher-Smith

Distributors/Wholesalers

- Aexxdis
- Amerinet
- AmerisourceBergen
- CH2
- Depolabo
- Galexis
- GAMMA Wholesale
- Geodis
- McMahan
- Owens & Minor

Healthcare providers/Retailers

- Alfred Hospital (Australia)
- Ascension Health (US)
- Capital District Health (Canada)
- CHU de Québec (Canada)
- CHU Dijon (France)
- HUG Geneva (Switzerland)
- London Drugs (UK)
- Mayo Clinic (US)
- Sisters of Mercy (US)
- Sobeys Pharmacy (UK)
- UHCS Augusta VA (US)
- Walgreens (US)
- Walmart (US)

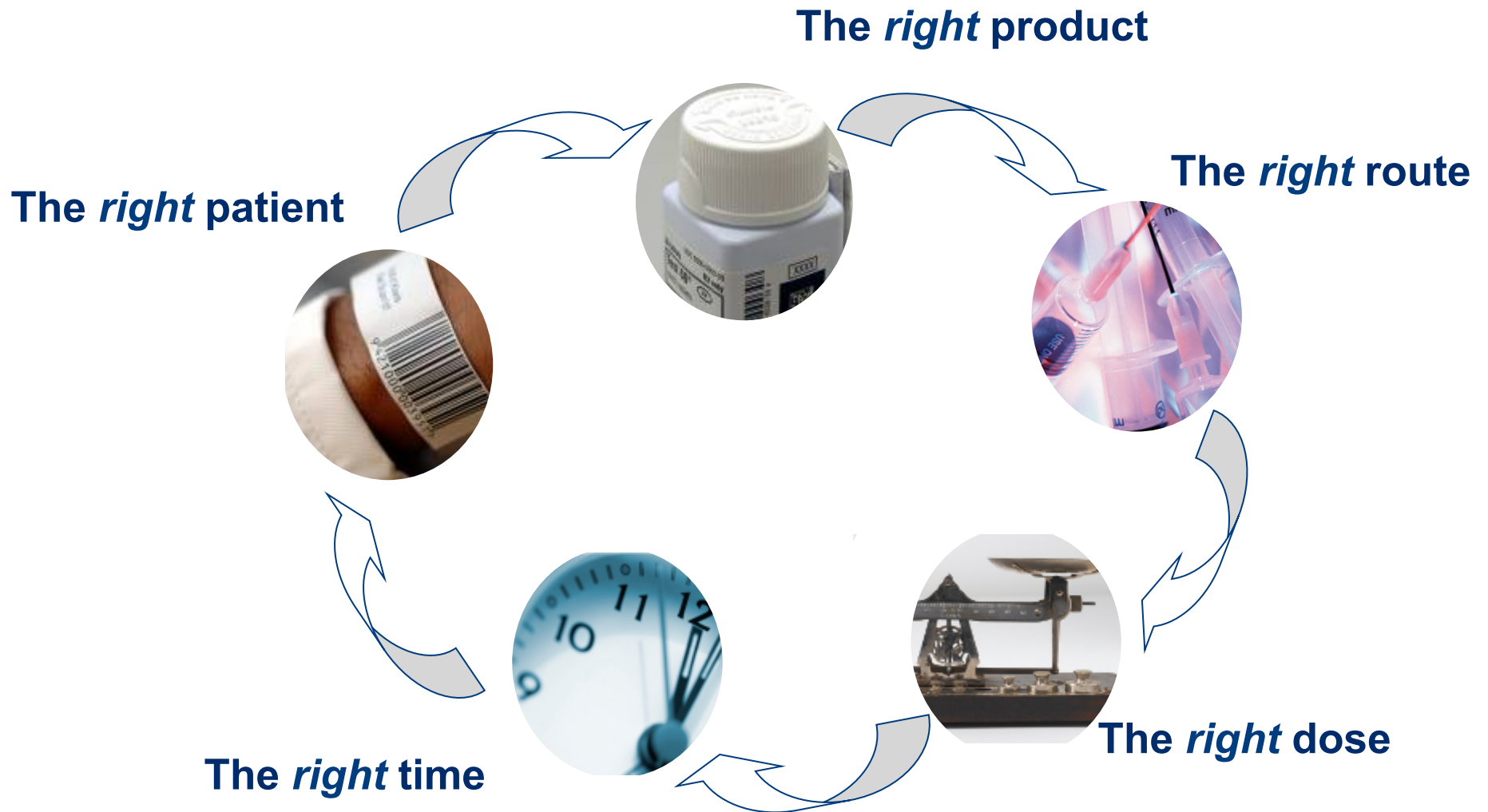
Associations

- AHA (US)
- CIP/ACL (France)
- CHeS (US)
- EAHP (Europe)
- EFPIA (Europe)
- Eucomed (Europe)
- FENIN (Spain)
- GIRP (Europe)
- HDMA (US)
- International Hospital Federation
- JFMDA (Japan)
- Medical Industry Association of Australia
