

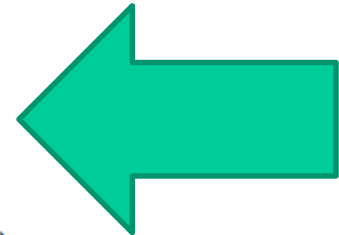


Patient and Logistic Safety using Barcodes on primary package

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)



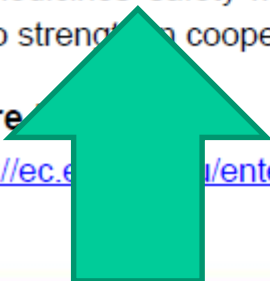
These proposals will now be transmitted to the European Parliament and the Council.

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



The Essence of Health Care



EMR Adoption ModelSM

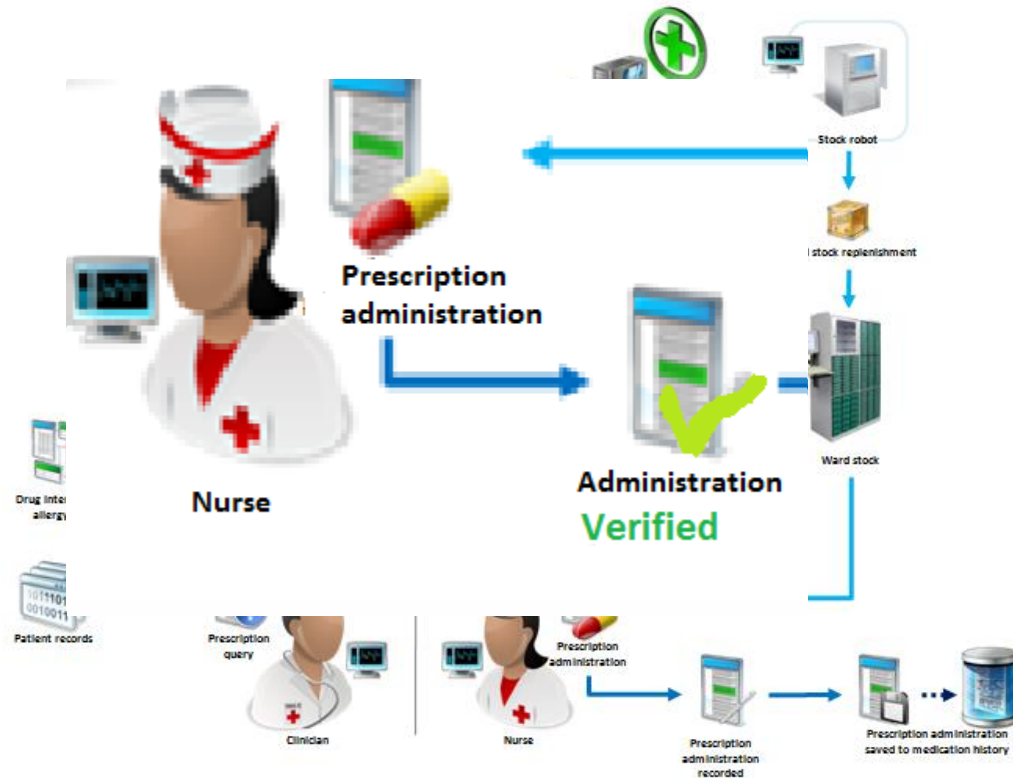
Stage	Cumulative Capabilities
Stage 7	Complete EMR; CCD transactions to share data; Data warehousing; Data continuity with ED, ambulatory, OP
Stage 5	Full complement of Radiology PACS
Stage 4	CPOE, Clinical Decision Support (clinical protocols)
Stage 3	Nursing/clinical documentation (flow sheets), CDSS (error checking), PACS available outside Radiology
Stage 2	CDR, Controlled Medical Vocabulary, CDS, may have Document Imaging; HIE capable
Stage 1	Ancillaries – Lab, Rad, Pharmacy - All Installed
Stage 0	All Three Ancillaries Not Installed

