



The Global Language of Business

Closed loop medication up to point-of-care scanning

Dennis Even, IT Director, Pfizer Inc, US





Dennis Even
Pfizer Inc., US



Michiel Duyvendak,
St. Antonius Hospital



Ad Deeben
TEVA



Iain Davidson
Royal Cornwall
Hospitals NHS Trust



**Sebastien Langlois-
Berthelot**
F. Hoffmann-La Roche Ltd

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



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



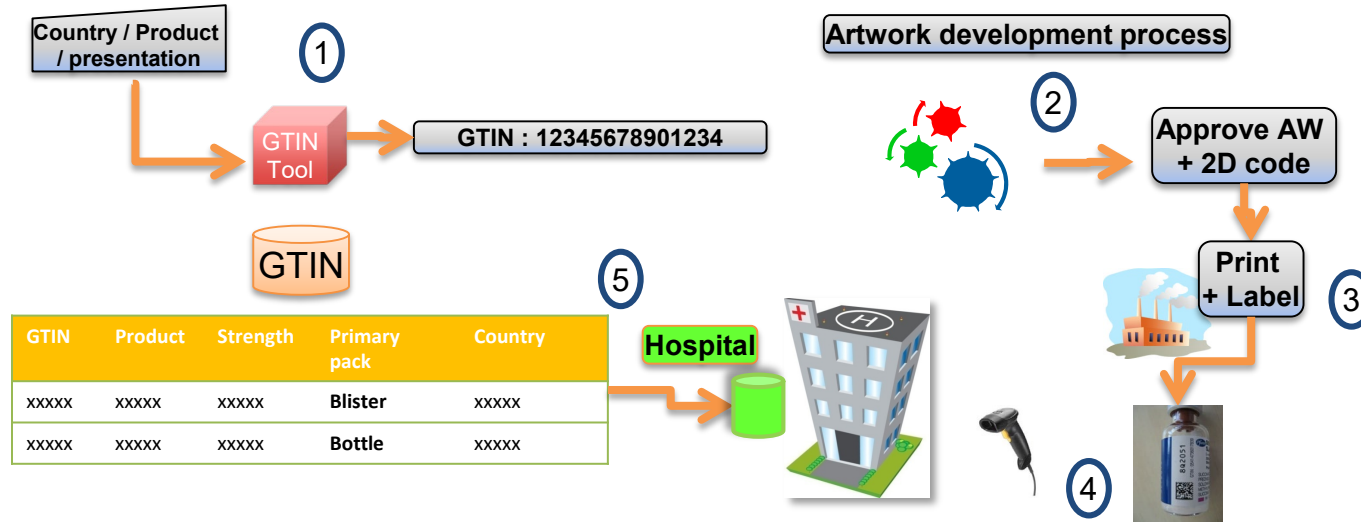
GTIN

Aligned product drug codes is foundational to overall success

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



Single Unit POC Scanning Process



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

US Story: Scanning at Point-of-Care

- April 2004, FDA mandated barcodes on labels by 2006 ¹
 - Predicted prevention of nearly 500,000 adverse events / transfusion errors over the 20 years (estimated cost savings of \$93 billion) ²
- 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% ³
- Evidence of reliance in 2017 with disruption (GS1 UPC-A replaced by some manufacturers with the GS1 DataMatrix)

Annotations:

1. Food and Drug Administration: FDA issues barcode regulation; fact sheet. Washington, DC: 2004. Available at:

<http://www.fda.gov/oc/initiatives/barcode-sadr/fs-barcode.html>.

2. FDA to require bar coding of most pharmaceuticals by mid-2006. Am J Health Syst Pharm 2004;61(7):644–5.

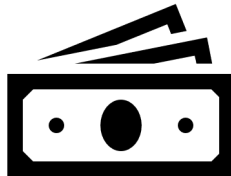
3. Research published by the Society for Academic Emergency Medicine (Bonkowski et al., 2013)



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?

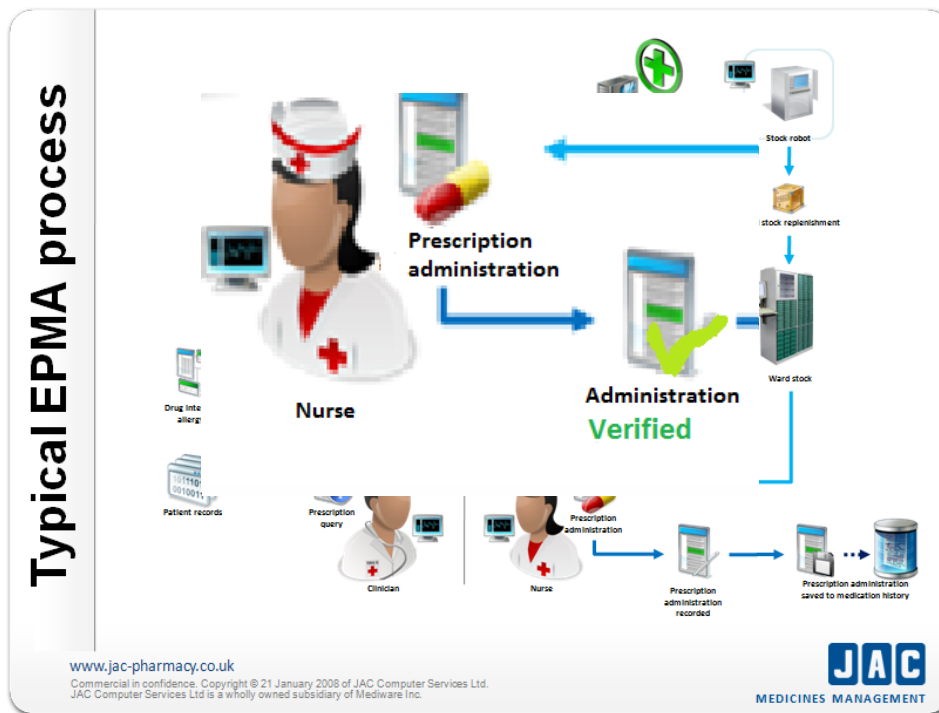
Dr. Michiel Duyvendak, Hospital Pharmacist,
Antonius Hospital Sneek & Emmeloord

GS1 Congres 26-03-2019
Conflict of Interest: None

The Essence of Health Care



Typical Process

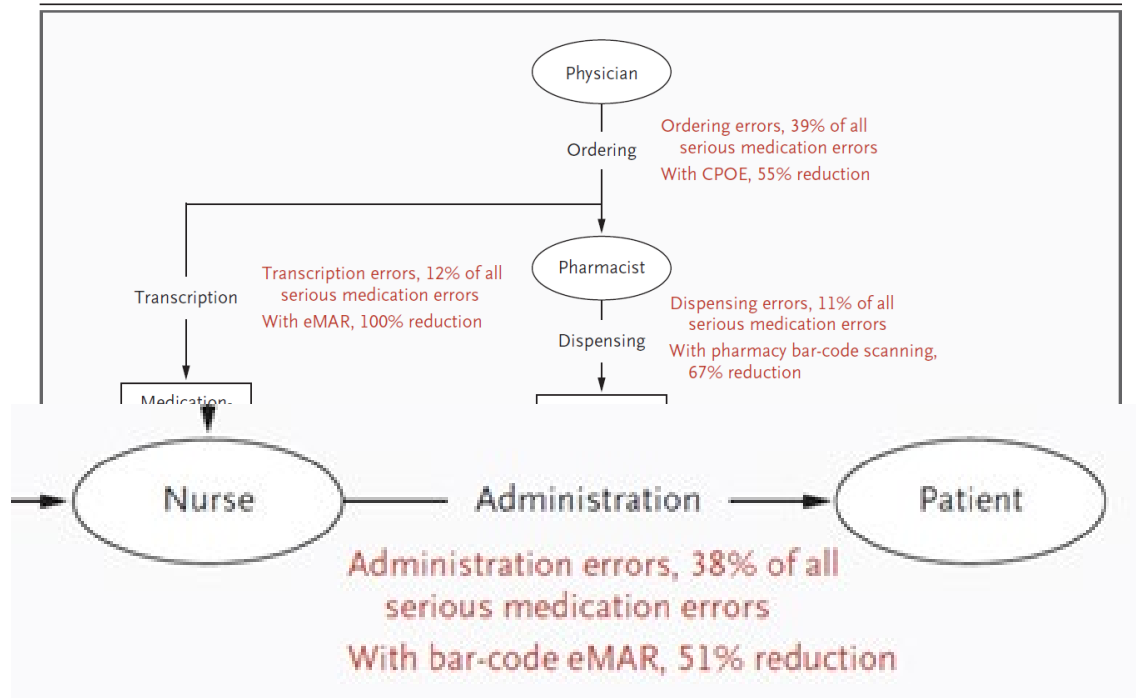


Optical Strenght and Weakness

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

The lrttees 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



- ❶ **Stijljaar 2017** Heel Drachten in de kleuren geel, rood en blauw
- ❷ **Friese Aanpak** Burgers denken mee over hun eigen leefomgeving
- ❸ **Landbouw Tweede Kamer** wil grenzen aan intensieve veehouderij
- ❹ **Elfstedentocht** 'Onbekende' winnaar van 1947 overleden

