Closed loop medication up to point-of-care scanning

Dennis Even, IT Director, Pfizer Inc, US
Closed Loop Medication Up to Point-of-Care Scanning

Pfizer Global Supply – Manufacturing and Quality Solutions

GS1 Global Healthcare Conference - Noordwijk

Dennis Even, Director Digital & Technology, Pfizer Inc
26th of March 2019

Copyright © Pfizer Inc. All rights reserved.
**Disclaimer:** This presentation outlines a general technology direction. Pfizer Inc has no obligation to pursue any approaches outlined in this presentation or to develop or use any functionality mentioned in this presentation. The technology strategy and possible future developments are subject to change and may be changed at any time for any reason without notice.

The views and opinions expressed in this presentation and any related discussion(s) are solely those of the individual presenter(s) and may not express the views of and opinions of Pfizer Inc.
Agenda

- The Basics: Coding & Systems
- Inherent Challenges
- US Story: Scanning at point of care
The Basics

Increase patient safety / decrease adverse drug events (ADE) by introducing technology

Unit Dose Coding / Hospital Unit Dose (HUD)

Barcode Medication Administration (BCMA): Dispense / Bedside Scanning

GTIN, Lot, Exp Date (Blister, Bottle, Tube, Syringe, etc)

Linking / ensuring prescribed medication is the provided medication

Aligned product drug codes is foundational to overall success

GTIN, Lot, Exp Date (Blister, Bottle, Tube, Syringe, etc)
Single Unit POC Scanning Process

1. GTIN Tool
2. Artwork development process
   - Approve AW + 2D code
3. Print + Label
4. Hospital
5. GTIN: 12345678901234

<table>
<thead>
<tr>
<th>GTIN</th>
<th>Product</th>
<th>Strength</th>
<th>Primary pack</th>
<th>Country</th>
</tr>
</thead>
<tbody>
<tr>
<td>xxxx</td>
<td>xxxx</td>
<td>xxxx</td>
<td>Blister</td>
<td>xxxx</td>
</tr>
<tr>
<td>xxxx</td>
<td>xxxx</td>
<td>xxxx</td>
<td>Bottle</td>
<td>xxxx</td>
</tr>
</tbody>
</table>

Copyright © Pfizer Inc. All rights reserved.
Inherent Challenges

Challenges vary depending on environmental variables and the stages of change

Physical
- Space
- Container Types / Materials
- Readability

People
- Process / Requirements Standardization
- Adoption
- End-User-Change-Management

Technology
- Master Data Alignment
- System Change Management

Copyright © Pfizer Inc. All rights reserved.
US Story: Scanning at Point-of-Care

• April 2004, FDA mandated barcodes on labels by 2006
  – Predicted prevention of nearly 500,000 adverse events / transfusion errors over the 20 years (estimated cost savings of $93 billion)

• Pfizer started HUD coding in 2003
  – GTIN, Exp Date, Lot

• Emergency department BCMA implementation reduced medication administration errors by nearly 67%, and wrong dose errors by 90%

• Evidence of reliance in 2017 with disruption (GS1 UPC-A replaced by some manufacturers with the GS1 DataMatrix)

Annotations:
3. Research published by the Society for Academic Emergency Medicine (Bonkowski et al., 2013)
US Story: Evolution

Medicinal barcode scanning has grown to much more…
BPOC – Barcode at point of care +++

- Target all patient points of care
- Electronic health records
- Testing services
- Payment services
- Prescription claims
- Reporting
- Etc
In Summary

The Basics: Coding, Systems, & Data Alignment

Unit dose coding & scanning has shown value and more

Challenges will be met along the way
thank you!
Medication Safety
Can Technology make life better?

Dr. Michiel Duyvendak, Hospital Pharmacist, Antonius Hospital Sneek & Emmeloord
GS1 Congres 26-03-2019
Conflict of Interest: None
The Essence of Health Care
Typical Process
Optical Strength and Weakness

An itvgnoieation of an Elsginh Urinvetsiy doseceverid taht it dseon’t mtetar in wcihh oedrr the lteetrts are wteitrn in a wrod. The olny itcnorapme is taht the fsrit and the lsat lteetr are sdntniag at the rhgit ltcioian.