Closed Loop Medication Administration

Typical Process



Typical EPMA process

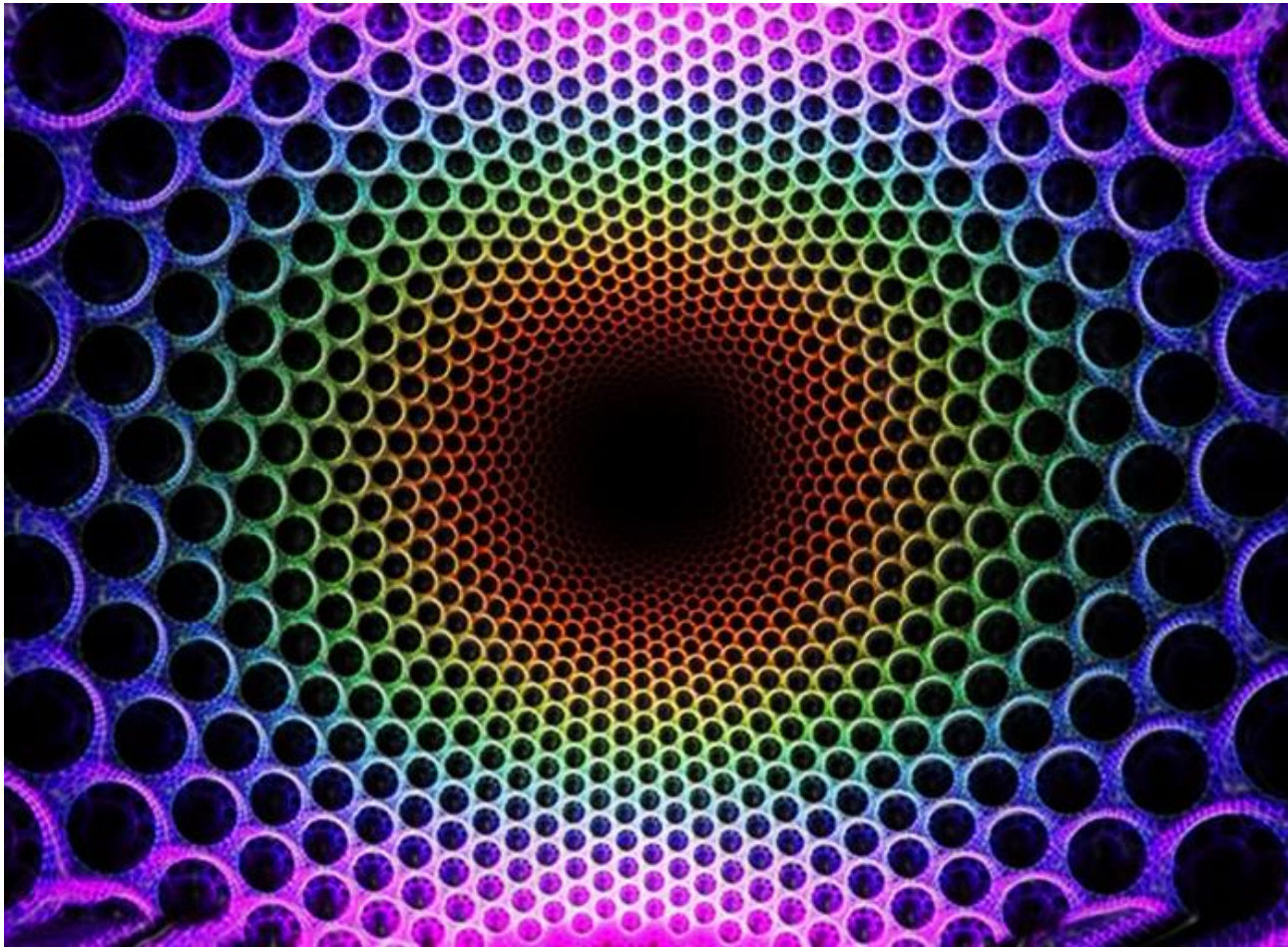


www.jac-pharmacy.co.uk

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JAC
MEDICINES MANAGEMENT

Optical Failure



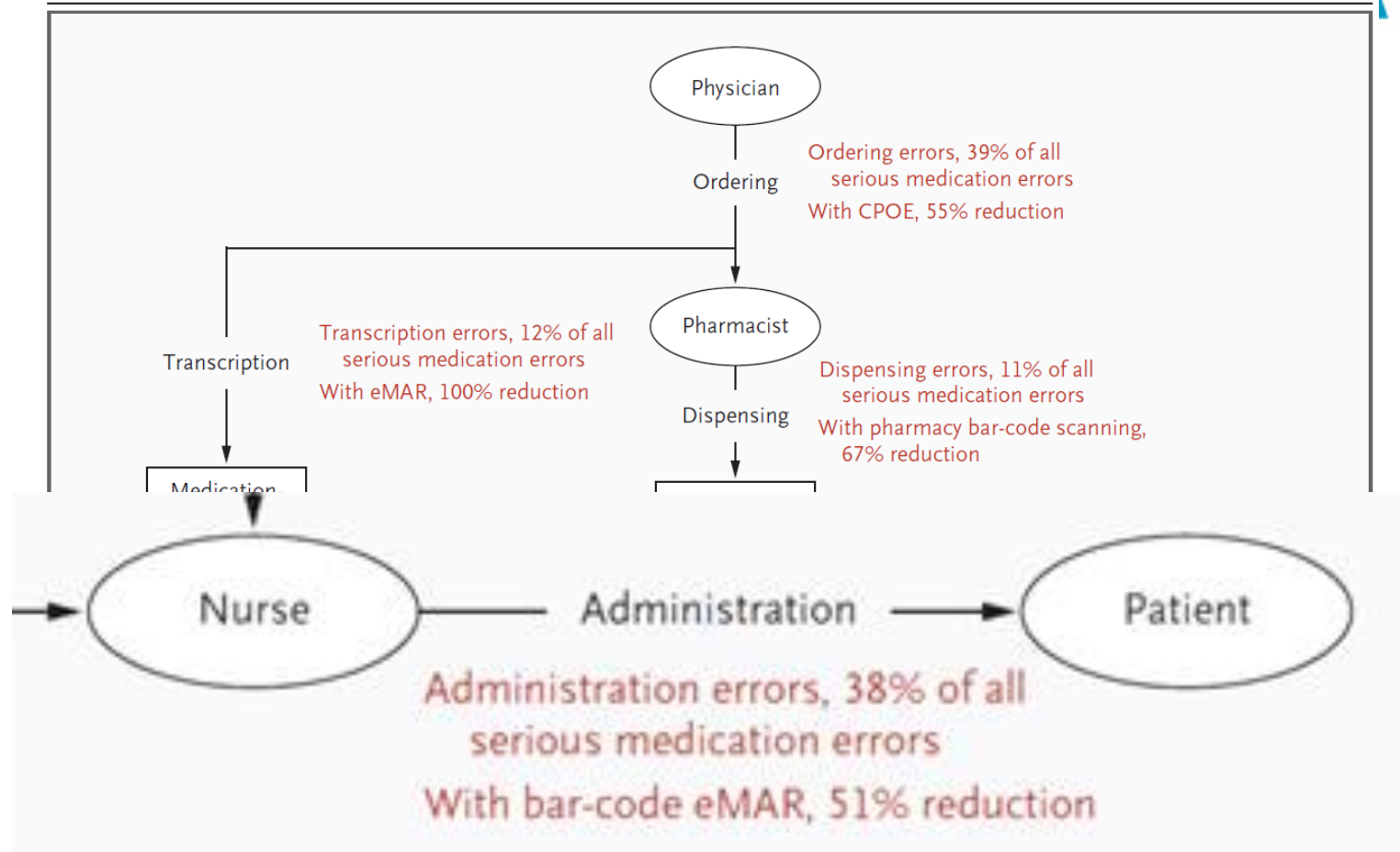
Optical Strength and Weakness



An investigation of an Elginh
Univetsiy discovered that it
doesn't matter in which order
the letters are written in a word.
The only important thing is that the
first and the last letter are
identical at the right location.