Meer macht

Stemlokalen in Nederland open voor Turks referendum



In Diverster, Amsterdam en Den Haag zijn gisteren stemlokalen opengestaan voor het Turkse referendum. Tienduizenden Turken No het referendum over de eenzijdige vrijgave van de grondwet van Turkije. Die aanpak staat de Turkse president Erdogan meer in het (al of heft) mee. (Foto: AFP)

Sneker medicijnmethode redt levens

Barcode op pillen verhindert fouten met medicatie in ziekenhuizen

Sneek: Als alle medicijnen in ziekenhuizen zijn voorzien van een barcode, zouden er in Nederland jaarlijks bijna vijftig doden minder vallen. Dat is de helft van de bijna honderd mensen die er nu per jaar in Nederland overlijden als gevolg van fouten met me-

dicatie in het ziekenhuis. Dat blijkt uit een proef die in het Antonius Ziekenhuis in Sneek is gehouden. Nu is Sneek rijder van Tilburg, Nijmegen en Harderwijk. Het ministerie van Volksgezondheid doet officieel onderzoek naar de medicatie methode. Daarbij worden door de ziekenhuisapotheker zelf, coördinatoren, verpleegsters en verpleegkundigen van de farmaceut afgevoerd dat niet heeft gedaan. Het laatste in-

ziekenhuizen is namelijk dat pillen niet per doosje, maar aan het bed per pil worden uitgegeven. De effecten van het nieuwe systeem zijn gunstig. Bij het onderzoek, als alle ziekenhuizen samen zouden werken, zou het aantal de vijf-tig doden ook 250 gevallen van ernstige gezondheidschade schelen, plus 30.000 menselijke 'ligdagen'. De kans dat de verpleging verkeerde pillen aan een patient geeft, is met de helft verminderd, zegt zieken-

huisapotheker Michiel Duyvendak van het Antonius. Hij kreeg gisteren als aanpak van de methode een Pluk van de organisatie die de barcode ontwikkelt, GS. Ongeveer 80 procent van de pillen heeft wel een barcode. Het grote risico zit bij de ontbrekende 20 procent. 'Alleen al door deze resterende medicijnen van barcodes te voorzien, bespaart u een enorme winst voor de patiëntveiligheid', zegt Duyvendak. Hij wil het liefst dat de leveranciers alle

Ziekenhuissterfte kan omlaag door barcode op alle medicijnen

Jos de Groot
REDACTIE BINNENLAND

Een barcode op alle ziekenhuismedicijnen kan per jaar de dood van bijna vijftig patiënten voorkomen. Jaarlijks overlijden honderd mensen in Nederlandse ziekenhuizen nadat ze verkeerde medicijnen hebben gekregen. Volgens onderzoek van het ministerie van Volksgezondheid zouden ook nog eens 250 patiënten minder ernstige gezondheidschade oplopen als alle medicatie is voorzien van een barcode en hebben ziekenhuizen gemiddeld tienduizend 'ligdagen' minder nodig. Ongeveer tachtig procent van alle medicatie is nu al standaard voorzien van een barcode. Om verschillende rede-

nen is de overige twintig procent dat niet. Een barcode identificeert producten met een unieke cijferreeks. Als een arts een medicijn altijd eerst kan scannen voor deze wordt toegediend, is de kans dat hij of zij een verkeerd doosje pakt veel kleiner. Onder andere het Antonius Ziekenhuis in Sneek plakt zelf al een code op verpakkingen waar fabrikanten dat nalaten.

Michiel Duyvendak (41), apotheker van het Antonius Ziekenhuis in Sneek en verantwoordelijk voor de test met barcoding aldaar, wijst onder meer de marktwerking in de zorg aan als boosdoener: "Producten voorzien van een barcode kost veel geld. Afnemers kijken gauw naar de laagste prijs en dus is het niet meteen aan-

trekkelijk voor de industrie om te investeren in barcoding."

Terwijl het systeem ook geld zou kunnen besparen, zegt Duyvendak. Want hoe minder mensen verkeerde medicijnen krijgen, hoe minder zorg ze nodig hebben. Duyvendak ziet nog meer voordelen. "Patiënten die thuiszitten, kunnen via een app hun medicatie scanen en zo bijhouden wanneer en in welke dosering ze hun medicijnen moeten innemen."

Voor zijn pionierschap op het gebied van barcoding van medicijnen ontving Duyvendak gisteren een bronzen pluim. De prijs werd hem toegekend door GS, de internationale organisatie die zich inzet voor standaarden op het gebied van elektronische bedrijfscommunicatie.

Barcoding 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 werkgroep Barcoding Geneesmiddelen



Implementation >95% UDP BCMA is Slow



Scanning on the Ward



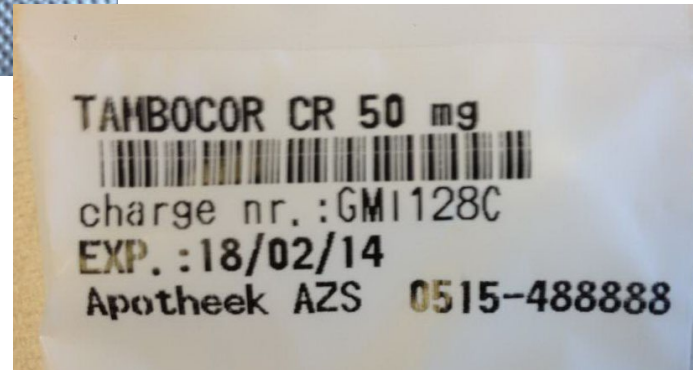
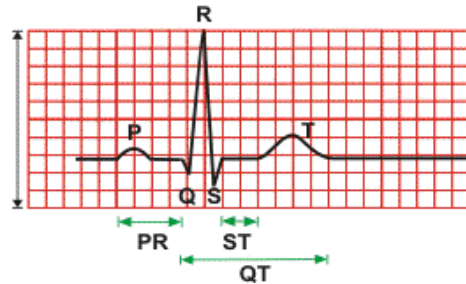
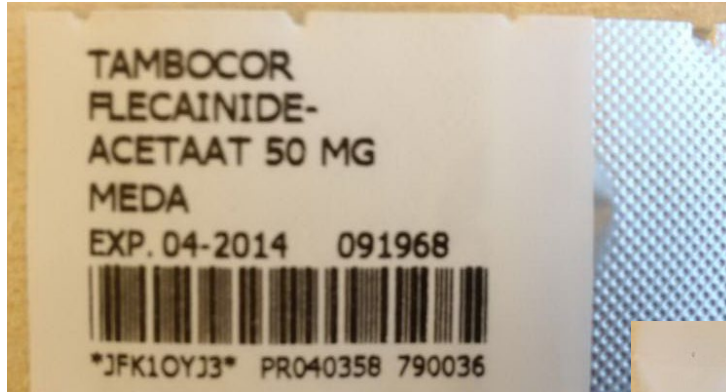
Patient Errors