The lrtteeus bteewen the fsrit and the lsat lteter in a wrod may be lectoad at rdonam. Bscueae we dno’t raed ecah ltteer at a tmie, we raed the wrod has a wlohe.
Results of BCMA

Ziekenhuissterfte kan omlaag door barcode op alle medicijnen

Joe de Grooth

redactie binnenland

Een barcode op alle ziekenhuismedicijnen kan per jaar de dood van bijna vijfhonderd patiënten voorkomen, maar is het moment voor de verkoop van ziekenhuismilitairen, niet voor de personen die deze medicijnen hebben gegeven. Volgens onderzoek van het ministerie van Volksgezondheid zouden ook nog eens 250 patiënten per jaar omkomen door ongelukken. Inmiddels arendje zijn gezondheidszorg beter op de loop. "Een barcode op alle medicijnen is een gouden doolhof voor een barcode. Om verschillende modellen in de overige twintig procent dus niet. Een barcode identificeert producten met een unieke cijferreeks. Als een arts een medisch sternstedentoch, 'Onbekende' winnaar van 1947 overleden

Sneker medicijnmethode redt leven

Knoflauwe oplossing continueert medicijnadministratie in ziekenhuizen

Sneker medicijnmethode redt leven

Knoflauwe oplossing continueert medicijnadministratie in ziekenhuizen

Barcording op de primaire verpakking van geneesmiddelen in ziekenhuizen

Een kosten-baten analyse

In opdracht van het Ministerie van VWS, Directie Geneesmiddelen en Medische Technologie
Het rapport is tot stand gekomen in samenwerking met de wettgroep Barcording Geneesmiddelen

Ref: 150246
7 november 2016
Implementation >95% UDP BCMA is Slow
Scanning on the Ward
Patient Errors
Recent Errors
Sound alike
Issues

High Risk

Unusable/Errornous Barcode

Protect from light/moist no unit dose pack
Good Manufacturing Practice
High risk medication (RTA)

Impact of Bar Code Errors

According to a USP MEDMARX report from 2006, 51% of the errors associated with bar code technology were the result of attaching the wrong bar code to a product. Affixing a bar code label indicating the wrong strength accounted for another 23% of the errors reported.

Photo courtesy of Carla Maslakowski
Antonius Sneek

Stock Keeping Units (SKU): 2012
SKUs dispensed/year: 3,522,500

Production
SKU: 63 (3.1%)
SKUs dispensed/year: 13,112 (0.4%)

Solid oral (tab/caps)
SKU: 854 (42.5%)
SKUs dispensed/year: 2,760,274 (78.4%)

Other
SKU: 1,095 (54.4%)
SKUs dispensed/year: 749,114 (21.2%)

Overall Barcode
SKU: 1,164 (57.9%)
SKUs dispensed/year: 2,870,483 (81.5%)

Overall No-Barcode
SKU: 848 (42.1%)
SKUs dispensed/year: 652,017 (18.5%)
<table>
<thead>
<tr>
<th></th>
<th>MAE</th>
<th>No MAE</th>
<th>Total</th>
<th>OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>WA</td>
<td>271 (4.7%)</td>
<td>3362 (58.0%)</td>
<td>3633 (62.7%)</td>
<td></td>
</tr>
<tr>
<td>No WA</td>
<td>16 (0.3%)</td>
<td>2144 (37.0%)</td>
<td>2160 (37.3%)</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>287 (5.0%)</td>
<td>5506 (95.0%)</td>
<td>5793 (100%)</td>
<td>3.06 [2.49-3.78]</td>
</tr>
</tbody>
</table>

Veen v/d et al., 2017: [https://doi.org/10.1093/jamia/ocx077](https://doi.org/10.1093/jamia/ocx077)
IMPROVING LIFE AT WORK
Medication Dispensing (Nursing) Home
Questions?

My Doctor said "Only 1 glass of alcohol a day". I can live with that.
EU-directive

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:
http://ec.europa.eu/enterprise/pharmaceuticals/index_en.htm
Software only solutions to closed loop verification cannot detect or fix several categories of errors.

