“From cow to C.O.W.”

Bedside Barcode Scanning prevents errors and even deaths

Bertil Lenderink
Hospital Pharmacy Midden-Brabant
Tilburg, The Netherlands
Proverb

Anything that can go wrong, will go wrong

BUT.... If things that can go wrong, do not; it would, in the end, have been better for us if they had done so!
Errare humanum est

• 1939
  – Faddis MO. Eliminating errors in medications.  

perseverare diabolicum

• 1962
  – Barker KN, McConnel WE. The problems of detecting 
    medication errors in hospitals. 
    Am J Hosp Pharm 19:360-69
Causes of medication errors

- failed communication (55%)
- mistakes pharmacy/nursing staff (5%)
- failed organisation (6%)

leads to

- incorrect drug administration (34%)
  - not given, unnecessary given, wrong time, wrong dose

Tilburg study 1971
Unit Dose Package
Medication Administration Registration
Unit Dose Packaging Machines

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Hospital Pharmacy Midden-Brabant
Guidelines Standard Unit Dose

- Materials
- Measures
- Labelling
  - boxes
  - unit dose cell
EAHP Summary

• Barcode standards for medicaments exist in 43% of EC countries
• In another 43% initiatives on standardisation are taken
• Barcode is used mostly to support the distribution process
• Barcode is used mostly on “outer/inner package”
• Pictographs are seldom used
Conclusion

- 25 years of unit-dose systems have diminished the number of medication errors in some countries tremendously but …
- it is still possible to further decrease this number by introducing a unit-dose package containing a barcode (and a pictograph) on the cell which can be used at the time of administration of the drug
Diversity oral Unit Dose Packages
Dutch guidelines new millennium

- Usage in- and outside hospital
- Environment
- Cell
  - Polypropylene
  - 35 x 20/40 mm
  - 2D barcode (articlenumber, lotnumber, expiry date)
- Box
  - carbon
  - removable top
  - 7 cells/strip, 14/28/56 per box
“Forward integration”

Pharmacy is not just about dispensing or distributing medicines;

It is a clinical risk management service!

Michael Yates
Audit Commision UK
Best practice recommendations IOM report

- Pharmacists in patient care rounds
- No concentrated medications on ward
- Improve voluntary reporting
- Use unit dose system
- Check patient identity
- Implement computerized prescribing
- Use barcoding
An ideal distribution system is a “Closed Loop” process

- Prescribe - doctor/nurse
- Authorise - doctor
- Accept - pharmacist
- Agree - doctor
- Dispense - pharmacy/nurse
- Administer - nurse
- Outcome - patient
- (Perhaps again) Prescribe - doctor/nurse
“Our distribution system is old-fashioned and insufficient”

From sticking labels to high-tech scanning
Conclusions pilot

- The hand-held terminal-system is not optimal yet
- Nurses were skeptical about bar-coded bracelets; patients didn't have any trouble with them.
- Nurses formed a favorable opinion about implementing a different (complete) system.
Theriak™ Therapy Management System

• Patient data and lab-values registration
  – Allergy, medication dependent variables
• CPOE, Prescribing
  – EPF, Clinical, Outpatient
• Decision Support, Authorisation
  – Medication info, Formulary, Cost
• Pharmacy review
• Dispensing, Preparation info
  – Intra/Internet
• Medication Administration Registration
• Medication review
• Logistics
Current hardware
Global Application for Coding Version 2004-003

Eenheids Aflevering Geschikte verpakking.
Version: definitief
Date: 24-12-2003
Document: Voorstel EAG.doc

6. Eisen EAG.
- Verpakking: per dosis verpakt en zonder hulpmiddelen afscheurbaar
- Etikettering: per dosis stofnaam + sterkte + vervaldatum + chargenummer + (indien noodzakelijk) doseervorm
- Geschikt voor geautomatiseerd toedieningsregistratiesysteem, bij voorkeur EAN/RSS
- Geschikt voor geautomatiseerd chargenummerregistratiesysteem (bijv. chargenummerbarcodes) (denk aan bloedproducten)
- Geschikt voor geautomatiseerd vervaldataumsysteem (bijv. vervaldataumbarcodes).
Press Release

FOR IMMEDIATE RELEASE
Wednesday, Feb. 25, 2004

HHS Announces New Requirements for Bar Codes
on Drugs and Blood to Reduce Risks of Medication Errors

DATES: Effective Date: This rule is effective on April 26, 2004.
Compliance Dates: Drug products that receive approval on or after
the rule's effective date must comply with the bar code requirement
within 60 days after the drug's approval date. Drug products that
received approval before the final rule's effective date must comply
with the bar code requirement within 2 years after the final rule's
effective date. Specific information on how the rule will be
implemented can be found in section II.I of this document.