- NACDS (US)
- Patient Safety Foundation (US)

... And many more ...



Ensuring the '5 Patient Rights'

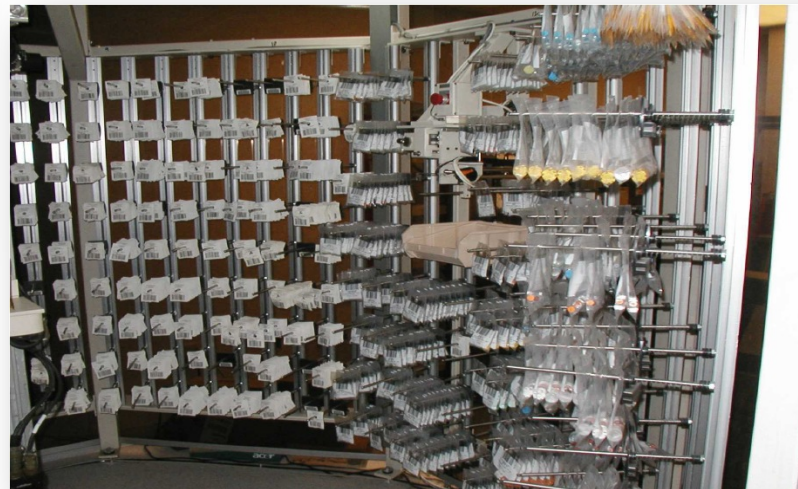




The Need for Global standards in Healthcare

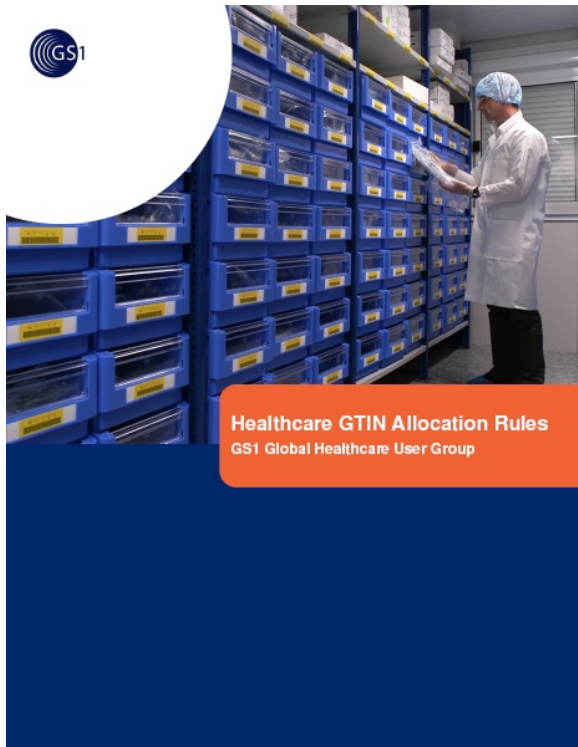


Re-bar coding by the hospital (or a 3rd party provider)





UPDATED: GTIN Allocation Rules for Healthcare



- Voluntary standards developed by GS1 Healthcare providing simple examples tailored for the global Healthcare sector
- Products in scope:
 - Pharmaceuticals (OTC and Rx)
 - Medical devices
- Local regulations may apply and take precedence over this voluntary guideline
- *Available online at www.gs1.org/healthcare*

Now including “level below the each” = primary packaging identification and marking