<table>
<thead>
<tr>
<th>Tablets</th>
<th>Barcodes</th>
<th>Medeye Software</th>
<th>MedEye Software + scanner</th>
<th>Legend</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baxtered</td>
<td></td>
<td></td>
<td></td>
<td>Does't detect</td>
</tr>
<tr>
<td>Extra pill in bag</td>
<td>Red</td>
<td>Yellow</td>
<td>Green</td>
<td></td>
</tr>
<tr>
<td>Pill missing from bag</td>
<td>Red</td>
<td>Yellow</td>
<td>Green</td>
<td></td>
</tr>
<tr>
<td>Split pill error</td>
<td>Red</td>
<td>Yellow</td>
<td>Green</td>
<td></td>
</tr>
<tr>
<td>Stopped prescription</td>
<td>Red</td>
<td>Yellow</td>
<td>Green</td>
<td></td>
</tr>
<tr>
<td>New prescription</td>
<td>Red</td>
<td>Yellow</td>
<td>Green</td>
<td></td>
</tr>
<tr>
<td>Wrong patient</td>
<td>Red</td>
<td></td>
<td>Green</td>
<td></td>
</tr>
<tr>
<td>Not Baxtered</td>
<td></td>
<td></td>
<td></td>
<td>Detects but can't fix</td>
</tr>
<tr>
<td>Extra pill given</td>
<td>Red</td>
<td>Red</td>
<td>Green</td>
<td></td>
</tr>
<tr>
<td>Too few pills given</td>
<td>Red</td>
<td>Red</td>
<td>Green</td>
<td></td>
</tr>
<tr>
<td>Pill needs to be split</td>
<td>Red</td>
<td>Red</td>
<td>Green</td>
<td></td>
</tr>
<tr>
<td>Stopped prescription</td>
<td>Red</td>
<td>Red</td>
<td>Green</td>
<td></td>
</tr>
<tr>
<td>New prescription</td>
<td>Red</td>
<td></td>
<td>Green</td>
<td></td>
</tr>
<tr>
<td>Non Tablets</td>
<td></td>
<td></td>
<td></td>
<td>Detects and fixes</td>
</tr>
<tr>
<td>Barcoded</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wrong medication</td>
<td>Yellow</td>
<td>Yellow</td>
<td>Yellow</td>
<td></td>
</tr>
<tr>
<td>Stopped prescription</td>
<td>Green</td>
<td>Green</td>
<td>Yellow</td>
<td></td>
</tr>
<tr>
<td>Wrong dose</td>
<td>Red</td>
<td></td>
<td>Red</td>
<td></td>
</tr>
</tbody>
</table>

Legend:
- Red: Doesn't detect
- Yellow: Detects but can't fix
- Green: Detects and fixes
Nurses can fix 100% of errors only if they use both software and hardware.

Errors per day detected by MedEye, by ability to fix

*Fixed with scanner* counts errors of extra pills in multi-dose bags; *Fixed with SW* counts errors medication already verified, wrong patient, extra pills in single-dose
Medication Adherence

Digital pills make their way to market

30 Jul 2012 | 21.31 GMT | Posted by Amy Maxmen | Category: Biology & Biotechnology

Digestible microchips embedded in drugs may soon tell doctors whether a patient is taking their medications as prescribed. These sensors are the first ingestible devices approved by the US Food and Drug Administration (FDA). To some, they signify the beginning of an era in digital medicine.

“About half of all people don’t take medications like they’re supposed to,” says Eric Topol, director of the Scripps Translational Science Institute in La Jolla, California. “This device could be a solution to that problem, so that doctors can know when to rev up a patient’s medication adherence.” Topol is not affiliated with the company that manufactures the device, Proteus Digital Health in Redwood City, California, but he embraces the sensor’s futuristic appeal, saying, “It’s like big brother watching you take your medicine.”
Requests to legislators

On top of counterfeit measures:

Request mandatory

• Single cell primary package
• GTIN in barcode on all levels => also the primary package.
• GTIN, Lot.nr en EXP. date on all levels and labels

• Request voluntarily
  • Labels in a more uniform lay-out
Reduction errors and risk of preventable ADE’s

Baseline error rate varied between 5.8% and 25.3% if time errors were included and between 1.6% and 27.3% when time errors were excluded.

Most studies show a 30–50% reduction in medication administration errors after implementation of BCMA when time errors are excluded. However, implementation of BCMA does not result in a consistent reduction when time errors are included.