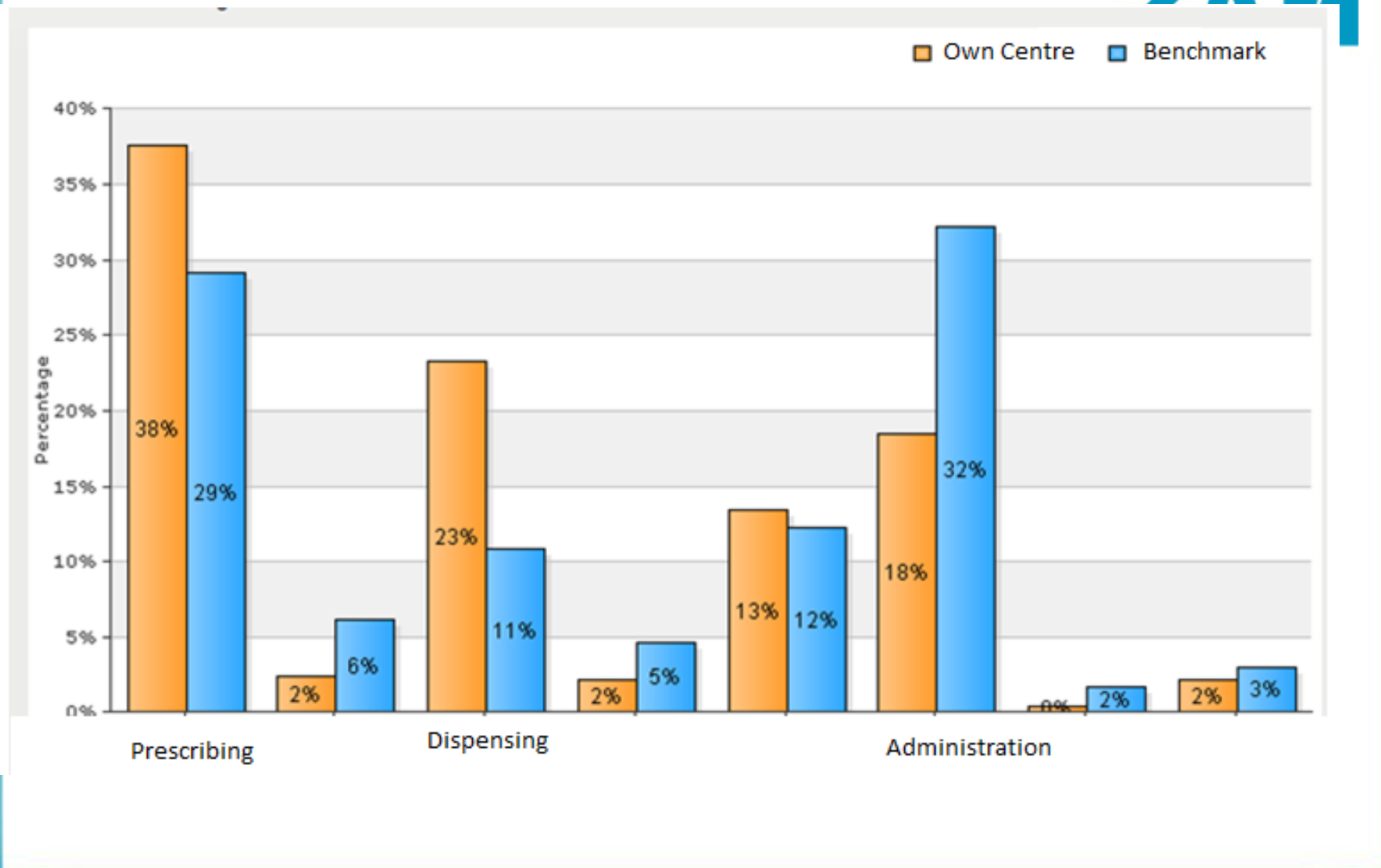
The letters between the first and
the last letter in a word may be
located at random. Because we
don't read each letter at a time,
we read the word has a whole.

Results of BCMA



Bates et al. JAMA 1995 E.Poon et al. NEJM 2010, Hassink et al. PW 2012

Medication Errors



Scanning in the mall



Scanning in the mall



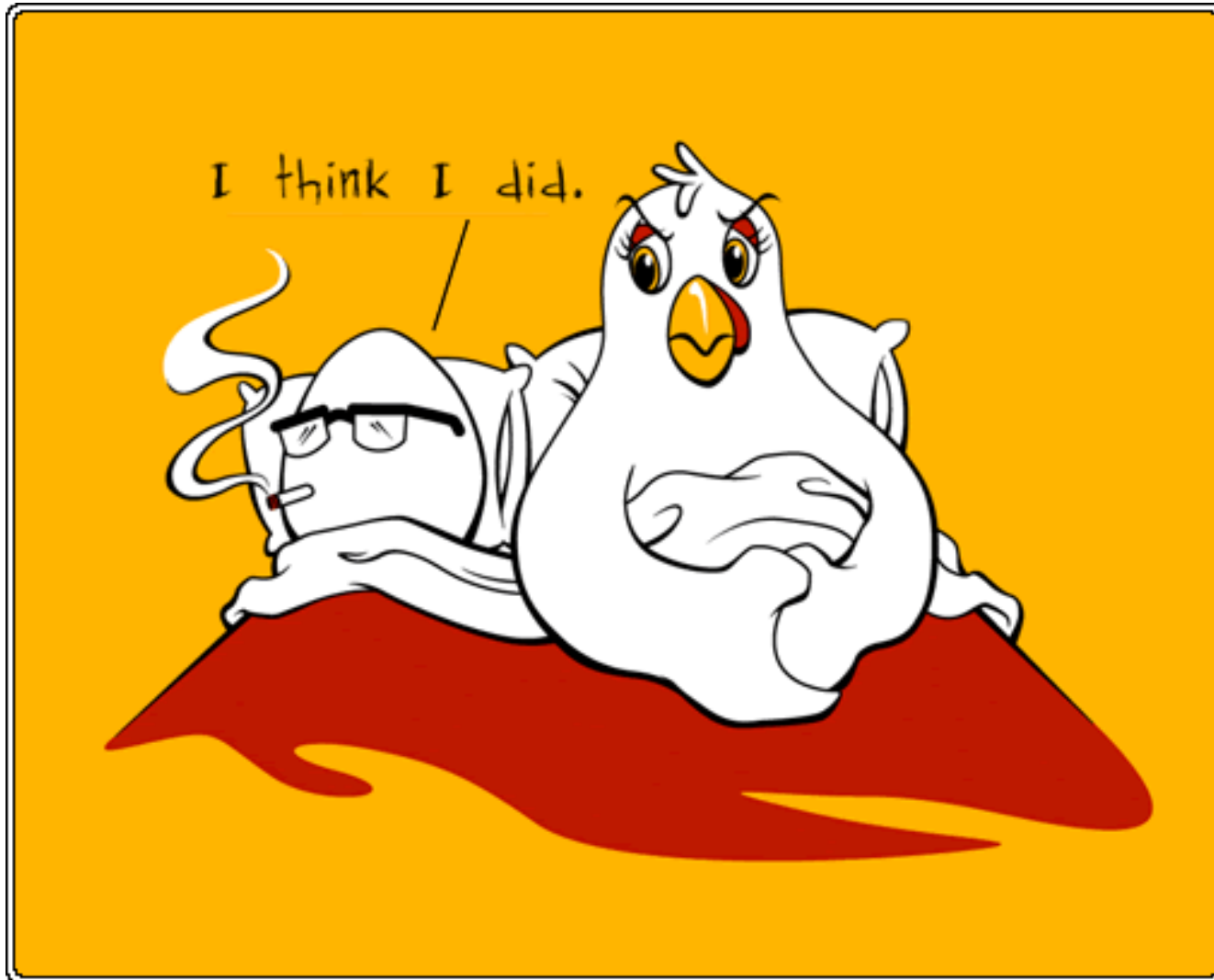
What if this was bedside?