Recent Errors



Sound alike



Issues



High Risk



Unusable/Errornous Barcode



Protect from light/moist no unit dose pack

Good Manufacturing Practice

Verpakken vaste orale medicatie met DTA (tray)		antonius zorggroep
Naam geneesmiddel: SALOFALK TABLET MSR 250MG Chargennummer: 130909/0004775604 Artikelnummer/barcode: 15563324 Magazijn: M1 Verpakking: 100 stuk Fabrikant: DR. FALK PHARMA BENELUX BV Leverancier: ALLIANCE HEALTHCARE B.V.		RESULTAAT Chargennummer: 1201335L Houdbaar t/m: 30-09-2015 04-10-2014
Akkoord: SALOFALK TABLET MSR 250MG ONGEPAKT Datum: 04-10-2013 Charge nr: 130909/0004775604 Artikelnummer: 15563324 Houdbaar t/m: 30-09-2015 Verpakking: 100 stuk Fabrikant: DR. FALK PHARMA BENELUX BV Leverancier: ALLIANCE HEALTHCARE B.V.		Uiterlijke kenmerken: a. rond / niet dootbaar b. geen inscriptie c. geel
Uitvoering: Breng de medicatie die omgepakt moet worden en controlevoorschrift in aparte bak naar de FDS-ruimte. (volg de kledingprocedure) Aantal te verpakken: Zijn de ruimte, apparatuur, werkblad, schoon en vrijgegeven? - Laat de medicatie vrijgeven voor verpakken - Verpak de medicatie met de FDS conform de procedure - Markeer de restdoos en vermeld de correcte aantal op de restdoos - Ruim alle restanten op en maak schoon volgens de schoonmaakprocedure - Vul de ruimte en apparatuur logboeken in - Plaats het omgepakte product inc. de originele verpakking terug in quarantaine - Laat het product vrijgeven door een apotheker		Akkoord: a) Ja / b) Ja / c) Ja / d) Ja 100 stuks (A) JA / NEE Paraaf: <i>[Handwritten signature]</i>
Opmerkingen: - Pak het artikel om binnen Chipsot - Indien niet mogelijk, laat het corrigeren Opbrengst: Aantal uitgeleend: stuks (B) Aantal vernietigd: stuks Reden(en) uitval: Netto aantal: 100 stuks (=A-B) Etiketten: Aantal aangemaakt: stuks Aantal gebruikt: stuks Aantal vernietigd: stuks		Bijzonderheden: Uitgevoerd: Datum: 04-10-2013 (apotheker) Vrijgegeven door: Datum: (apotheker) GOEDGEKEURD / AFGEKEURD

Afkennenlijst barcoderen		ziekenhuis				
Degene die barcodeert, noteert het geneesmiddel, plakt een voorbeeldetiket en vult zijn/haar naam in. Een tweede persoon controleert of het juiste etiket op het juiste middel is geplakt en vult vervolgens, ter controle, zijn/haar naam in. Aan het eind van de dag controleert en parafeert de receptapotheeker. Lijsten gaarne in de order laten.						
Naam middel	Voorbeeld van etiket	Naam plakker	Naam controleur	Aantal etiketten afgedrukt	Aantal etiketten geplakt	Aantal etiketten vernietigd
Morfine 100mg/ml ampul 1ml		B	Ai	121	120	-
Fentanyl matrix 12mg/12ml		Ai	Ai	81	80	-
Fentanyl matrix 25mg/12ml		M	Ai	71	70	-
Allopurinol tablet 300mg PR		Ai	PM	181	180	-
Clonidine schuim voor cuion 0,5mg/1g		UR	PM	5	4	-
Poester Aer 100/6mg/100 120D		UR	PM	7	6	-
Datum: 3-10-2013		Paraaf receptapotheeker:				

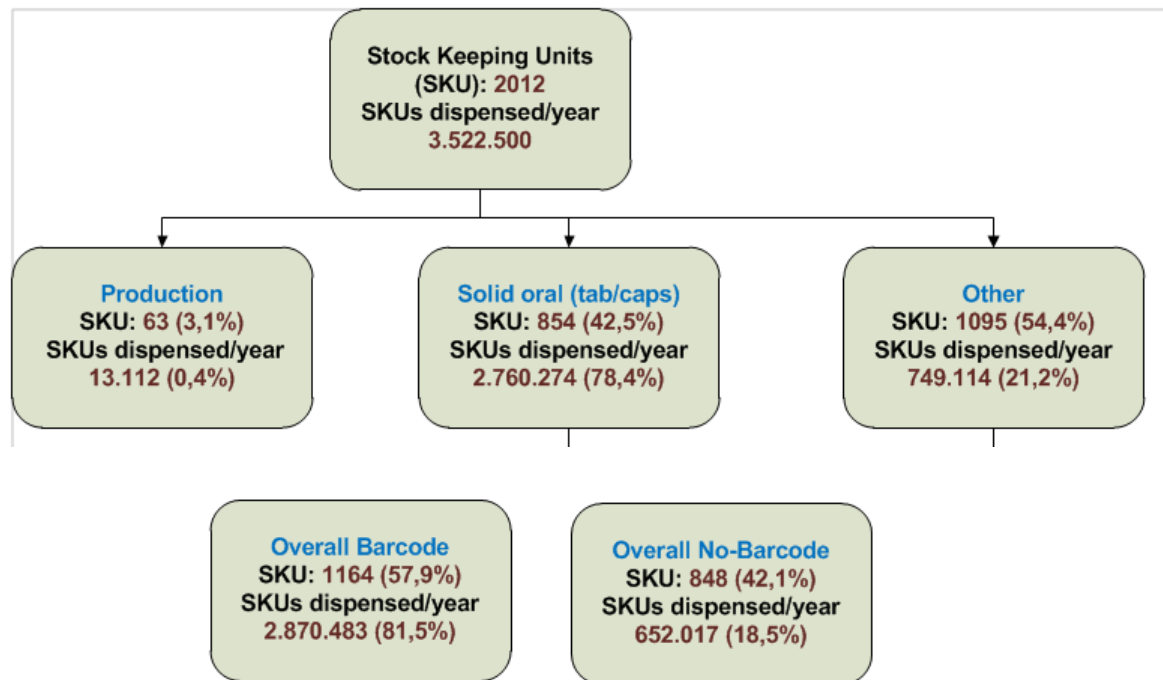
High risk medication (RTA)

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



Workarounds and Errors

	MAE	No MAE	Total	OR (95% CI)
WA	271 (4.7%)	3362 (58.0%)	3633 (62.7%)	
No WA	16 (0.3%)	2144 (37.0%)	2160 (37.3%)	
Total	287 (5.0%)	5506 (95.0%)	5793 (100%)	3.06 [2.49- 3.78]



rijksuniversiteit
 groningen

Veen v/d et al., 2017: <https://doi.org/10.1093/jamia/ocx077>

IMPROVING LIFE AT WORK

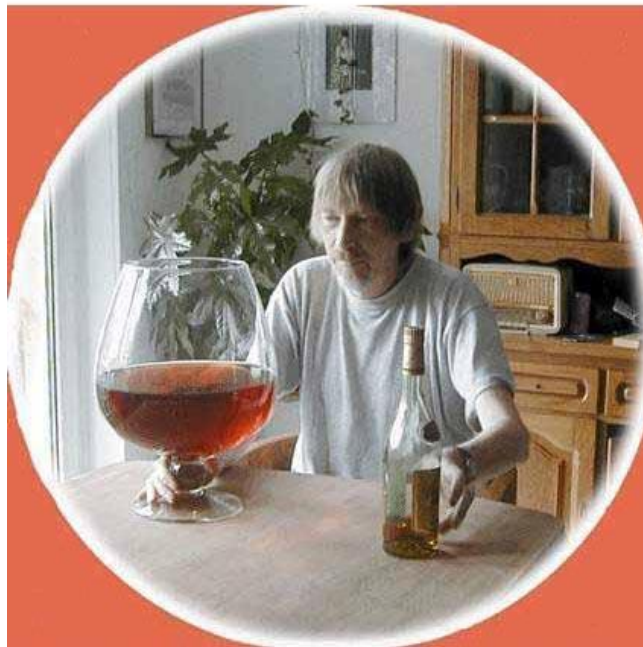


Medication Dispensing (Nursing)Home



Questions?