Morris *et al* found that BCMA reduced the risk of preventable ADEs by 47% and Poon *et al* showed a 50.8% reduction in potential ADEs. In this latter study the reduction in many of the potential ADEs could be attributed to improved medication administration documentation.

*Effects of bar code-assisted medication administration (BCMA) on frequency, type and severity of medication administration errors: a review of the literature*

Jeroen Hassink,1 Mark Jansen,1 Pieter Helmons2 European Journal of Hospital Pharmacy 2012;19: 489–494
Table 2  Number of observations, and error rates before and after BCMA implementation

<table>
<thead>
<tr>
<th>Study</th>
<th>Ward type</th>
<th>No of observations</th>
<th>Frequency of errors including time errors</th>
<th>Change from baseline</th>
<th>Frequency of errors excluding time errors</th>
<th>Change from baseline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paoletti et alP</td>
<td>Cardiac telemetry</td>
<td>308</td>
<td>25.3%</td>
<td>1.6%</td>
<td>1.6%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Poon et alP</td>
<td>Medical</td>
<td>2008</td>
<td>ND</td>
<td>28.5%</td>
<td>ND</td>
<td>ND</td>
</tr>
<tr>
<td>Paoletti et alP</td>
<td>Medical-surgical</td>
<td>320</td>
<td>15.6%</td>
<td>2.9%</td>
<td>53.5%</td>
<td>0.045</td>
</tr>
<tr>
<td>Franklin et alP</td>
<td>Surgical</td>
<td>1473</td>
<td>7.0%</td>
<td>ND</td>
<td>ND</td>
<td>ND</td>
</tr>
<tr>
<td>Helmons et alP</td>
<td>Medical-surgical</td>
<td>888</td>
<td>10.7%</td>
<td>2.6%</td>
<td>56.9%</td>
<td>ND</td>
</tr>
<tr>
<td>Poon et alP</td>
<td>Surgical</td>
<td>3528</td>
<td>ND</td>
<td>ND</td>
<td>ND</td>
<td>ND</td>
</tr>
<tr>
<td>De Young et alP</td>
<td>ICU</td>
<td>775</td>
<td>19.7%</td>
<td>ND</td>
<td>ND</td>
<td>ND</td>
</tr>
<tr>
<td>Helmons et alP</td>
<td>ICU</td>
<td>374</td>
<td>12.6%</td>
<td>ND</td>
<td>ND</td>
<td>ND</td>
</tr>
<tr>
<td>Poon et alP</td>
<td>ICU</td>
<td>1187</td>
<td>ND</td>
<td>ND</td>
<td>ND</td>
<td>ND</td>
</tr>
<tr>
<td>Morris et alP</td>
<td>NICU</td>
<td>46090</td>
<td>6.7%</td>
<td>ND</td>
<td>ND</td>
<td>ND</td>
</tr>
<tr>
<td>Ros et alP</td>
<td>Neurology</td>
<td>3614</td>
<td>5.8%</td>
<td>48.5%</td>
<td>&lt;0.0008</td>
<td>ND</td>
</tr>
<tr>
<td>Poon et alP</td>
<td>Overall</td>
<td>6723</td>
<td>16.7%</td>
<td>11.5%</td>
<td>41.4%</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

*a* Excluding time and technique errors.

†Reduction calculated based on numbers presented in original publication (number of errors per ward type/number of observed doses per ward type ×100%).

§Reduction calculated based on numbers presented in original publication.

<table>
<thead>
<tr>
<th>Study</th>
<th>No of observations</th>
<th>Frequency of errors including time errors</th>
<th>Change from baseline</th>
<th>Frequency of errors excluding time errors</th>
<th>Change from baseline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poon et alP</td>
<td>ICU</td>
<td>775</td>
<td>19.7%</td>
<td>ND</td>
<td>ND</td>
</tr>
<tr>
<td>Helmons et alP</td>
<td>ICU</td>
<td>374</td>
<td>12.6%</td>
<td>ND</td>
<td>ND</td>
</tr>
<tr>
<td>Poon et alP</td>
<td>ICU</td>
<td>1187</td>
<td>ND</td>
<td>ND</td>
<td>ND</td>
</tr>
<tr>
<td>Morris et alP</td>
<td>NICU</td>
<td>46090</td>
<td>6.7%</td>
<td>ND</td>
<td>ND</td>
</tr>
<tr>
<td>Ros et alP</td>
<td>Neurology</td>
<td>3614</td>
<td>5.8%</td>
<td>ND</td>
<td>ND</td>
</tr>
<tr>
<td>Poon et alP</td>
<td>Overall</td>
<td>6723</td>
<td>16.7%</td>
<td>ND</td>
<td>ND</td>
</tr>
</tbody>
</table>