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RSS & Composite Symbology Barcode FAQ and Tutorial

- RSS-14
- RSS-14 Truncated
- RSS-14 Stacked
- RSS-14 Limited
- RSS-14 Composite
- RSS Limited Composite
- RSS Stacked Composite
- EAN-13 Composite
Findings Netherlands

- < 50% of units available in unit dose
- < 50% of unit doses have bar code
- Some CPOE-systems cannot use EAN-RSS
- Most affordable scanners cannot read EAN-RSS or 2D-barcodes
Current challenges in bar coding

- Only 35% manufacturers bar code
- Trend towards fewer unit-dose form
- No uniform standard for medication barcodes
- No standard for relabeling/in house barcoding
- In house repackaging unreimbursed
- No affordable scanners
- “Floating” nurses
- Patient-specific medications
Failure Mode and Effects Analysis

- **People**: Technician labels incorrectly
  - Pharmacist checks incorrectly
  - Uncoded medication to ward
- **Material**: Barcode becomes unscannable
  - Not available
  - Small items, obscuring of info
  - Multi-dose items
AANTAL  MERKNAAM  GEN. NAAM  ART. NUMMER  STERKTE  MAG. CODE  GEN. NR.
510  EFEXOR XR 150MG CAPSULE MGA  VENLAFAXINE (ALS HYDROCHLORIDE)  1053418

Quarantaine artikel.

RVG / EUNUM : 20863 /

Vervaldatum: 8-2007

Charge nr.: 48848
Aantal ontvangen : 510
Aantal verpakkingen: 17
Prt. 1 ..........
Naar centraal magazijn
Prt. 2 ..........

!!! PICTOGRAM "NIET VERPULVEREN" OF!

GS1 HUG Berlin 310107
**A. Klant- en artikelgegevens**

Klantenaam: TWEE STEDEN ZIEKENHUIS
Artikelen: Tjoapack

**B. Farmaceutische gegevens geneesmiddel**

Farmaceutische vorm: tablet mg
Omschrijving: N

**C. Beschrijving verpakkingshandleidingen**

Special verpakkingscondities: nvt

**D. Eilen verpakking**

Omschrijving: Formaat (lbh mm): Omschrijving: Formaat (dubbel mm):

Blister: 126 x 50 Ondoo k. 146.8.33
By blister: Overdoos 31.2.x.52 x 148

**E. Bijgevoegde materialen**

Omschrijving artikel: Aantal per ondoo k. Einheid Artikelen: Tjoapack

**F. Eilen bedrukking en etiketten**

Omschrijving: Kleurcode etiket: Formaat (mm x mm):

Blisteretiket: Wit 25 x 127
Omdoos etiket: Blanco 48 x 127
Overtottoilet: Blanco 48 x 127

Chargenummer en verwijstdatum conform de orderovereenkomst tussen de klant en Tjoapack.

G. Goedkeuring alle BDV-onderdelen

Naam: H. A. M. van B. 
Paraff: 81.4.65
Examples made by wholesaler
“Home made” bar codes
Non-oral “Unit” Dose Packages
Failure Mode and Effects Analysis

- Equipment: Not (correctly) functioning
  Package not standardised
- Environment: Not enough space
- Methods: Article not in G-standard - trials
  Needed before barcoding
  Personalised medication
  Uncoded home medications
LET OP!!

STEKKER IN HET STOPCONTACT???
Other hardware

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Hospital Pharmacy Midden-Brabant
Trustworthy partners in patient-safety ??

Sucralfaat Sandoz® suspensie 1
5 g suspensie (1 sachet)
bevat sucralfaat hydraat overeenkomend met 1 g sucralfaat

5 g suspensie

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Hospital Pharmacy Midden-Brabant
Lilly Announces Individual Bar Coding on All Insulin Vials

February 7, 2005

Industry believes bar codes may reduce risk of medication errors in hospital settings

INDIANAPOLIS, Feb 07, 2005 (PRNewswire-FirstCall via COMTEX) -- As part of its long-standing commitment to patient safety, Eli Lilly and Company (NYSE: LLY) has announced that it is including bar codes on individual vials of its insulin products including Humulin® and Humalog®.

The bar codes -- much like the linear bar codes found on many retail products -- have been included on Lilly's insulin product outer packaging in the past, but this marks the first time the bar codes are being included on the vial labels.

The bar coding is part of a larger effort within the health care industry to decrease medication errors. In February 2004, the U.S. Food and Drug Administration (FDA) issued a new regulation that requires all new pharmaceuticals to be bar coded upon launch in the marketplace and all existing medications be bar coded within two years of the ruling. Lilly completed its bar coding of insulin vials 18 months before the FDA's deadline, and the bar codes appear on vials for nine insulin products.

Bar code labeling on prescription drugs is projected to reduce error by 500,000 instances over the next 20 years with an estimated savings of $93 billion in additional health care costs, patient pain and suffering and lost wages, according to the FDA. Studies by U.S. Pharmacopeia in 2003 indicate insulin products have the highest rates of errors in a hospital setting.
Reliable partners in patient-safety ??
Reliable partners in patient-safety ??
Reliable partners in patient-safety!!

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Reliable partners in patient-safety!!
Reliable partners in patient-safety!!
George Bernard Shaw

I don’t believe in circumstances!

The people who get on in this world are those who get up and look for the circumstances they want, and, if they cannot find them make them (themselves)
Your challenge!