- A. Wrong number
- B. Wrong specimen
- C. No Error



Implementation >95% UDP BCMA is Slow





Scanning on the Ward



Wrong Drug



Test Statica (Cito) Toedieningsregistratie
Patiëntnummer 1846997 91j | Patiënt is opgenomen op ZDUM/1/4

Selecteer patiënt | Afdeling: ZDUM | 14-10-2013 - 21-10-2013 | 00:00 | Verlopen toedieningen

ORAAL	14okt	15okt	16okt	17okt	18okt
DICLOFENAC-NATRIUM TABLET MSR 50MG BAXTER 3 x per dag (1; 1-2; 1 stuk) DICLOFENAC NATRI Bij voorkeur een half uur VOOR het eten Pas op met alcohol i.v.m. maagklachten Heel doorslikken, niet kauwen Bij maagklachten NA het eten innemen Startdatum: 27-09-2013 Stopdatum: -- regel toevoegen	08:00 ZN 1STUK 1-2STUK*	08:00 ZN 1STUK 1-2STUK	08:00 1STUK STUK 1-2STUK	08:00 1STUK STUK 1-2STUK	08:00 1STUK
PARACETAMOL TABLET 500MG 1 x per dag 1000 milligram PARACETAMOL CF T Startdatum: 16-10-2013 Stopdatum: 17-10-2013 regel toevoegen			10:30 1000MG		
IV CLEMASTINE INJVLT 1MG/ML AMP 2ML 1 x per dag 2 milligram TAVEGYL INJVLT 1M Kan het reactievermogen verminderen Pas op met alcohol Startdatum: 16-10-2013 Stopdatum: 17-10-2013 regel toevoegen			10:30 2MG		
IV DEXAMETHASON INJVLT 4MG/ML (BASE... 1 x per dag 2 stuk DEXAMETHASON CF Startdatum: 16-10-2013 Stopdatum: 17-10-2013			10:00 2STUK		
GEMCITABINE INFUUS 1800 mg GEMCITABINE INFUL Startdatum: 16-10-2013 Stopdatum: 17-10-2013					
METHYLPREDNISOLON INFUSIEPOEDER 50... 1 x per dag 100 milligram SOLU MEDROL INFU! Bij kamertemperatuur bewaren (15-25) Startdatum: Stopdatum:			10:00 100MG		

Bevestigen

?

ZOUTOPLOSSING PCH NEUSSPRAY 8MG/ML is niet voorgeschreven voor patiënt Test Statica, M, 20-04-1922
Dit wel toedienen?

Ja Nee

Scannen

Patiëntnummer 1846997

Geneesmiddel 8711218014049

Sluiten

Current status



Issues



High Risk



Protect from light/moist no unit dose pack

Unusable/Errornous Barcode
(gemfibrozil TEVA 600mg scans 900mg!)

Issues



Opiods



Suppositories,
Slippery Surface



No flat surface



Ampuls, Small



Small strips

Workarounds and Errors



rijksuniversiteit
groningen

	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%)	10.8 (6.51- 17.94)

including time-window medication administration errors (470) the OR was 34.3 (95% CI 20.85-56.51)



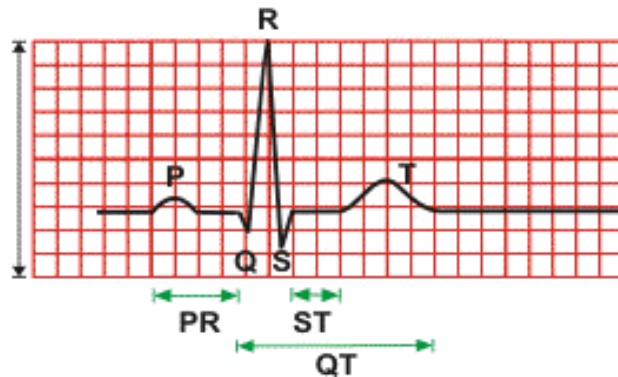
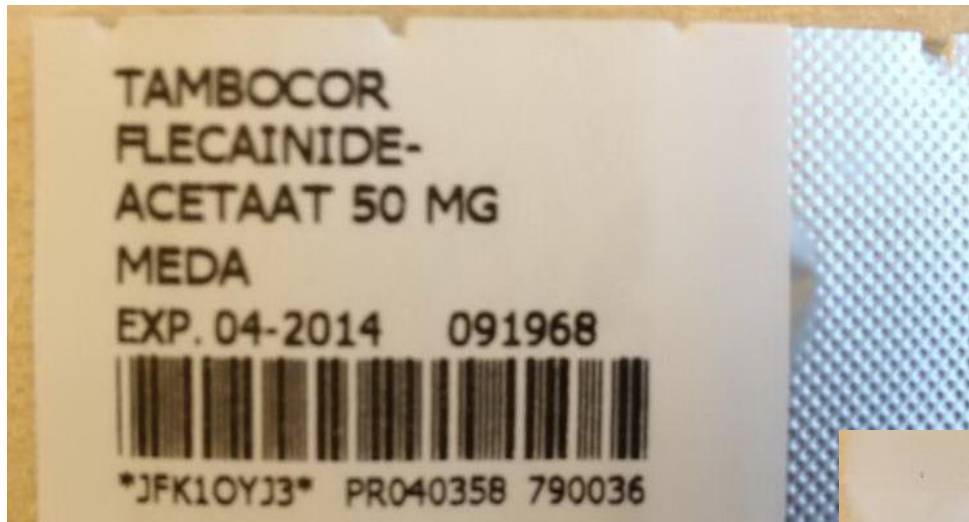
Patient Errors



Recent Errors



Sound alike



Good Manufacturing Practice



Verpakken vaste orale medicatie met DTA (tray)

antoniüs ziekenhuis

Naam geneesmiddel: SALOFALK TABLET MSR 250MG	Chargennummer: 12101355L	RESULTAAT
Chargennummer ompakken: 130909/0004775604	Houdbaar t/m: 30-09-2015	
Artikelnummer/barcode: 15563324	Na ompakken houdbaar t/m (Max 1 jaar): 04-10-2014	

Magazijn: M1

Verpakking: 100 stuk **Verpakking eindproduct:** 30 stuk

Fabrikant: DR. FALK PHARMA BENELUX BV

Leverancier: ALLIANCE HEALTHCARE B.V.