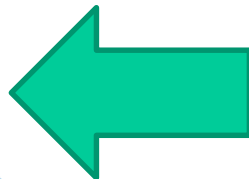
My Doctor said "Only 1 glass of alcohol a day". I can live with that.



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)



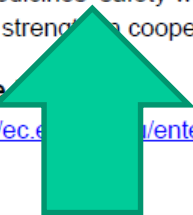
These proposals will now be transmitted to the European Parliament and the Council.

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

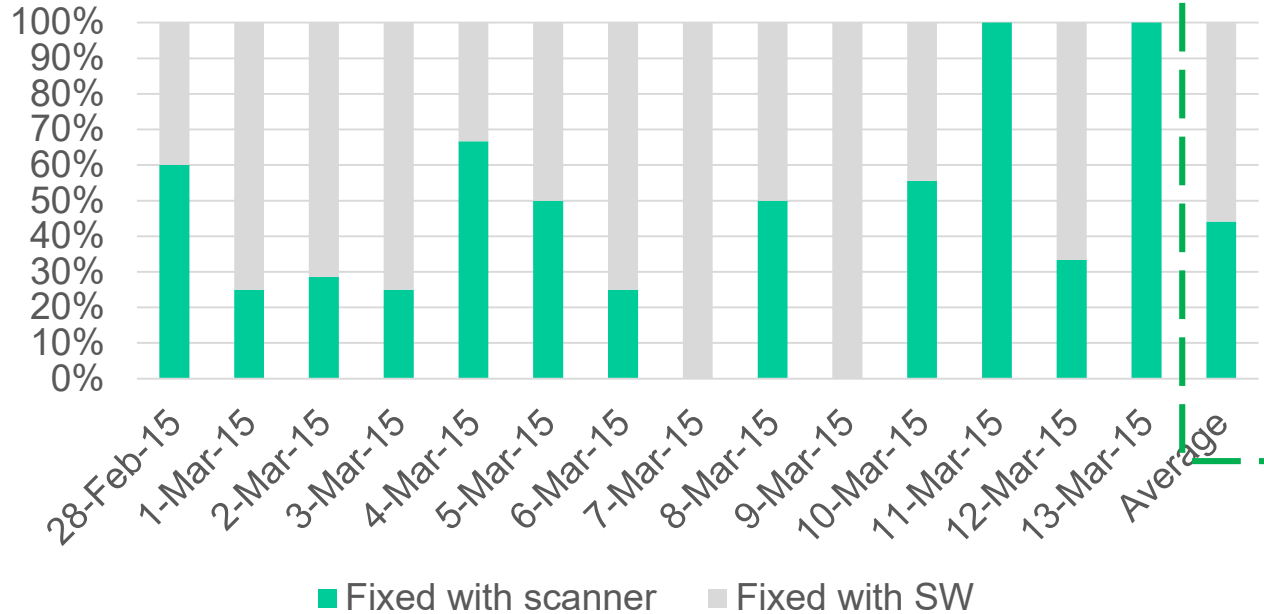


Software only solutions to closed loop verification cannot detect or fix several categories of errors

	MedEye Software			
	Barcodes	Medeye Software	+ scanner	Legend
Tablets				
<u>Baxtered</u>				
Extra pill in bag	Doesn't detect	Doesn't detect	Doesn't detect	Doesn't detect
Pill missing from bag	Doesn't detect	Doesn't detect	Doesn't detect	Doesn't detect
Split pill error	Doesn't detect	Doesn't detect	Doesn't detect	Doesn't detect
Stopped prescription	Doesn't detect	Doesn't detect	Doesn't detect	Doesn't detect
New prescription	Doesn't detect	Doesn't detect	Doesn't detect	Doesn't detect
Wrong patient	Doesn't detect	Doesn't detect	Doesn't detect	Doesn't detect
<u>Not Baxtered</u>				
Extra pill given	Doesn't detect	Doesn't detect	Doesn't detect	Doesn't detect
Too few pills given	Doesn't detect	Doesn't detect	Doesn't detect	Doesn't detect
Pill needs to be split	Doesn't detect	Doesn't detect	Doesn't detect	Doesn't detect
Stopped prescription	Doesn't detect	Doesn't detect	Doesn't detect	Doesn't detect
New prescription	Doesn't detect	Doesn't detect	Doesn't detect	Doesn't detect
Non Tablets				
<u>Barcoded</u>				
Wrong medication	Doesn't detect	Doesn't detect	Doesn't detect	Doesn't detect
Stopped prescription	Doesn't detect	Doesn't detect	Doesn't detect	Doesn't detect
Wrong dose	Doesn't detect	Doesn't detect	Doesn't detect	Doesn't detect

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.

Table 2 Number of observations, and error rates before and after BCMA implementation

Study	Ward type	No of observations		Frequency of errors including time errors		Change from baseline	p Value	Frequency of errors excluding time errors		Change from baseline	p
		Baseline	Post-BCMA	Baseline	Post-BCMA			Baseline	Post-BCMA		
Paoletti <i>et al</i> ⁹	Cardiac telemetry	308	318	25.3%	19.2%	24.1%	0.065	1.6% [*]	1.6% [*]	0.0%	0.959
Poon <i>et al</i> ¹⁰	Medical	2008	2232	ND	ND	ND	ND	5.3% [†]	3.8% [†]	28.5% [‡]	ND
Paoletti <i>et al</i> ⁹	Medical-surgical	320	310	15.6%	10.0%	35.9%	0.035	6.3% [*]	2.9% [*]	53.5%	0.045
Franklin <i>et al</i> ¹¹	Surgical	1473	1139	7.0%	4.3%	38.6%	0.005	ND	ND	ND	ND
Helmons <i>et al</i> ¹²	Medical-surgical	888	697	10.7%	8.2%	23.6%	ND	8.0%	3.4%	56.9%	ND
Poon <i>et al</i> ¹⁰	Surgical	3528	3856	ND	ND	ND	ND	9.8% [†]	5.4% [†]	45.1% [‡]	ND
De Young <i>et al</i> ¹³	ICU	775	690	19.7%	8.7%	56.0%	<0.001	3.6%	4.2%	-16.3%	ND
Helmons <i>et al</i> ¹²	ICU	374	394	12.6%	13.5%	-7.0%	ND	11.0%	9.9%	9.7%	ND
Poon <i>et al</i> ¹⁰	ICU	1187	1230	ND	ND	ND	ND	27.3% [†]	16.5% [†]	39.5% [‡]	ND
Morris <i>et al</i> ¹³	NICU	46090	46308	6.7%	8.0%	-14.7% [‡]	ND	ND	ND	ND	ND
Ros <i>et al</i> ²⁰	Neurology	3814	4300	5.8%	7.0%	-20.4%	<0.03	1.7%	0.8%	48.5%	<0.0008
Poon <i>et al</i> ¹⁰	Overall	6723	7318	16.7% [§]	12.2% [§]	27.3%	0.001	11.5%	6.8%	41.4%	<0.001

^{*}Excluding time and technique errors.

[†]Frequency 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.

[§]Only time errors.

BCMA, bar code-assisted medication administration; ND, not determined.

Table 3 Severity of observed errors or (potential) ADEs before and after implementation of BCMA

	Outcome measure	Baseline	Post-BCMA	% Change from baseline	p Value
Poon <i>et al</i> ¹⁰	Percentage clinically significant potential ADEs	1.8	0.9	48.5	<0.001
	Percentage serious potential ADEs	1.3	0.6	54.1	<0.001
	Percentage life-threatening potential ADEs	0.03	0.01	53.9	0.34
Franklin <i>et al</i> ¹¹	Mean score of potential error severity*	2.7	2.5		0.39
Morris <i>et al</i> ¹⁴	n/1000 doses of preventable ADEs†	0.86/1000 doses	0.43/1000 doses	47	0.044

*Scoring on a scale from 0 to 10 where 0 is no effect and 10 is death.