**Effects of bar code-assisted medication administration (BCMA) on frequency, type and severity of medication administration errors: a review of the literature**

Jeroen Hassink, 1 Mark Jansen, 1 Pieter Helmons 2  European Journal of Hospital Pharmacy 2012; 19: 489–494
Table 3  Severity of observed errors or (potential) ADEs before and after implementation of BCMA

<table>
<thead>
<tr>
<th>Outcome measure</th>
<th>Baseline</th>
<th>Post-BCMA</th>
<th>% Change from baseline</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poon et al(^\text{a})</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Percentage clinically significant potential ADEs</td>
<td>1.8</td>
<td>0.9</td>
<td>48.5</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Percentage serious potential ADEs</td>
<td>1.3</td>
<td>0.6</td>
<td>54.1</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Percentage life-threatening potential ADEs</td>
<td>0.03</td>
<td>0.01</td>
<td>53.9</td>
<td>0.34</td>
</tr>
<tr>
<td>Franklin et al(^\text{b})</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean score of potential error severity(^\text{c})</td>
<td>2.7</td>
<td>2.5</td>
<td></td>
<td>0.39</td>
</tr>
<tr>
<td>Morris et al(^\text{d})</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n/1000 doses of preventable ADEs(^\dagger)</td>
<td>0.86/1000</td>
<td>0.43/1000</td>
<td>47</td>
<td>0.044</td>
</tr>
</tbody>
</table>

\(^\text{a}\) Scoring on a scale from 0 to 10 where 0 is no effect and 10 is death.
\(^\text{b}\) Severity was assigned using the National Coordinating Council for Medication Error Reporting and Prevention index. All preventable ADEs were assigned class E (temporary harm that required intervention) except five cases assigned to class G because it was not possible to exclude permanent harm.
ADE, adverse drug event; BCMA, bar code-assisted medication administration.
Scannable dose.
Ad Deeben
Distributie en terhandstelling geneesmiddelen in verpleeghuis

Het artikel presenteert een onderzoek naar de efficiëntie van de distributie en terhandstelling van geneesmiddelen in verpleeghuizen. Het onderzoek werd door de EAV-garanties clare identificatie gedaan, waarbij de kosten 3 cents per dosis bedragen. Hierbij werd een identificatiedienst in de verpleeghuizen geïntroduceerd, waardoor er een duidelijke verbetering in de administratie van de geneesmiddelen was waargenomen. De resultaten van dit onderzoek laten zien dat een effectieve en efficiënte distributie van geneesmiddelen leidt tot een vermindering van deadministratiesoeuvre en daardoor een verbetering van de zorgafdracht voor de patiënten.
Development of the EAV packaging in time

1984 EAV introduction, Printed (EAG suitable unit dose)

1990 EAV JFK barcode Sticker
- Scannable JFK code on stickers for paper patient file.

2000 EAV JFK barcode
- Scannable JFK code for identification and record in electronic patient file.

2018 EAV GTIN barcode
- Scannable 2D matrix code for identification and record in electronic patient file.

Not in the RA dossier:

- Scannable JFK code for identification and record in electronic patient file.
EAV NL (EAV = Unit Delivery Package)

- The first EAV packaging was created in 1983
- The first Teva customer: Haagse Ziekenhuizen
- 2015 EAV portfolio Teva NL >200 SKU
- EAV packaging is expensive
- Customer does not want to pay for it
- Hospitals do not use the JFK code (do not scan JFK)
- Conversion JFK to GTIN in 2019
Solutions providers: scannable dose