Akkoord:

SALOFALK TABLET MSR 250MG OMPAKT
Exp. dte: 04-10-2014
Chargenr: 12101355L
AZS ch.nr: 130909/0004775604
Inhoudsel per verpakking: 30

Uiterlijke kenmerken:
a. rond / niet deelbaar
b. geen inscriptie
c. geel

Akkoord:
a) Ja / Nee
b) Ja / Nee
c) Ja / Nee

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 ingevuld?
- Plaats het omgepakte product inc. de originele verpakking terug in quarantaine
- Laat het product vrijgeven door een apotheker

Ompakken binnen Chipsoft:
- Pak het artikel om binnen Chipsoft
- Indien niet mogelijk, laat het corrigeren

Opbrengst:
Aantal uitgevallen: stuks (B)
Aantal vernietigd: stuks
Reden(en) uitval:

Netto aantal:
Aantal aangemaakt: stuks
Aantal gebruikt: stuks
Aantal vernietigd: stuks

Etiketten:
Aantal aangemaakt: stuks
Aantal gebruikt: stuks
Aantal vernietigd: stuks

Bijzonderheden:

Uitgevoerd: Datum: 04-10-2013

Vrijgafte door: Datum: (apotheker)
GOEDGEKEURD / AFGEKEURD

Paraaf:

Paraaf:

Altruktatum/lijst: 04-10-2013 10:21:54 Type: 004 // 1000012

Antoniüs ziekenhuis

Aftekenlijst barcoderen

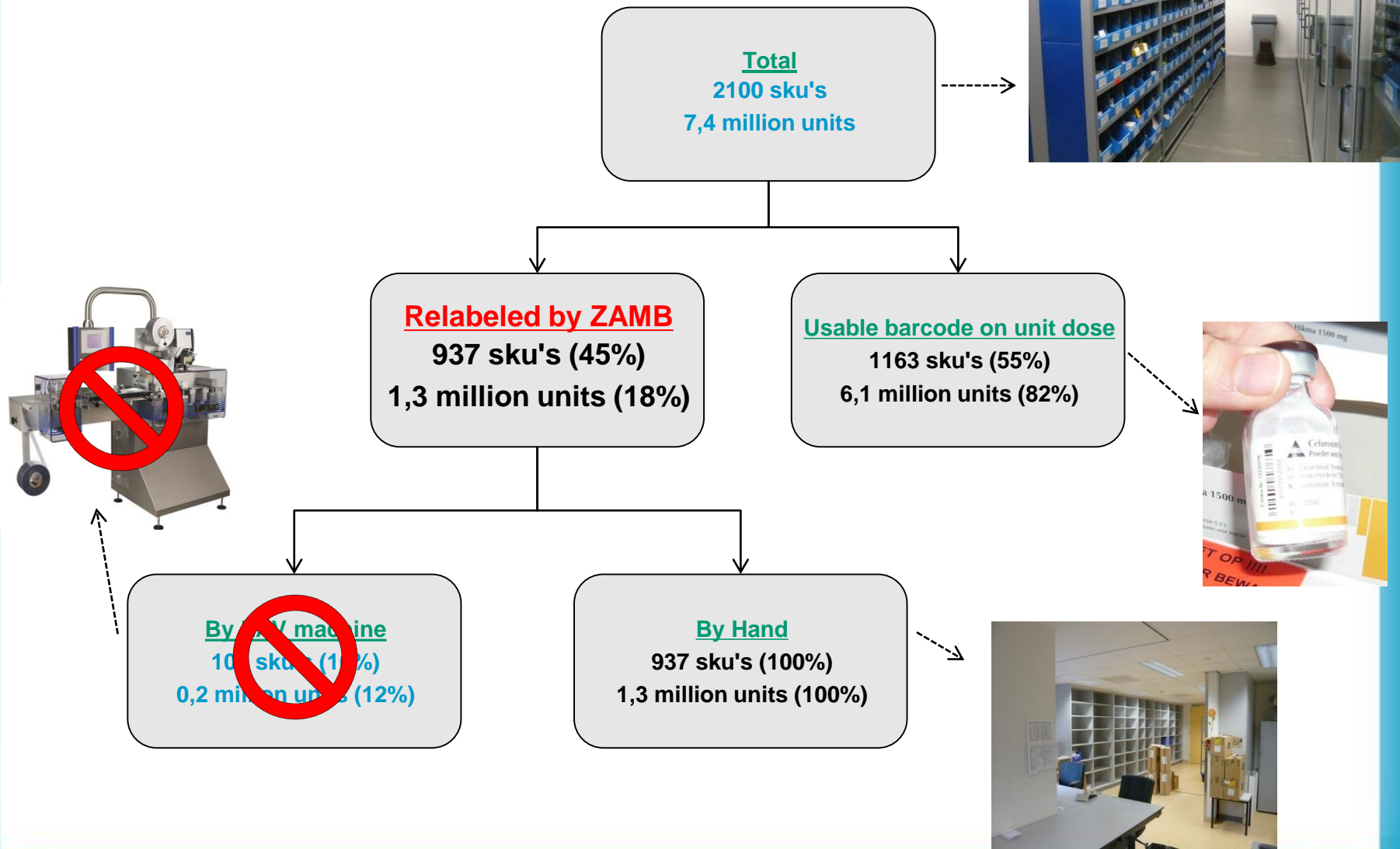
Degene die barcodeert, noteert het geneesmiddel, plakt een voorbeeldetiket en vult zijn/haar naam in. Een tweede persoon controleert of het juiste etiket op het juiste middel is geplakt en vult vervolgens, ter controle, zijn/haar naam in. Aan het eind van de dag controleert en parafeert de receptapotheker. Lijsten gaarne in de ordner laten.