†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.

A healthcare professional, wearing a white lab coat, is using a handheld grey scanning device to scan a blister pack held in their other hand. In the background, a patient with brown hair, wearing a blue hospital gown, is lying in a bed, looking towards the camera. The scene is set in a clinical environment with a white wall.

Scannable dose.

Ad Deeben

Medisch Contact May 1984

Distributie en terhandstelling geneesmiddelen in verpleeghuis

De medicamenteuze therapie neemt een belangrijke plaats in bij de diverse therapieën die de arts bedenkt ten dage ter beschikking staan. De hierbij behorende medicamenten behoren niet alleen met zorg te zijn bereid, van vitaal farmaceutisch belang is ook dat de voorgeschreven medicatie op de juiste wijze en tijd wordt toegediend. Inzicht in en controle op de medicamenteuze therapie moet op elk moment mogelijk zijn. Binnen de intramurale gezondheidszorg heeft dit geleid tot invoering van diverse geneesmiddelenbewakingsregistratiesystemen in ziekenhuizen. In verpleeghuizen zijn dergelijke systemen nog niet of nauwelijks ingevoerd. In onderstaand artikel¹ wordt ontwerp en inbouw van een geneesmiddelenbewakingsstelsel in een verpleeghuis beschreven.

Het oude systeem

In het Utrechtse verpleeghuis "Albert van Koningh" functioneert sinds enkele jaren een geneesmiddelenregistratiesysteem². Dit verpleeghuis heeft een capaciteit van 260 bedden, verdeeld over acht afdelingen (verdelingen) (twee psychogeriatric, twee reactivering, twee verpleegbehoefte en twee begeleidingsbehoefte). De geneesmiddelenverzorging vindt plaats vanuit de apothekes van het Academisch Ziekenhuis Utrecht (AZU). In dit (oude) geneesmiddelenregistratiesysteem wordt uitgegaan van de door de arts geschreven medicatieprescriptie (MO). Deze is verantwoordig van Non Carbons Reproducing

(NCR)-papier en bestaat uit een origineel met drie doorklappen (geel, groen en roze). Het witte origineel is bestemd voor de apothekes, de roze doorklap voor de patiëntentafel van de verpleging, de groene doorklap voor het medisch secretariaat en de gele doorklap voor de patiëntentafel van de arts. De verpleging schrijft aan de hand van de MO's een medicatiekaart welke wordt gebruikt bij het uitzetten van de medicatie. Elke patiënt krijgt per toedieningsrondje een bekortje met medicatie uitgereikt. De geneesmiddelen worden op naam van de patiënt door het verplegend personeel bij de AZU-apotheek besteld. Dagelijks vindt geneesmiddelentransport plaats tussen AZU en verpleeghuis. Op elke afdeling bevindt zich een geneesmiddelenvoorraad onder beheer van de verpleging.

Redenen tot verandering

Uit een onlangs gehouden onderzoek³ is gebleken dat deze handelwijze als geneesmiddelenregistratiesysteem voor zowel arts als verpleging volstond. Wenselijk zijde de normen op dit gebied echter veranderen⁴ en bovendien zijn er enkele zwakke punten te constateren: Er vindt geen verantwoording van de toediening plaats; het geneesmiddelenbeheer is niet identificeerbaar op het moment van toediening; er is nauwelijks controle mogelijk op de aflevering van de medicatievoorziening op de afdelingen; bij het niet tijdig voorkomen van een middel wordt dit van anderen geleend; ook hier is de kans op fouten aanwezig. In het AZU zelf is sinds enige tijd een geneesmiddelenregistratiesysteem ingevoerd⁵, gebaseerd op richtlijnen van het ministerie, dat bovengenoemde bezwaren bijzich geheel omliep. De bedoeling was nu, uitgaande van het AZU-model en gebaseerd op richtlijnen van overheidswet, het huidige geneesmiddelenregistratiesysteem te herzien en een nieuwe methode voor de toediening en begeleiding van geneesmiddelen door te voeren. Hierbij zou enerzijds de kwaliteit van de farmaceutische therapie worden bevorderd en anderzijds op de lange duur een kostenbesparing kunnen worden verkregen. Een en ander heeft geresulteerd in het ontwerpen en invoeren van de methode die hierna wordt beschreven.

Het nieuwe systeem

De belangrijkste wijziging ten aanzien van het hiervoor beschreven systeem betreft de verantwoording en registratie van de medicatie

toediening door de verpleging. Verder is de medicatie nu als EAV⁶ geleverd en is de opdrak van de MO gewijzigd. De distributie van geneesmiddelen wordt geregeld vanuit een centraal geneesmiddelendepot in het verpleeghuis met behulp van medicatievoorzieningsagents. De groene doorklap van de MO is komen te vervallen, daar het medisch secretariaat slechts sporadisch discrepantie ontdekte tussen MO en vermelding door de arts in de patiëntentafel. In het geneesmiddelendepot is een apothekersassistent werkzaam; zij verzorgt de geneesmiddelenlevering naar de afdelingen. Afhankelijk van de structuur van de afdeling zijn één of twee medicatievoorzieningsagents (m.v.v.) aanwezig⁷. Dit zijn verplaatsbare kastjes, waarin zich borden, voorzetten van de naam van de betreffende patiënt, bevinden. De m.v.v. wordt eens per week in het geneesmiddelendepot met geneesmiddelen gevuld. Terug op de afdeling wordt de medicatie vanuit de m.v.v. op grond van de MO aan de patiënt verspreid. De meer gedetailleerde gang van zaken is als volgt:

De medicus schrijft voor iedere medicatie (wijziging) een MO uit. Het origineel (wrt) gaat naar het geneesmiddelendepot. Op basis hiervan wordt de medicatie verstrekt. De gele doorklap bezwaart de arts in de patiëntentafel; de roze doorklap (uitgegeven in arts' steviger) (pauze) (niet) nemen met een verantwoordingsblad in de uitdekkingsklap van de verpleging. Op vaste toedieningsmomenten wordt de medicatie vanuit de m.v.v. aan de hand van de uitdekkingsklap aan de patiënt verspreid. Bij de patiënt wordt in deze uitdekkingsklap de toe te dienen medicatie opgezocht en vervolgens toegediend, waarbij het behulp van het etiket aan de achterkant van de EAV wordt gecontroleerd of men het juiste geneesmiddel in handen heeft. Er wordt in het desbetreffende vakje van het verantwoordingsblad geantwoord. Er wordt dan rechtstreeks van een doorklap van de door de arts geschreven MO toegediend. Deze dient leersbaar en volledig te zijn ingevuld. Indien dit niet het geval is, staat steeds weer een volgende vlotte afwerking van de medicatievoorziening in de weg. De verpleging en apothekersassistenten hebben hierbij een signaleerende functie. De toediening van vloeistoffen welke niet als EAV zijn verpakt wordt ook verantwoord, evenals de terhandstelling van "zonnig" medicatie. Indien de medicatie slechts op bepaalde dagen is voorgeschreven, dient op de overige dagen in het desbetreffende vakje van het

Distribution medicines in nursing homes

Identification on unit level

Costs 3 cents per dose

EAV guarantees clear identification



¹ De geneesmiddelen van dit artikel zijn: Beetholker, student farmacie, Universiteit van Amsterdam; Drs. P. van der Aalst, apotheker, Academisch Ziekenhuis Utrecht (AZU); Drs. J. H. G. van der Aalst, Afdeling Praktische en Sociale Farmacie, Rijksuniversiteit Utrecht; Drs. G. van der Aalst, Wetenschappelijk medisch onderzoek Farmaceutische, Academisch Farmaceutisch Ziekenhuis Utrecht (AZU); Prof. Dr. P. A. M. N. de Boer, Dr. A. A. S. van der Aalst, wetenschappelijk onderzoek Farmaceutische, Universiteit van Amsterdam; Drs. van der Aalst, apotheker, Universiteit van Amsterdam.

