Achieving single unit pharmaceutical traceability

“know the flow,
halt the fault”

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Disclosure

BE NICE TO PHARMACISTS BECAUSE WE CAN KILL U WITH ONE MISTAKE
WestfriesGasthuis Hospital

- 500 beds
- 160,000 first patient visits
- 3200 staff
- 250 medical specialists
Visibly active, personally present and embedded in healthcare!
Achieving single unit pharmaceutical traceability

- What is the problem?
- What are possible solutions?
- What are the problems to the solutions?
- Where are we at?
What’s the problem?

- **39%** Prescribing
- **12%** Transcribing
- **11%** Logistic

50% caught

- **38%** Administer
- **2%** caught

Of every 100 errors...

- **20**
- **6**
- **6**
- **37**

... reach the patient

Bates DW, JAMA 1995;274:29
BCMA results

Where are we now?

### INSTALLED BASE OF KEY COMPONENTS

<table>
<thead>
<tr>
<th></th>
<th>Germany</th>
<th>Italy</th>
<th>Spain</th>
<th>Netherlands</th>
<th>Poland</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacy in Hospital</td>
<td>89.3%</td>
<td>100.0%</td>
<td>99.2%</td>
<td>100%</td>
<td>96.0%</td>
</tr>
<tr>
<td>Pharmacy IS</td>
<td>50.9%</td>
<td>75.1%</td>
<td>95.9%</td>
<td>99.7%</td>
<td>74.4%</td>
</tr>
<tr>
<td>ePrescribing</td>
<td>34.8%</td>
<td>35.1%</td>
<td>54.3%</td>
<td>94.7%</td>
<td>7.6%</td>
</tr>
<tr>
<td>eMAR, of which</td>
<td>37.6%</td>
<td>31.8%</td>
<td>88.3%</td>
<td>77.3%</td>
<td>7.8%</td>
</tr>
<tr>
<td>Available at bedside</td>
<td>14.0%</td>
<td>73.7%</td>
<td>75.3%</td>
<td>96.7%</td>
<td>0.0%</td>
</tr>
<tr>
<td>ADM Unit-Dose</td>
<td>3.6%</td>
<td>5.9%</td>
<td>35.1%</td>
<td>40.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Bar code / RFID, of which</td>
<td>79.5%</td>
<td>92.3%</td>
<td>77.4%</td>
<td>93.1%</td>
<td>64.6%</td>
</tr>
<tr>
<td>for Medication</td>
<td>40.3%</td>
<td>26.3%</td>
<td>31.1%</td>
<td>65.7%</td>
<td>4.2%</td>
</tr>
<tr>
<td>CLMA (self-perception)</td>
<td>3.5%</td>
<td>10.5%</td>
<td>34.0%</td>
<td>41.1%</td>
<td>0.0%</td>
</tr>
</tbody>
</table>

Source: HIMSS Analytics Europe, eHospital Census, 2012
Why don’t we use barcodes?

Lack of (standardised) barcode use on a European level
Development US

- 1964 Since 1964 (Barker) Unit dose
- 1999 Institute of Medicine (IOM) report: ‘To Err is Human: Building a Safer Health System’
- 2001 Federation of American Hospitals (FAH) called for barcoding on primary packaging
- 2002 JCAHO new set of medication use standards
- 2006 FDA's final regulation: mandatory barcode labelling primary packaging for drugs supplied to hospitals
- 2014 Use has increased: 1.4% (2002) → 88.4% (2014)
Netherlands?

- 1969 single unit pharmaceuticals are used in Dutch hospitals
- 1992 NVZA Standards for Unit dose (single units)
- 2000 New Standards NVZA
  - Including 2D barcode
- 2012 EAHP statement

**EAHP STATEMENT ON THE NEED FOR BARCODING OF THE SINGLE DOSE ADMINISTERED IN HOSPITALS**

**JUNE 2012 (UPDATE FROM 2007 & 2010 STATEMENTS)**

**What is meant by barcoding of the single dose?**

By “single dose” EAHP refers to the single item of medicine in an individual packaged component. This could for example include the single medicine within a perforated multi-dose blister pack, a syringe, a vial or an ampoule.

**For the primary purpose of reducing medication errors and protecting patient safety, EAHP’s statement calls for each single dose of medicine used within hospitals and supplied to the hospital by manufacturers or wholesalers to include an individual barcode in GS1 datamatrix format.**
1. Legislative proposals:
- to tackle the growing issues of counterfeiting and illegal distribution of medicines (see Memo)
- to enable citizens to have access to high-quality information on prescription-only medicines (see Memo)
- to improve patient protection by strengthening the EU system for the safety monitoring ('pharmacovigilance') of medicines (see Memo)

These proposals will now be transmitted to the European Parliament and the Council.

2. A political communication:
- to discuss with Member States ways to improve market access by making pricing/reimbursement decisions more transparent;
- to develop initiatives to boost EU pharmaceutical research;
- to intensify cooperation with major partners (US, Japan, Canada) to improve medicines' safety worldwide;
- to strengthen cooperation with emerging partners (Russia, India, China).

More information
http://ec.europa.eu/enterprise/pharmaceuticals/index_en.htm
Netherlands?

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- 1992 NVZA Standards for Unit dose (single units)
- 2000 New Standards NVZA
  - Including 2D barcode
- 2012 EAHP statement
- 2011-2019 FMD
- 2015 NVZA policy paper

- 5%(2012) to 35%(2016) barcode scanning
NVZA position paper

- All medication used in hospitals should be available in **Single Unit of Use Packages**
  - Unit Dose administration
- All Single Unit of Use Packages should **contain the correct barcode**
  - record the administration of medication electronically
  - significantly contributes to greater medication safety
NVZA position paper
Single Unit of Use packaging

- **Labelling**
  - for each unit the following items are present:
    name of substance + strength + expiry date + batch number + (if necessary) method of administration
  - Single dose level: barcode in GS1 Data Matrix format including GTIN, expiry date, and batch number.
- **The GS1 standard**
  - at the primary (single dose), secondary, and tertiary level (case/shipper) packaging.
Single unit of use
Presence of barcoding

% of drugs with barcoding on primary package

- Oraal: 58%
- Parenteraal: 19%
- Cutaan: 31%
- Oculair: 32%
- Inhalatie: 6%
- Rectaal: 4%

Figuur 1. Overzicht inventarisatie Albert Schweitzer (Bartels, 2015)

80% of 0.5 billion doses administered has a barcode
How to overcome these obstacles?

Repackaging
- Pharmacies
- Wholesalers
Packaging
- Drug companies

Standardisation of European (Medication) suppliers
47 deaths prevented by using barcodes
Report on Cost Benefit

Hospital setting

• 47 deaths can be prevented
• 21 mio € cost reduction
• Included
  - direct health care costs
  - Gained qualy’s
• Cost of barcodes on remaining 20% 
  - 9 -20 mio €
Report on Cost Benefit

- Excluded
  - Indirect healthcare cost (extra diagnostics etc)
  - Managing of errors
  - Logistical benefits
  - Reduction of waste
  - Reduction of extra checks
- Could also apply to other care settings
  - Psychiatric hospitals
  - Long stay care
  - Home care
  - ...
Improving out-patient compliance

In-patient learns how to use medication
Way to go?

- Willingness to invest?
- Willingness to pay?
- Law?
- Inspectorate?

- Joint effort
  - Health care providers
  - Industry
  - Government

- Europe
Conclusions

• Unbelievable that we accept risks
• Incomprehensible that we have not already solved the issue
• Unthinkable that we leave it at this.
It is possible!

Thank you for your attention!