Naam middel	Voorbeeld van etiket	Naam plakker	Naam controleur	Aantal etiketten afgedrukt	Aantal etiketten geplakt	Aantal etiketten vernietigd
Morfine 10mg/ml ampul 1ml		B	Ai	121	120	-
Fentanyl matrix 12mcg/4hr		Ai	Ai	81	80	-
Fentanyl matrix 25mcg/4hr		PA	Ai	71	70	-
Allopurinol tablet 300mg PHT		Ai	PA	181	180	-
Clarelux schuim voor culaan 0,5mg/1g		UR	PA	5	4	-
Foster Aex 100/6mg/100 120D		UR	PA	7	6	-

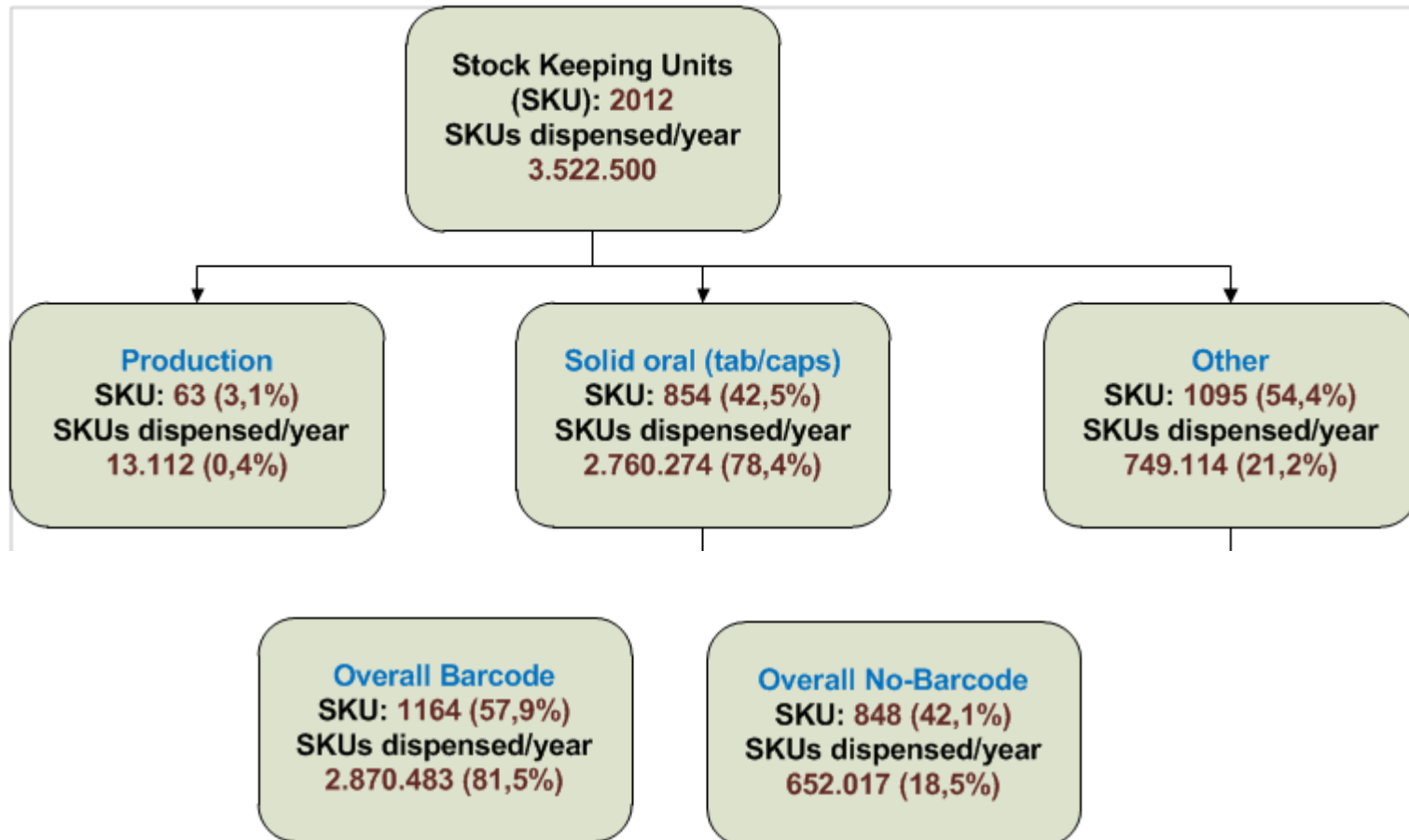
Datum: 3-10-2013

Paraaf receptapotheker:

KPI's Tilburg 2014



Antonius Sneek



High risk medication (RTA)



Logistical Considerations

Given that most syringes have a relatively limited surface area for labeling, 2D DataMatrix or Aztec bar codes are preferred due to their small size and speed of scanning success.



Photo courtesy of Medi-Dose, Inc / EPS, Inc

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

How to overcome these obstacles?



Repackaging



Standardization of Medication suppliers





IMPROVING LIFE AT WORK



Site Specific vs Industry



Medication Dispensing (Nursing)Home

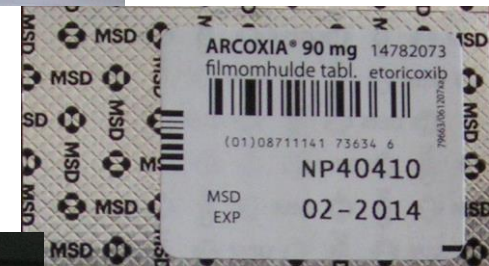
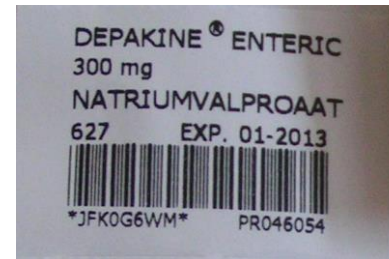


Our needs



EAG of all single unit packages eg.