² EAV: Elektronische Verpleegkaart, waarbij iedere dosis (medicatie, infusie, etc.) wordt geregistreerd en gecontroleerd.

³ P. van der Aalst, M. de Boer, S. de Boer.

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



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
 - Swisslog (<http://www.medicalexpo.com/prod/swisslog/product-70236-666345.html>)
 - 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

Splitting bulk if more
presentations

Purchase order CPO

Serialization

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

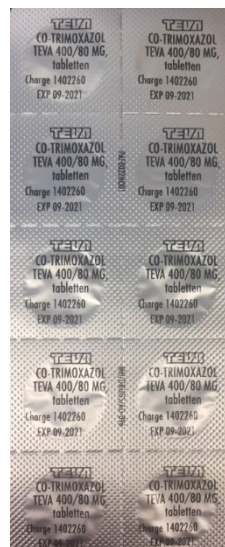
Reflection aluminium

White background for readability

Perforated blister

Symmetrical blister

Adjustment registration file



A close-up photograph showing a healthcare professional in blue scrubs with a stethoscope around their neck, gently holding the hand of a patient. The patient is wearing a white hospital gown with a small blue pattern. The background is softly blurred, showing a warm-toned interior. The text "Next steps, the future" is overlaid in white on the lower left, with a green horizontal line below it.

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

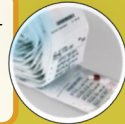


Nursing home

5. Medication distribution system



6. Baxter, packed per intake moment scannable



Hospital

7. Scannable dose bedside scanning



Closed loop medication management system



Figure 4. Illustration 'Closed loop Medication Management'. Adapted and acquired with permission from: <http://cstproject.ca/news/closed-loop-medication-management-safety-win> Copyright 2014, Clinical & Systems Transformation (CST).

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?

A close-up photograph of a baby with light brown hair and dark eyes, looking directly at the camera with a determined, slightly pouting expression. The baby is wearing a green long-sleeved shirt with a white collar. They are holding a large, clenched fist of sand in their right hand. The background is a blurred beach scene with sand and waves.

Let's Do This!

TOGETHER

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

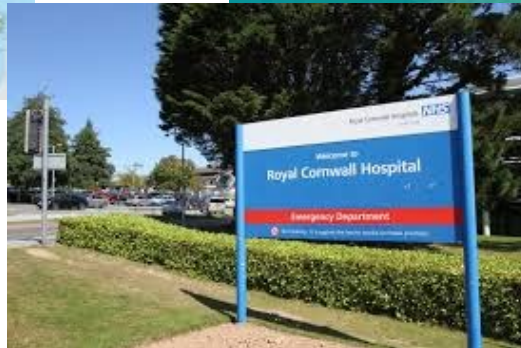
BPharm. MRPharmS. MSc. FFCI.

Royal Cornwall Hospitals NHS Trust

One + all | we care

Royal Cornwall Hospitals

NHS Trust



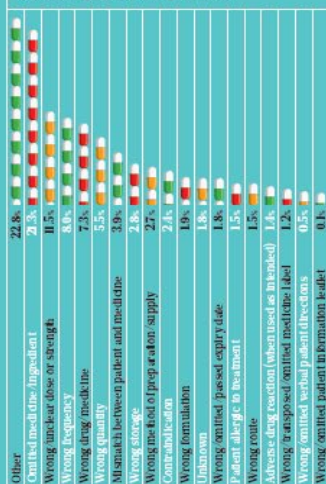
MEDICATION ERRORS: WHERE DO THEY HAPPEN?

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

DAWN CONNELLY & MARTIN COTTERELL

TYPES OF ERROR

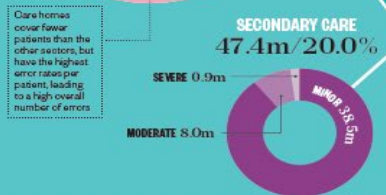
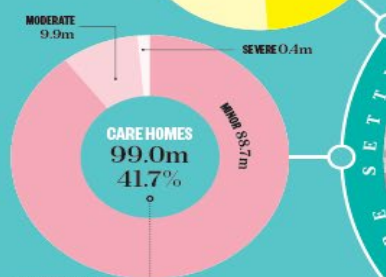
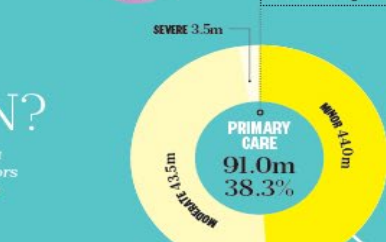
Around 204,000 medicines-related incidents were reported to England's National Reporting and Learning System during 2017-2018.



Source: Data obtained via a Freedom of Information request submitted to The Pharmaceutical Journal in 16-18 improvement. Incidents reported to the NLRB as occurring between 1 April 2017 and 31 March 2018.



Error rates per patient are lowest in primary care but most medicines are used, so the overall number of errors is second highest



The World Health Organization wants to reduce severe avoidable medication-related harm globally by 50% by 2022



Prescribing errors are most likely to cause moderate harm (41.2% of moderate errors)

Deaths owing to definitely avoidable adverse drug reactions per year:

712

NHS costs of definitely avoidable adverse drug reactions per year:

£98.5m



POTENTIAL SOLUTIONS

Several strategies can be employed to reduce medicines-related harm.

- Roll out and optimise electronic prescribing and medicines administration systems

- Roll out proven interventions, such as PINCER, where pharmacists identify patients who are at risk from hazardous prescribing (see page 95)

- Improve the information available to patients to promote joint decision-making

- Use patient-friendly packaging and labelling
- Improve shared care across different settings

- Embed adequate training to safe and effective medicines use in undergraduate training and continuing professional development

- Encourage reporting of medication errors (see page 124)
- Reduce inappropriate polypharmacy

Source: Department of Health and Social Care. The report of the expert working group on reducing medication-related harm. February 2016.

MARTIN COTTERELL

MINOR: Error with little or no potential to cause harm
MODERATE: Error with potential to cause moderate harm
SEVERE: Error with potential to cause severe harm

Source: Policy Research Unit in Economic Evaluation of Health & Care Interventions. The prevalence and economic burden of medication errors in the NHS in England. February 2016.

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.

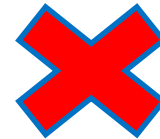


RESEARCH & EVALUATION

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

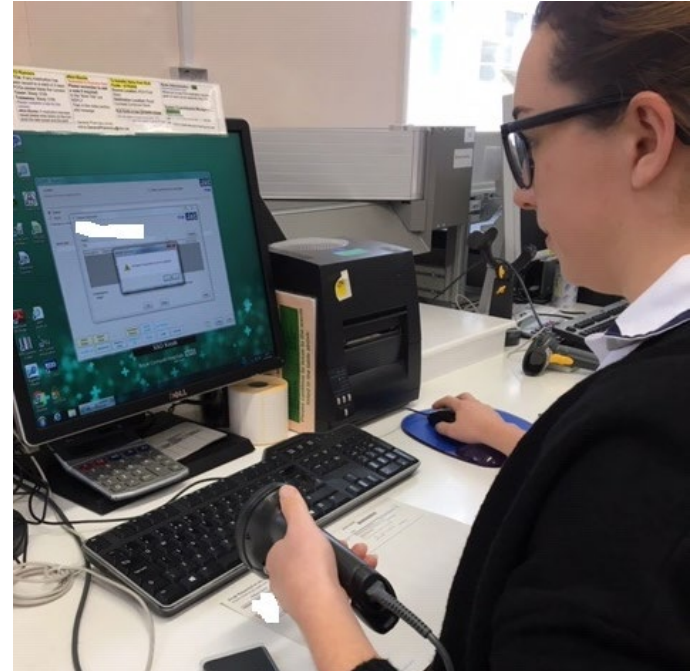
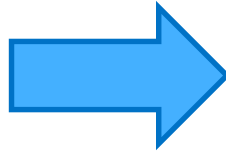
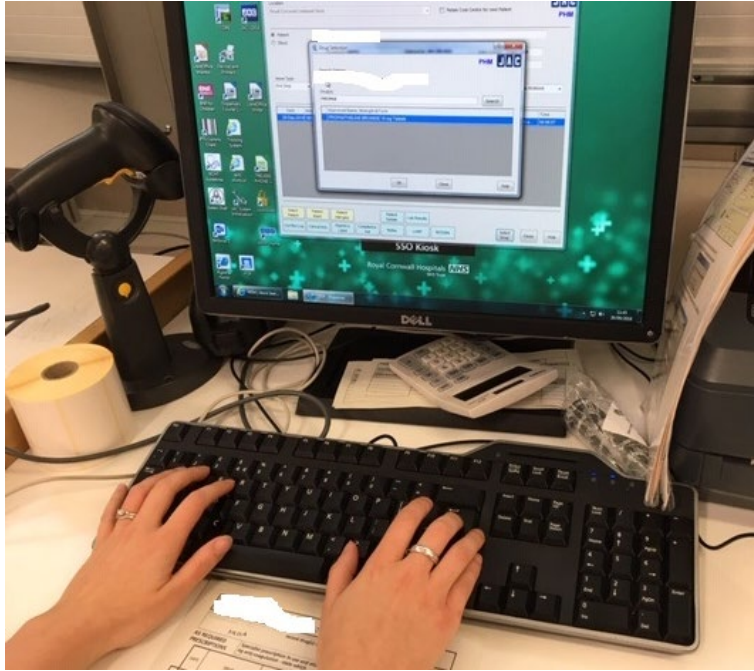
One + all | we care