- **Manufacturers**
  - As a registered product EAV
  - As part of the label
- **Repackers**
  - CPO registered EAV
  - Re-label in assignment under the responsibility of hospitals
- **Wholesale**
  - Re-label *Not registered* under the responsibility of hospitals
- **Hospital automation**
  - Various systems, method to code, re-label
  - Compounding products
  - EPD (patients dossier) File 007 GTIN

- Baxter packed per intake moment
- UDP
- MedEye
- Local solutions for compounding
- etc.
Current EAV creation process (+/- 5% market volume)

Ordering Bulk
- Receiving bulk at CPO
- Bulk entry in Oracle by planner
- Inspection & release bulk by QA
- Bulk Certificate by ERP / Copy CoA on the network by QA

Serialization
- Splitting bulk if more presentations
- Purchase order CPO
- Batch creation and bulk allocation
- Batch documentation to CPO
- Splitting bulk if more presentations CPO 1 batch

FG Receive at pre wholesale
- Ready report by planning
- Sampling pre wholesale
- Inspection & release by QA
Apply a scannable code to the existing blister?

Issues that arise

- The space on the blister is limited
- Reflection aluminium
- White background for readability
- Perforated blister
- Symmetrical blister
- Adjustment registration file
Next steps, the future
Medication administration, compliance and safety

Home situation

1. Medicines from the pack
2. Medication app support
3. Packed per intake moment, Baxter scannable
4. Informal, care support

Nursing home

5. Medication distribution system
6. Baxter, packed per intake moment scannable

Hospital

7. Scannable dose bedside scanning

https://www.youtube.com/watch?v=kETBLiiW1bc reconciliatie
Closed loop medication management system

- 200 SKU with JFK code available
- 3 Hospitals scan upon administration
- Introduction GTIN in file 007 in 2017
- Adjustment hospital systems to use file 007 in 2018
- Conversion from JFK to GTIN

Now there is a standard

Is there coordination & alignment

- Hospitals
- Pharmaceutical companies
- IT systems in Hospitals en Pharmacies
- Data source pharma and GS1
- EU countries

Willing to pay, can extra costs be charged?
Let's Do This!
Disclaimer

This presentation includes certain information that Teva deemed fit to present at this time. This presentation includes a summary of the issues addressed herein, in specific context, and not the full information that Teva has on such matters, and it is not intended to supersede or replace the need to review public reports and statements published by Teva in accordance with applicable law or otherwise. In any event of discrepancy between the figures contained in this presentation and the figures contained in Teva’s public reports, figures contained in public reports shall be deemed correct.

This presentation and the accompanying remarks contain forward-looking statements, which express the current beliefs and expectations of management. Such statements involve a number of known and unknown risks and uncertainties that could cause our future results, performance or achievements to differ significantly from the results, performance or achievements expressed or implied by such forward-looking statements. Important factors that could cause or contribute to such differences include risks relating to: our ability to develop and commercialize additional pharmaceutical products, including our ability to develop, manufacture, market and sell biopharmaceutical products, competition for our innovative products, especially COPAXONE® (including competition from innovative orally-administered alternatives, as well as from potential purported generic equivalents), competition for our generic products (including from other pharmaceutical companies and as a result of increased governmental pricing pressures), competition for our specialty pharmaceutical businesses, our ability to achieve expected results through our specialty, including innovative, R&D efforts, the effectiveness of our patents and other protections for innovative products, decreasing opportunities to obtain U.S. market exclusivity for significant new generic products, our ability to identify, consummate and successfully integrate acquisitions, the effects of increased leverage as a result of recent acquisitions, the extent to which any manufacturing or quality control problems damage our reputation for high quality production and require costly remediation, our potential exposure to product liability claims to the extent not covered by insurance, increased government scrutiny in both the U.S. and Europe of our agreements with brand companies, potential liability for sales of generic products prior to a final resolution of outstanding patent litigation, our exposure to currency fluctuations and restrictions as well as credit risks, the effects of reforms in healthcare regulation and pharmaceutical pricing and reimbursement, any failures to comply with complex Medicare and Medicaid reporting and payment obligations, governmental investigations into sales and marketing practices (particularly for our specialty pharmaceutical products), uncertainties surrounding the legislative and regulatory pathways for the registration and approval of biotechnology-based products, adverse effects of political or economical instability, corruption, major hostilities or acts of terrorism on our significant worldwide operations, interruptions in our supply chain or problems with our information technology systems that adversely affect our complex manufacturing processes, any failure to retain key personnel or to attract additional executive and managerial talent, the impact of continuing consolidation of our distributors and customers, variations in patent laws that may adversely affect our ability to manufacture our products in the most efficient manner, potentially significant impairments of intangible assets and goodwill, potential increases in tax liabilities, the termination or expiration of governmental programs or tax benefits, environmental risks and other factors that are discussed in our Annual Report on Form 20-F for the year ended December 31, 2013 and in our other filings with the U.S. Securities and Exchange Commission (“SEC”).