- *Solid oral (tablets, capsules, ..)*
 - *Solid/Liquid parenteral (ampoules, syringes, vials)*
 - *Liquids (minims, unit dose morphine solution, etc)*
 - *Ointments etc (not available in NL)*
- label should contain:
- *Nonproprietary and proprietary names.*
 - *Dosage form.*
 - *Strength*
 - *Expiration date*
 - *Control number (lot number)*
 - *Barcode GTIN*

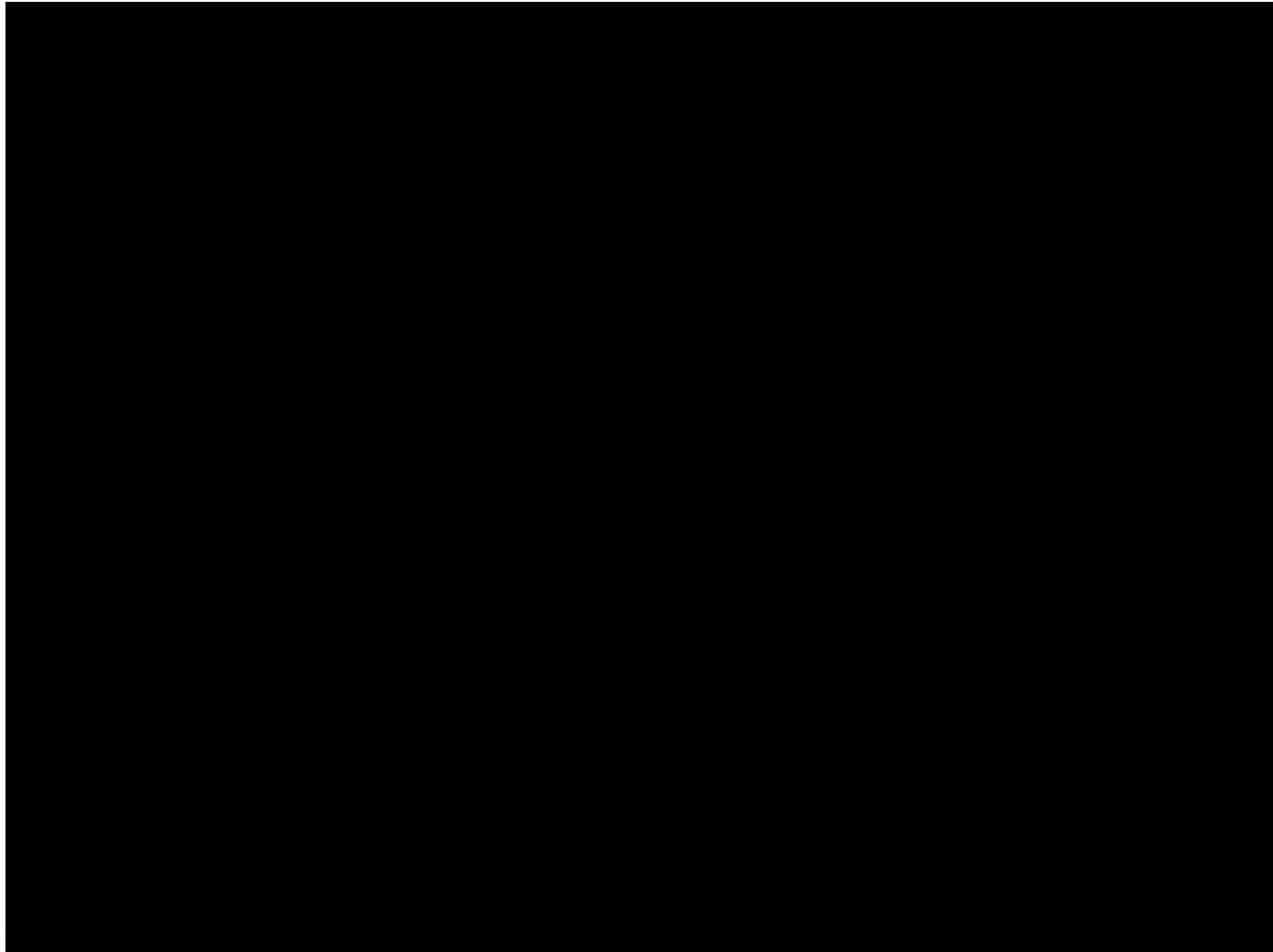


De voordelen op een rij



- **Medicatieveiligheid op moment van toedienen.**
- **Mogelijk maken Recall op unit dose.**
- **Registratie chargenummer biologicals.**
- **Ketenbrede oplossingen.**

Creating Safe Environment



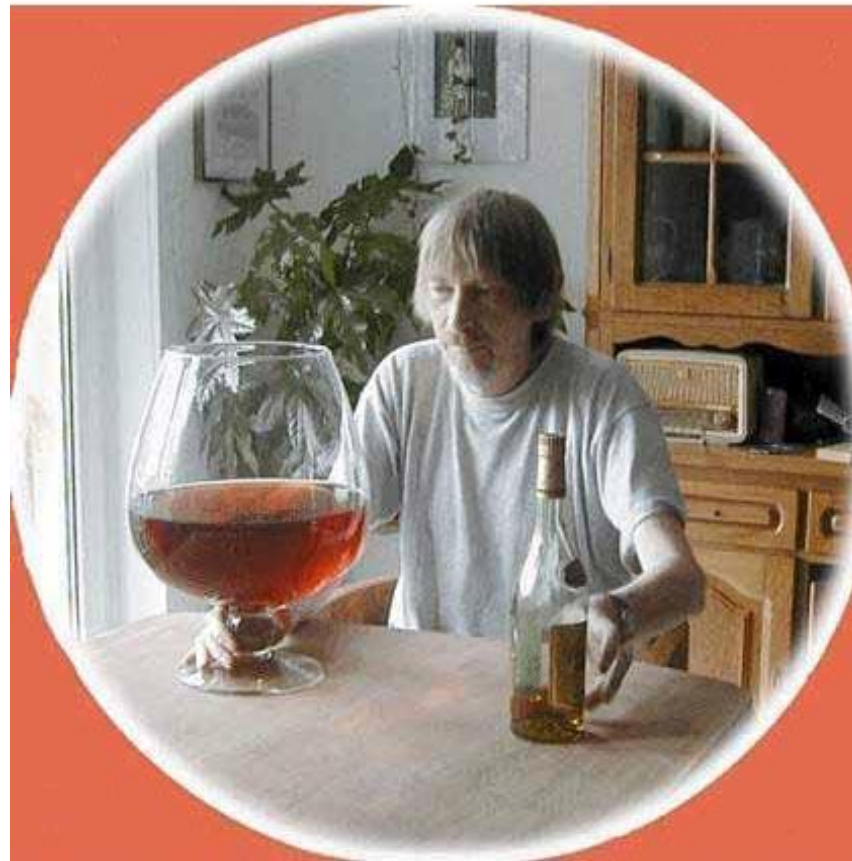
Yes You Can



Questions?