Royal Cornwall Hospitals
NHS Trust



One + all | we care

Royal Cornwall Hospitals
NHS Trust



Barcode Enabled Dispensing

BOTOX WARD			BOTOX WARD	
Hospital No	Patient name	Verified	Note	
C804047	EDISCHARGE, MAXIMS NINETY	✓	Stock at RCCS: 11 containers 0 du at ROBOT Stock at RCCS: 0 containers 0 du at ROBOT	Ordered by: MRS ESTHER DRYDEN Clinically checked by: MR IAN NICHOLLS
			DOXYCYCLINE 100 mg Capsules STAT dose 100 mg oral	27/02/2014 08:34 Reply
				Dispensed by: Checked by:
CRITICAL MEDICINE				
C804047	EDISCHARGE, MAXIMS NINETY	✓	Stock at RCCS: 44 containers 0 du at ROBOT	Ordered by: MRS ESTHER DRYDEN Clinically checked by: MR IAN NICHOLLS
			AMOXICILLIN 500 mg Capsules 500 mg oral THREE times a DAY (Morning, Lunchtime + Night)	27/02/2014 08:42 urgently required ASAP ASAP
				Dispensed by: Checked by:
CRITICAL MEDICINE				

RESULTS

Safer Dispensing ($P < 0.001$)

Prevented Error Rates Reduction

	Error type	Dispensing Error Monitoring Period 1 (barcode non mandatory)		Dispensing Error Monitoring Period 2 (barcode mandatory)	
		Prevented Incidents	Rate (%)	Prevented Incidents	Rate (%)
Bar-code Insensitive Errors	Administrative	4	0.11	2	0.04
	Label directions	13	0.35	7	0.15
Total Bar-code Insensitive Errors		17	0.46	9	0.19
Barcode Sensitive Errors	Wrong patient	1	0.03	0	
	Drug strength	5	0.13	0	
	Drug form	3	0.08	0	
	Drug name	2	0.05	0	
	Cost centre	1	0.03	0	
Total Bar-code Sensitive Errors		12	0.32	0	
Total Number of prevented Errors		29		0	
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**



Technical Check



Patient Record



Outpatient Diary



Help



Dispensary Manager



Dispensing



Fast Return



Admit Discharge
Transfer



Clinical Drug
Information



Patient



Configuration



Reporting



User Management



System Info

1

Co-Codamol Tablets

60 tablets

ONE tablet to be taken FOUR times a day, when required for pain



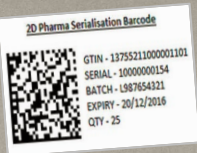
Mr. Alex Krasnov

16-FEB-2018

Lviv Hospital Pharmacy, Lviv Hospital, LVIV, LV
Oblast

KEEP OUT OF REACH OF CHILDREN

2

**Co-codamol
Tablets****30
500
mg**

100 tablets

[Home](#)
[Patient Finder](#)

Name of Pharmacy is Displayed Here

[Name of User](#)
[My Account](#)
[Logout](#)

POJAR, Cosmin (Mr)
 Born **14-Jul-1991 (23y)**
 Gender **Male**
 National No. **123 456 7890**

Address **Strada Cometi Nr. 340, 70123, Cluj-Napoca, CJ, Romania**
 Hospital No. **567898E**
 Allergy Status **Recorded Allergies**

Consultant **Chandrasekhar**
 Ward Admissions
 Body Surface Area **2.1 sqm (e)**
 Weight **81 kg (e)**
 Height **188 cm**

Communication Zone

[Clinical Drug Information](#)
[Help](#)

Technical Check
Patient Medication Record

DISPENSING EPISODE: 23-JUNE-2017 @ HH:MM (Number of Items = 5)
 STATUS: PENDING

Amoxicillin 500 mg Capsules x 28

Bendroflumethazide 5 mg Tablets x 28

Aspirin EC 75 mg Tablets x 28

Enalapril 5mg Tablets x 28

Simvastatin 20mg Tablets x 28

Product

Enalapril 5 mg Tablets

Directions

Advanced

Expiry Date

Batch Number

Decommission

	Action	User
4:MM	Dispensed	Ethan Richardson
4:MM	Checked	Paula Oughton
4:MM	Dispensed	Ethan Richardson
4:MM	Checked	Paula Oughton

Provide Steroid Card

Provide Warfarin Booklet

End Technical Check

Send for Re-Dispensing

Error

Confirm & Next

Amoxicillin 500 mg Capsules x 28

Bendroflumethazide 5 mg Tablets x 28

Aspirin EC 75 mg Tablets x 28

Enalapril 5mg Tablets x 28

Simvastatin 20mg Tablets x 28

Product

Enalapril 5 mg Tablets

Directions

Advanced

Expiry Date

Batch Number

Decommission

	Action	User
4:MM	Dispensed	Ethan Richardson
4:MM	Checked	Paula Oughton
4:MM	Dispensed	Ethan Richardson
4:MM	Checked	Paula Oughton

Provide Steroid Card

Provide Warfarin Booklet

End Technical Check

Send for Re-Dispensing

Error

Confirm & Next

Amoxicillin 500 mg Capsules x 28

Bendroflumethazide 5 mg Tablets x 28

Aspirin EC 75 mg Tablets x 28

Enalapril 5mg Tablets x 28

Simvastatin 20mg Tablets x 28

Product

Enalapril 5 mg Tablets

Directions

Advanced

Expiry Date

Batch Number

Decommission

	Action	User
4:MM	Dispensed	Ethan Richardson
4:MM	Checked	Paula Oughton
4:MM	Dispensed	Ethan Richardson
4:MM	Checked	Paula Oughton

Provide Steroid Card

Provide Warfarin Booklet

End Technical Check

Send for Re-Dispensing

Error

Confirm & Next

Amoxicillin 500 mg Capsules x 28

Bendroflumethazide 5 mg Tablets x 28

Aspirin EC 75 mg Tablets x 28

Enalapril 5mg Tablets x 28

Simvastatin 20mg Tablets x 28

Product

Enalapril 5 mg Tablets

Directions

Advanced

Expiry Date

Batch Number

Decommission

	Action	User
4:MM	Dispensed	Ethan Richardson
4:MM	Checked	Paula Oughton
4:MM	Dispensed	Ethan Richardson
4:MM	Checked	Paula Oughton

Provide Steroid Card

Provide Warfarin Booklet

End Technical Check

Send for Re-Dispensing

Error

Confirm & Next

JAC Medicines Management
 Powered by TECKNOWORKS

Technical Check Alert

WARNING
The dispensed product
does not match the issued
product

Override

Acknowledge

Wider Application

Prescription form for Park Grange Care Home. The form includes fields for patient name, age, and address. The prescription is for 3,000ml Latulose, to be given in accordance with GP instruction on MAR chart. The form is signed by Dr R Jones on 10/01/2014.