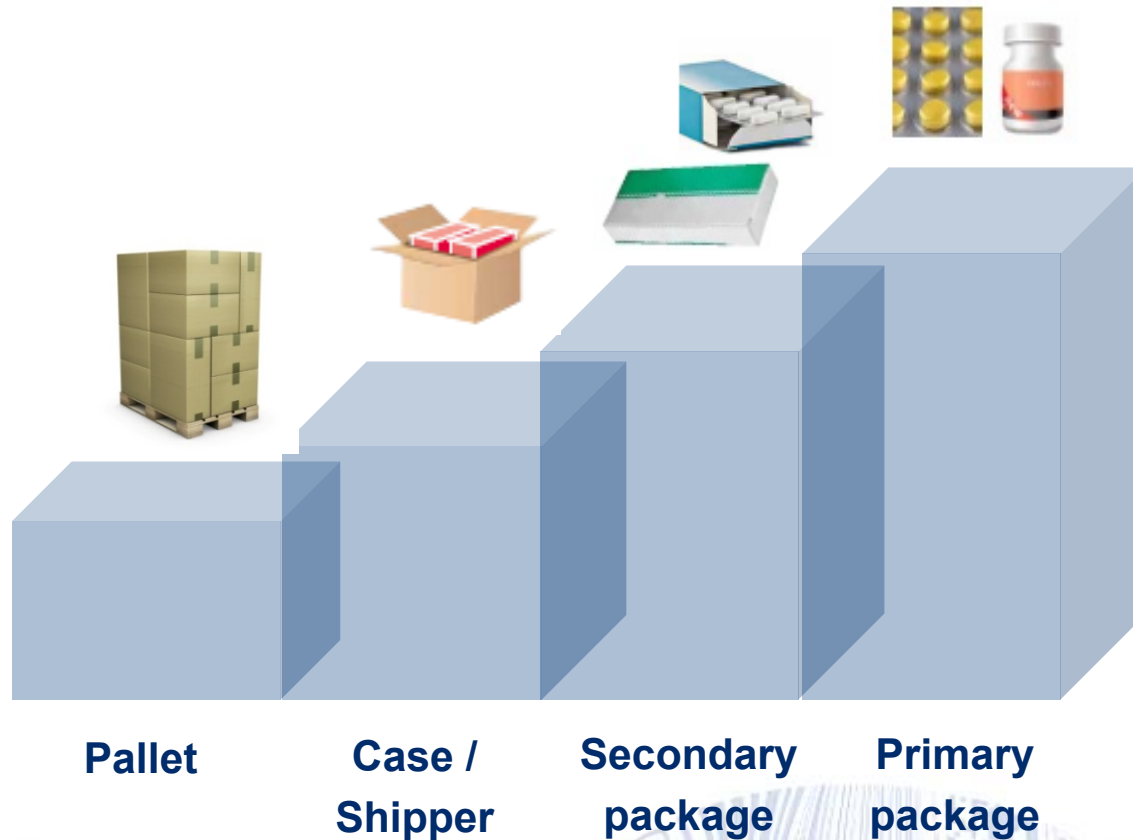


GTIN = Global Trade Item Number

- A *trade item* is any item (product or service) upon which there is a need to retrieve pre-defined information and that may be priced, or ordered, or invoiced at any point in any supply chain. This includes individual items as well as all their different configurations in different types of packaging.
- The Global Trade Item Number™ (GTIN™) is used for the unique identification of trade items worldwide. GTINs may be 8, 12, 13 or 14-digits in length. Their data structures require up to 14-digit fields, and all GTIN processing software should allow for 14 digits.