Forward-looking statements speak only as of the date on which they are made, and we undertake no obligation to update any forward-looking statements or other information contained in this presentation, whether as a result of new information, future events or otherwise. You are advised, however, to consult any additional disclosures we make in our reports to the SEC on Form 6-K.

Teva owns or has the proprietary rights in the information contained in this presentation.
Advanced Medicines Management
Medication Errors & the Role of Bar-Code Scanning

GS1 Global Healthcare Conference 2019
Iain Davidson-Chief Pharmacist
BPharm. MRPharmS. MSc. FFCI.
Royal Cornwall Hospitals NHS Trust
MEDICATION ERRORS: WHERE DO THEY HAPPEN?

Reducing medicines-related harm requires a clear understanding of where and when errors occur. This visual summary shows the latest estimates for England per year.

Dawn Connelly & Martin Cotterell

TOTAL ERRORS

237.4 million

The World Health Organization wants to reduce severe avoidable medication-related harm globally by 50% by 2022.
Overworked pharmacist's error led to death of grandmother who died from the ‘wrong pills’

Mr White said the two boxes were “side by side on the shelf and have similar branding”.

Mr White claimed to have carried out the required checks under the pharmacy standard operation procedures.
RESEARCH & EVALUATION

The Adoption of Barcode Scanning Technology in an Acute NHS Hospital Pharmacy
Barcode Enabled Dispensing

<table>
<thead>
<tr>
<th>Hospital No</th>
<th>Patient name</th>
<th>Verified</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>C804047</td>
<td>EDISCHARGE, MAXIMS</td>
<td></td>
<td>Stock at RCCS: 11 containers 0 du at ROBOT</td>
</tr>
<tr>
<td></td>
<td>NINETY</td>
<td></td>
<td>Stock at RCCS: 0 containers 0 du at ROBOT</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>DOXYCYCLINE 100 mg Capsules STAT dose</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>100 mg oral</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>C804047</td>
<td>EDISCHARGE, MAXIMS</td>
<td></td>
<td>Stock at RCCS: 44 containers 0 du at ROBOT</td>
</tr>
<tr>
<td></td>
<td>NINETY</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>AMOXICILLIN 500 mg Capsules</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>500 mg oral THREE times a DAY (Morning, Lunchtime + Night)</td>
</tr>
</tbody>
</table>

**‘GLN’**

**‘GTIN’**

**‘GSRN’**
RESULTS
## Safer Dispensing (P<0.001)
### Prevented Error Rates Reduction

<table>
<thead>
<tr>
<th>Error type</th>
<th>Dispensing Error Monitoring Period 1 (barcode non mandatory)</th>
<th>Dispensing Error Monitoring Period 2 (barcode mandatory)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Prevented Incidents</td>
<td>Rate (%)</td>
</tr>
<tr>
<td>Bar-code Insensitive Errors</td>
<td>Administrative</td>
<td>4 0.11</td>
</tr>
<tr>
<td></td>
<td>Label directions</td>
<td>13 0.35</td>
</tr>
<tr>
<td>Total Bar-code Insensitive Errors</td>
<td></td>
<td>17 0.46</td>
</tr>
<tr>
<td>Barcode Sensitive Errors</td>
<td>Wrong patient</td>
<td>1 0.03</td>
</tr>
<tr>
<td></td>
<td>Drug strength</td>
<td>5 0.13</td>
</tr>
<tr>
<td></td>
<td>Drug form</td>
<td>3 0.08</td>
</tr>
<tr>
<td></td>
<td>Drug name</td>
<td>2 0.05</td>
</tr>
<tr>
<td></td>
<td>Cost centre</td>
<td>1 0.03</td>
</tr>
<tr>
<td>Total Bar-code Sensitive Errors</td>
<td></td>
<td>12 0.32</td>
</tr>
</tbody>
</table>

| Total Number of prevented Errors | 29                  | 9                  |
| Number of non-stock items dispensed | 3730               | 4667               |
| Prevented Error Rate (%)         | 0.78                | 0.19 (P<0.001)     |
Next Steps