To be a trustworthy and reliable partner (together with clients and users of your products) in the permanent improvement of medication and patient-safety by offering barcode labeled unit doses.
Take home message

All intelligent thoughts have already been thought; what is necessary is only to try to think them again.

Knowing is not enough; we must apply! Willing is not enough; we must do!

Johann Wolfgang von Goethe
(1749 - 1832)
Berlin 2007

The GS1 HUG-meeting that brought down the wall between producers and users of a barcoded unit dose
Information

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Hospital Pharmacy Midden-Brabant
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5000 LA Tilburg, The Netherlands

Email: awlenderink@zamb.tsz.nl
“Dutch” bar-code

- On unit of use
- Readable
  - article number
  - 2 D OK, 1D better untill.....
- lotnumber, expiry-date
Closing the loop of the medication use process using electronic medication administration registration

• Bertil W. Lenderink and Toine C.G. Egberts


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T.C.G. Egberts: Department of Pharmacoepidemiology and Pharmacotherapy, Utrecht Institute for Pharmaceutical Sciences (UIPS), P.O. Box 80 082, 3508 TB Utrecht, The Netherlands

Key words
Bedside pharmacy
Hospital pharmacy
Medication use process
Registration and documentation
The Netherlands

Abstract
Recent reports and studies of errors in the medication use process have raised the awareness of the threat to public health. An essential step in this multi-stage process is the actual administration of a medicine to the patient. The closed loop system is thought to be a way of preventing certain

able studies originate from the USA, studies conducted in other countries such as the United Kingdom² and the Netherlands⁴ have shown similar results. This strongly implies that medication errors are a major public health problem in many western as well as developing countries.

In light of these findings, we were therefore highly motivated to analyse the medication use process and to implement improvements, where necessary. The major conclusion from this particular analysis is that:
1) A medication order should contain all necessary items in such way that interpretation is only possible in a single manner and that there should not be more than one copy;
2) During the time of administration to the patient the uniquely identifiable medicine should be verified against the original medication order.
In addition, we concluded that these goals could only be achieved using electronic medication order entry
Cijfers MIP TSz Tilburg

- 2002 en 2003
  - 750 meldingen: 300 vallen, 300 medicatie
    - 1998/9 100 ; 2000/1 200
- 2004 t/m september
  - 263 medicatie
  - 224 toedienfout (85%)
    - 99% te voorkomen mbv MO-gekoppelde MAR
    - 41 andere
      - 50% te voorkomen mbv Theriak
Cijfers MIP TSz Tilburg 2004

- 224 gemelde toedienfouten
  - 59 voorgeschreven maar niet toegediend
  - 64 niet voorgeschreven wel toegediend
    - 80% verwisseling middel
    - 10% verwisseling patiënt
    - 10% onterecht gegeven
  - 10 onjuiste toedieningsvorm/route
  - 5 onjuiste toedieningswijze
  - 81 verkeerde dosis (incl. pompstand)
  - 5 verkeerd tijdstip (> 1,5 uur te vroeg/te laat)
# Summary cost benefit study

2 Steden Ziekenhuis  
**Cash Flow Analysis**  
Summary 
Kosten/Baten analyse Theriak

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<th>Year</th>
<th>Total Cash Outflows</th>
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**TOTAL COSTS**

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**TOTAL BENEFITS**

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**Cumulative NCF**

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**Discounted Cash Flows (DCF)**

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**Cumulative DCF with WACC - 4.00%**

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**Internal Rate of Return (IRR)**

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**Payback Period**

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**Discounted Payback Period**

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### Medication Administration Return-on-Investment (ROI) Model

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<th>Value</th>
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<tbody>
<tr>
<td># beds</td>
<td>400</td>
</tr>
<tr>
<td>Occupancy rate</td>
<td>0.90</td>
</tr>
<tr>
<td>Avg. # patients</td>
<td>360</td>
</tr>
<tr>
<td>Meds per patient</td>
<td>4</td>
</tr>
<tr>
<td>Daily dose frequency</td>
<td>4</td>
</tr>
<tr>
<td>Meds per day</td>
<td>5,760</td>
</tr>
<tr>
<td>365 days/year</td>
<td>x 365</td>
</tr>
<tr>
<td>Meds admin. Per year</td>
<td>2,102,400</td>
</tr>
<tr>
<td>Error rate (1%-7%; assume best)</td>
<td>1%</td>
</tr>
<tr>
<td># of medication errors per year</td>
<td>21,024</td>
</tr>
<tr>
<td>Cost per error (assume minor)</td>
<td>x $75</td>
</tr>
<tr>
<td>Total error costs per year (best case)</td>
<td>$1,576,800</td>
</tr>
</tbody>
</table>
Summary Business Case Findings

The cost-benefit analysis shows that the investment will generate a positive net cash value.

Financial Impact:

- 5 Year NCV = € 619,000
- Revenue time = 3.2 year
- Project Costs = € 1,200,000
- Yearly expected yields = € 450,000

Deloitte & Touche

Tweesteden