Packaging levels



Different packaging levels require different GTIN's



Capturing the identification by using GS1's semantics



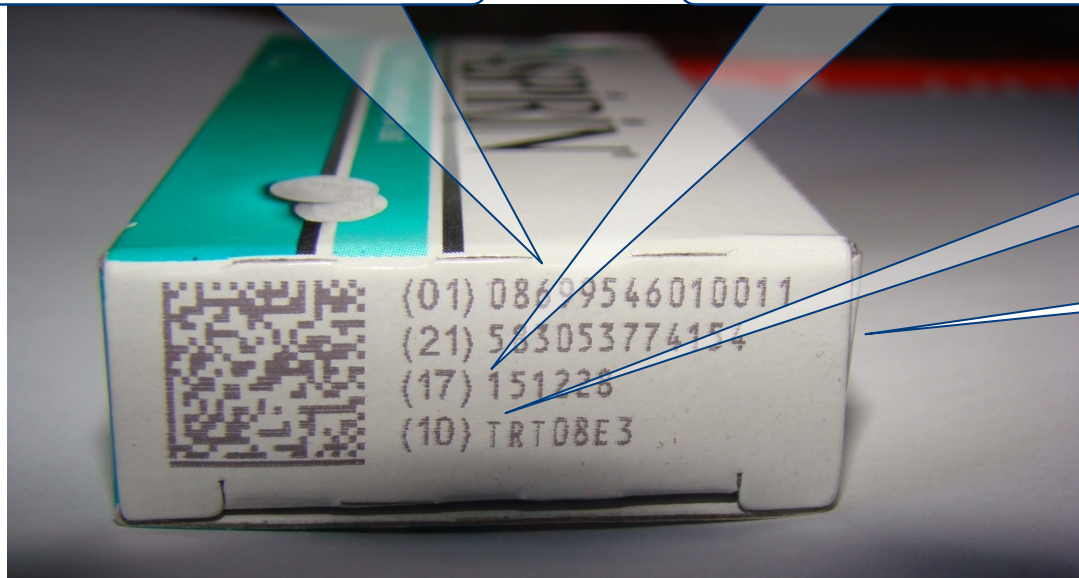
(01)1022222333334(17)091231(10)A1345B(21)1234

GTIN

Expiry Date

Lot/Batch Number

Serial Number





LBE..... Level Below the Each

- «Each» (secondary package) is a fundamental concept for GDSN (catalogue) and corresponds to the smallest saleable unit (always GTIN 12 or 13)
- In the retail market, the smallest unit will be scanned at POS (S=sale)
- In the Healthcare industry, there is a smaller unit, which will be scanned at the POC (C=care)





Some new definitions...

Thanks to EAHP and other global experts

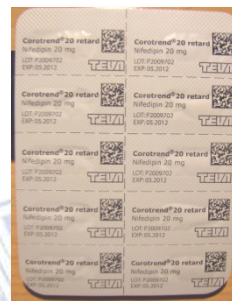
- **Single unit** = Single item of medicine/Medical device without any package, for example the single tablet in a blister or bottle, the syringe as such.



- **Single unit package** (GS1 primary package) is the one that contains one discrete pharmaceutical dosage form. i.e. a tablet, a certain volume of a liquid *or* that is the immediate package for a medical device like a syringe



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close up of a data matrix on a vial



New definitions also

- **Multiple unit package** (can also be GS1 primary package) – Immediate package for a medicine with more than one single unit



- **OUT OF SCOPE: Unit dose** (unit dose is the prescribed dose for a **patient** while single unit relates to the **product**)



Standard = agreement of industry



- Single unit – allocation is responsibility of brand owner, not expected to be marked in AIDC format
- Single unit package = primary package = GTIN, other data attribute like lot/batch number, expiry date, serial number are voluntary
- Secondary package = GTIN and attribute data (expiry date and/or lot/batch number and/or serial number)



New McKinsey & Company report quantifies supply chain issues in Healthcare



New McKinsey report “Strength in unity: The promise of global standards in healthcare”

Highlights the cost savings and patient safety benefits of adopting a single global supply chain standard in healthcare

Available at:

<http://www.gs1.org/healthcare/mckinsey> or

http://www.gs1.org/docs/healthcare/McKinsey_Healthcare_Report_Strength_in_Unity.pdf

Source: <http://www.mckinsey.com>



Huge cost savings and patient safety benefits when adopting a single global standard in healthcare

- “Implementing **global standards** across the entire healthcare supply chain **could save 22,000-43,000 lives** and avert 0.7 million to 1.4 million patient disabilities”
- “Rolling out such standards-based systems globally **could prevent tens of billions of dollars’ worth of counterfeit drugs** from entering the legitimate supply chain”
- [We] “estimate that **healthcare cost could be reduced by \$40 billion-\$100 billion globally**” from the implementation of global standards
- “Adopting **a single set of global standards** will cost significantly less than two” (between 10-25% less cost to stakeholders)

SOURCE: McKinsey report, “Strength in unity: The promise of global standards in healthcare”, October 2012



To Err is human...



...and nobody wants to harm patients!



The best way forward to prevent medication errors

Customer pressure/requirements?



Regulation/directive?



Agreement between stakeholders?