Integration of GS1 into other Steps in the Dispensing Process & Barcode Medicines Administration
Co-Codamol Tablets 60 tablets
ONE tablet to be taken FOUR times a day, when required for pain

Mr. Alex Krasnov 16-FEB-2018
Lviv Hospital Pharmacy, Lviv Hospital, LVIV, LV Oblast
KEEP OUT OF REACH OF CHILDREN
WARNING
The dispensed product does not match the issued product
Wider Application

For patients under my care at Park Grange Care Home

Bulk prescription

3,000ml Latulose
To be given in accordance with GP instruction on MAR chart.

Dr R Jones 10/01/2014

For patients under my care at Park Grange Care Home

Bulk prescription

3,000ml Latulose
To be given in accordance with GP instruction on MAR chart.

Dr R Jones 10/01/2014
Barcode Medicines Administration
Manufacturers Take Note!
Scan4Safety

Right Patient:
Setting standards to make sure we always have the right patient and know what product was used with which patient, when.

Right Product:
Setting standards to make sure our staff have what they need, when they need it.

Right Place:
Setting standards to make sure that patients and products are in the right place.

Right Process:
Setting standards and implementing common ways of working to deliver better and more easily repeatable patient care.

Improve Efficiency
Improve Patient Safety
Release Time to Care
Thank You For Listening
Closed loop of medication up to point-of-care scanning
Global GS1 Healthcare Conference, 26 March 2019
Sébastien Langlois-Berthelot
Barcode Implementation on Roche Pharmaceutical Products

Secondary vs. Primary Packaging

Barcodes on Secondary Packaging

- No barcode: 3%
- Linear barcode (EAN/UPC): 30%
- GS1 DataMatrix (containing at least GTIN, Expiry Date and Batch Number): 67%

Barcodes on Primary Packaging

- No barcode: 72%
- Linear barcode (US): 14%
- GS1 DataMatrix (containing GTIN only): 10%
- GS1 DataMatrix (containing GTIN, Expiry Date and Batch Number): 4%

Percentage of marketed Stock Keeping Units worldwide (March 2019)
Closing the loop of medication = Barcoding below unit of sale

Challenges and Opportunities for pharmaceutical manufacturers

**Challenges**

- Diversity of primary packaging (blisters, bottles, syringes, ampoules…)
- Small containers and labels
- Diversity of printing technology and packaging equipment
- Adding Batch and Expiry Date requires substantial time and investment

**Opportunities**

- Manufacturers and Healthcare Providers are familiar with DataMatrix due to secondary packaging implementation
- Identification of the product with a barcode will allow more safety at point of care scanning
- GTIN in the barcode already supports right medication identification, e-prescription, bedside scanning and link to master data
Roche’s Journey to Single Unit Barcodes
*First Attempts to Meet Hospitals Needs (2011-2016)*

- **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)

*GS1 DataMatrix with GTIN only*

*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!

In parallel to technical preparation for inclusion of expiry date and batch, we want to increase the number of primary packaging with at least static GS1 DataMatrix (GTIN only) to support first immediate benefits for Healthcare Providers and Patients.

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

Endorsed by
Benefits of including the GTIN in a DataMatrix on the primary packaging

Beyond making product identification at point of care safer and more reliable, GTIN on primary packaging allows a number of new opportunities:

- Link with **IDMP** (Identification of medicinal products): a set of ISO norms which support a harmonized nomenclature of pharmaceutical products at different levels

- Ability to use **GDSN** (Global Data Synchronization Network) to share Primary Pack GTINs and product data attributes with Healthcare Providers

- Sharing of **digital content** (electronic leaflets, patient educational material) with the future **GS1 Digital Link** standard, currently in preparation
Doing now what patients need next