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



Stappenplan



- **Prioritering High-Risk**
- **Identificatie eerst vervolgen**
- **Chargennummer + Expiratie**

Implementatie barcodesysteem



- **GMP Ompakfaciliteit, vanwege 45% niet scanbaar op UnitDose**
- **Vele ZH hanteren barcode eis al in inkoopvoorwaarden maar bij onvoldoende marktaanbod niet te handhaven**
- **Alle ZH gebruiken nu EVS, volgende stap is barcodescanning**
- **Technologie is beschikbaar (hardware, software, ondersteuning bij storingen)**
- **Aandacht voor Attitude (adequate communicatie, training, discipline)**

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

Reductie in aantal fouten en risico op vermijdbare 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

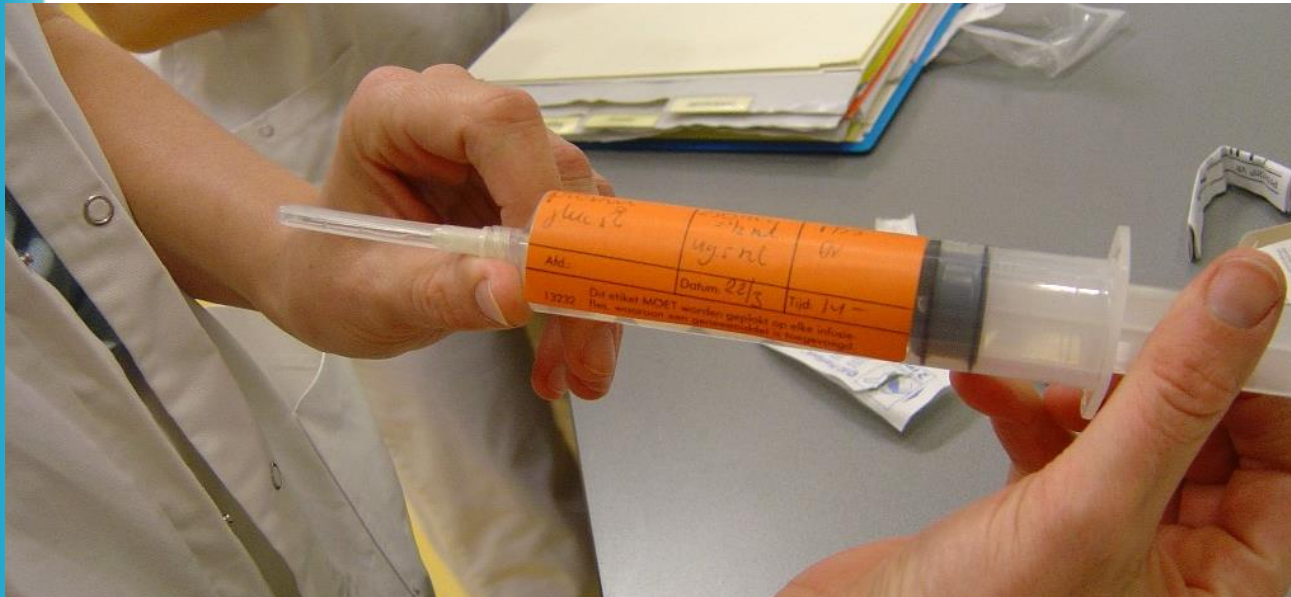
	Outcome measure	Baseline	Post-BCMA	% Change from baseline	p Value
Poon <i>et al</i> ¹⁰	Percentage clinically significant potential ADEs	1.8	0.9	48.5	<0.001
	Percentage serious potential ADEs	1.3	0.6	54.1	<0.001
	Percentage life-threatening potential ADEs	0.03	0.01	53.9	0.34
Franklin <i>et al</i> ¹¹	Mean 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.

Preparations on the ward



GEFUROXIM INJECTIEPOEDER 750MG (IM/IV) FL		IV
		3 x per dag 750 MG
Patient: 5153731, Test, X. Afdeling: C08-P		
Datum/tijd: 23-08-2012 11:49:34		
Toedientijd:	Houdbaar:	
Intuusvloeistof + hoeveelheid (bij perfusorspuit)		P1
ml		P2

Preparation Assistance



Geneesmiddel

Genmid.nr.: 10186 KNMP-nummer: 13935666

Memo gen: FUR011 Generieke naam: FUROSEMIDE

memkode eti: FUR011 Etiketnaam: FUROSEMIDE INJVLST

Etiketnaam kort: FUROSEMIDE CF 40MG

Bewaking eenh.: ML Max. gebr.duur: 0

gebr.aanw.: []

Taxe-prijs: 9,54 V. v.prijs: 9,5400 per: 10,0 st BTW

NZI-kode: 462110 [Geneesmiddelen Algemeen](#)

Onderhoud NZI-code door KNMP uitschakelen

Voorr. etiket: [] etiketeksten: []

Balkteksten: []

Opmerkingen bij invoer MD

Acuut oedeem: 20-40mg als bolus i.v.
Acuut hartfalen: 80-120mg als bolus i.v.
Bij persistent oedeem en/of nierfunctiestoornis

Mons.bl.sp: []
Onderwrd.: []

Indicatie: Voor toediening gereed maken Samenstelling

Formularium Eigen bereid. Vergif In quarant. Verv.dat.verp.

Koel bewaren: genesm.wet: R Pomp: ret.perio

Vrd.lokatie R-S-teksten Gev.-symbolen Distributie arr. Muteer artikel Info instelling Bestel historie Korting/opslag OK Annuleren

Generieke memocode

Samenstelling FUROSEMIDE INJVLST 40MG = 100ML

Nieuw Open Verwijder Toediening Ende

Geneesmiddel: 10186 FUROSEMIDE CF 40MG INJVLST

Totaal geneesmiddel: 1,000 ML

Totaal componenten: 100,000 ML te wijzigen bij voorschrijven

Geneesmiddel	Omschrijving	Hoeveelheid	D.Eh.	Sterkte	S.Eh.
	FUROSEMIDE CF 40MG INJVLST	40,000	MG	1,000	ML
10819	INF NAACL 0,9% FL 100ML	100,000	ML	900,000	MG

Bijzonderheden

Enter data or press ESC to end.