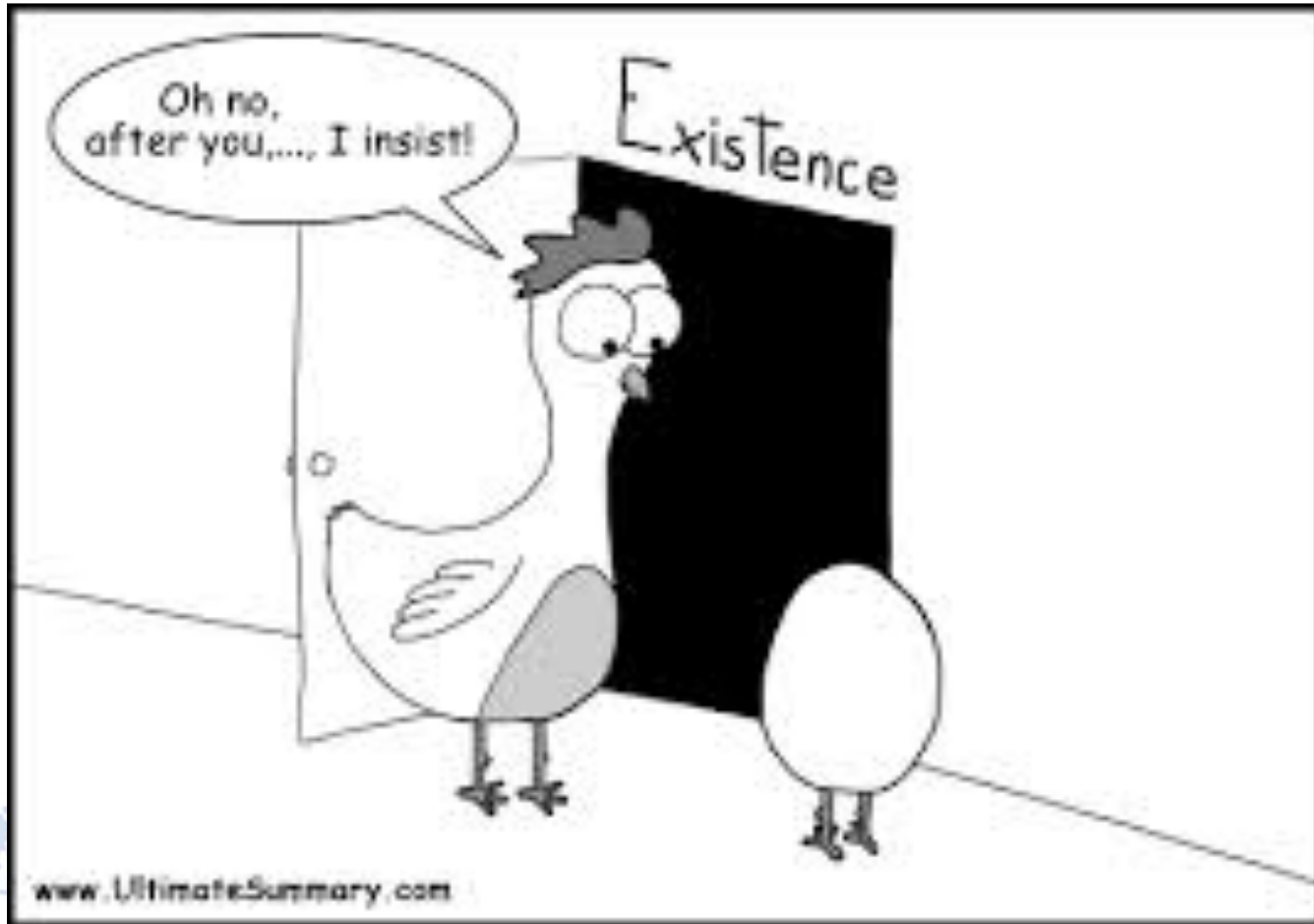
Experiences and developments – some examples

- **US:** 60% of all hospitals scan covering 70% of all hospitals beds
- **Denmark:** Amgros requiring identification on primary packaging level for certain products
- **Brasil and Argentina:** Bedside scanning in multiple hospitals
- **France:** New requirements for identification on LBE level
- **Taiwan:** Study shows benefits – regulation?
- **Netherlands:** Hospitals prove benefits
- **Austria and Switzerland:** Cytostatics from production to bedside

...and there are others



We must overcome this...





Global standards enable **patient safety** worldwide !





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