For patients under my care at Park Grange Care Home

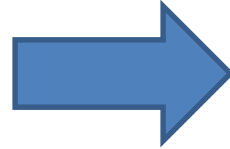
Bulk prescription

3,000ml Latulose

To be given in accordance with GP instruction on MAR chart.

Signature of Doctor: Dr R Jones Date: 10/01/2014

NHS



Prescription form for Park Grange Care Home. The form includes fields for patient name, age, and address. The prescription is for 3,000ml Latulose, to be given in accordance with GP instruction on MAR chart. The form is signed by Dr R Jones on 10/01/2014. A QR code is visible on the form, circled in red.

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.

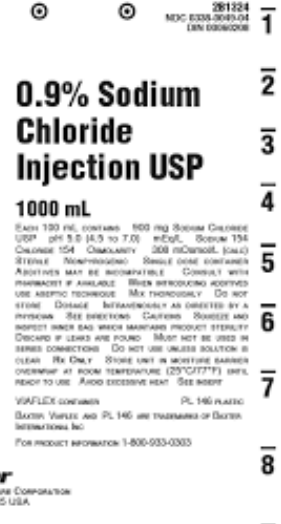
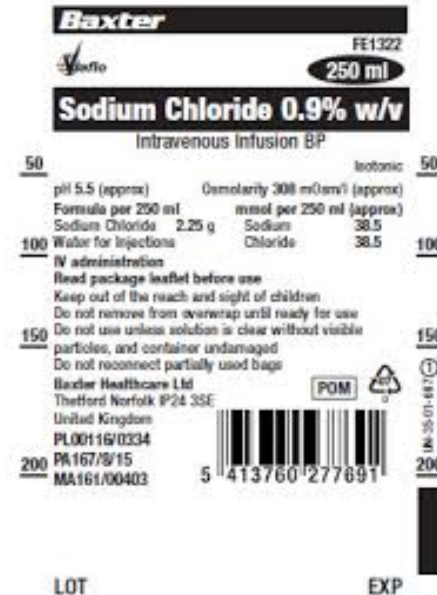
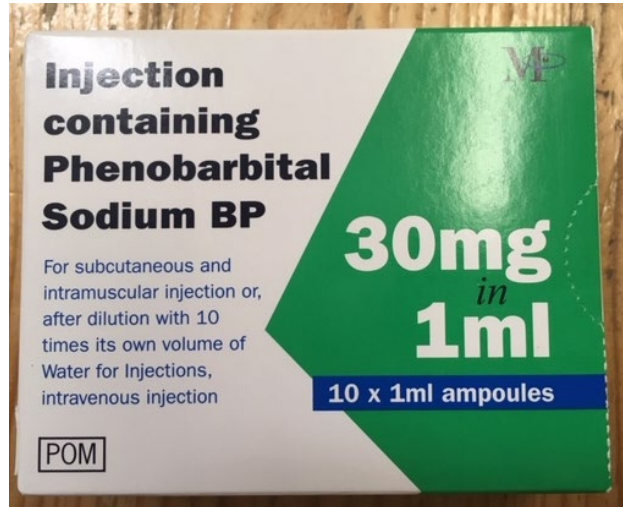
Signature of Doctor: Dr R Jones Date: 10/01/2014

NHS

Barcode Medicines Administration



Manufacturers Take Note!





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
Care

Release Time to

Thank You For Listening



Closed loop of medication up to point-of-care scanning

Global GS1 Healthcare Conference, 26 March 2019

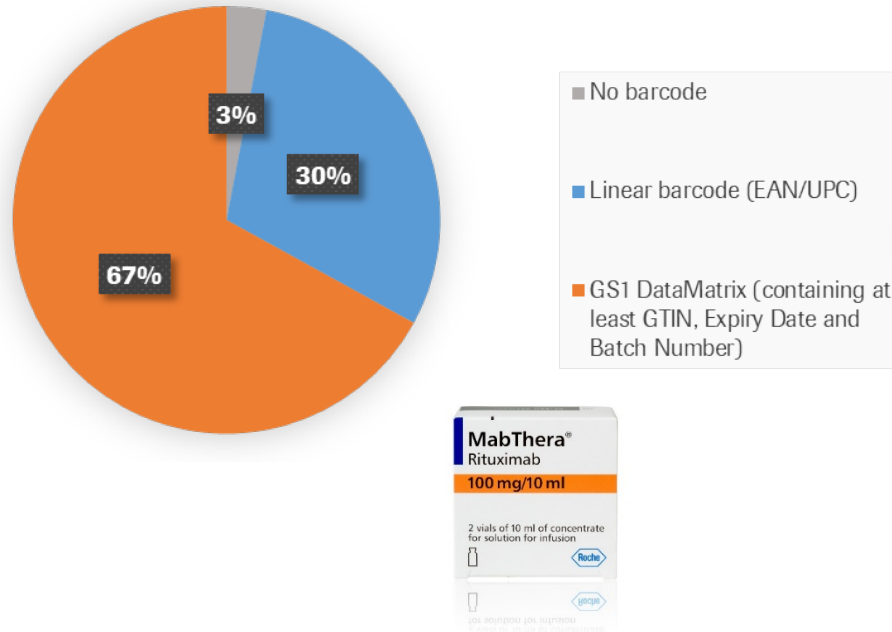
Sébastien Langlois-Berthelot



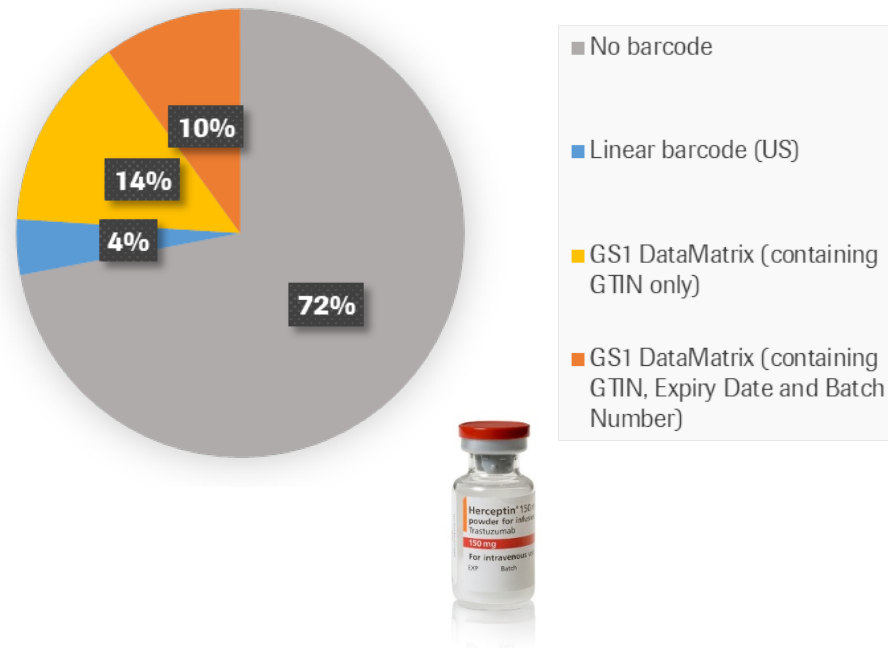
Barcode Implementation on Roche Pharmaceutical Products

Secondary vs. Primary Packaging

Barcodes on Secondary Packaging



Barcodes on Primary Packaging



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)

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)



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   European Federation of Pharmaceutical Industries and Associations



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 stakeholders¹ or regulators² already require manufacturers to identify primary packages with barcodes. Hospital implementation can be observed in various places³, 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.

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

GS1 DataMatrix with at least a GTIN



GTIN

Product Data

IDMP Nomenclature

Digital Content (e-leaflet, patient supporting material)

*Doing now what patients
need next*