

# Medication errors 2011

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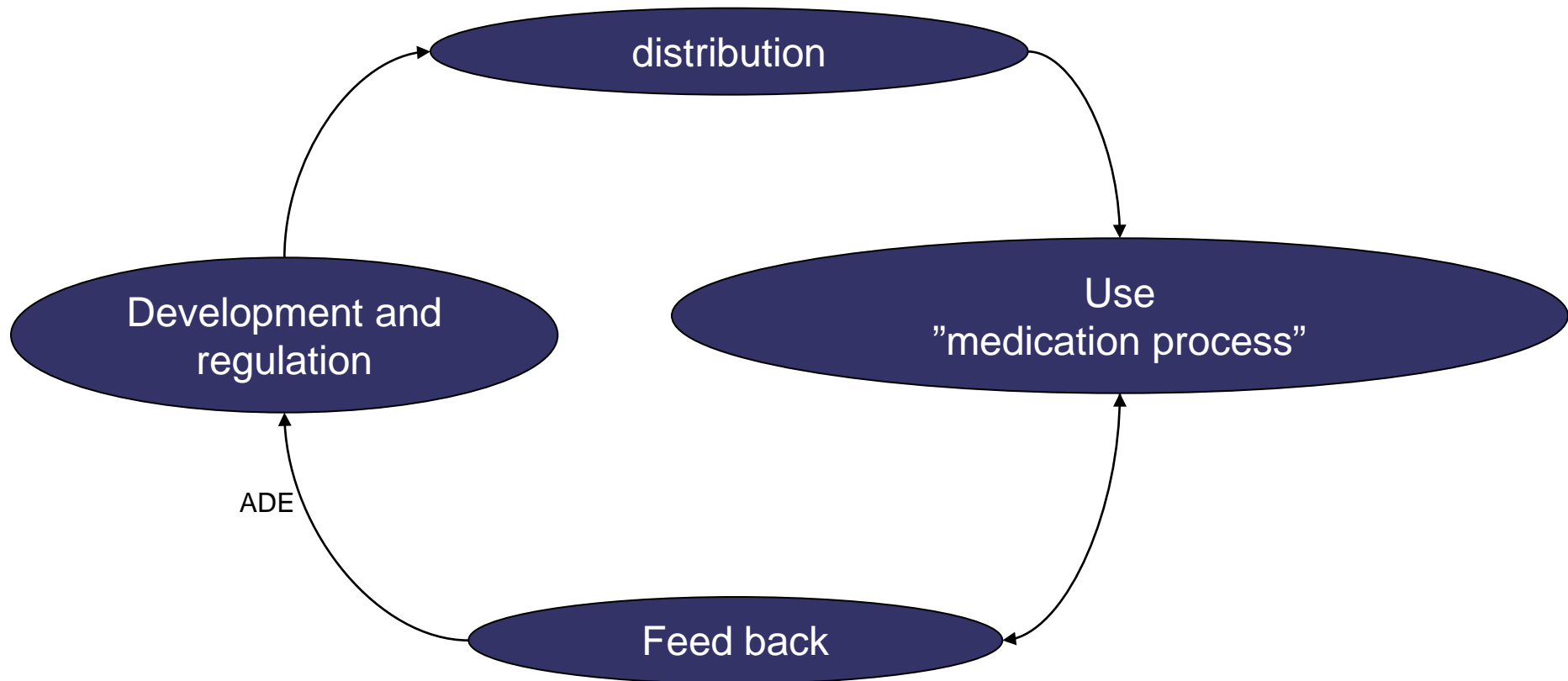
Consultant for Danish Society for Patient Safety  
on medication safety



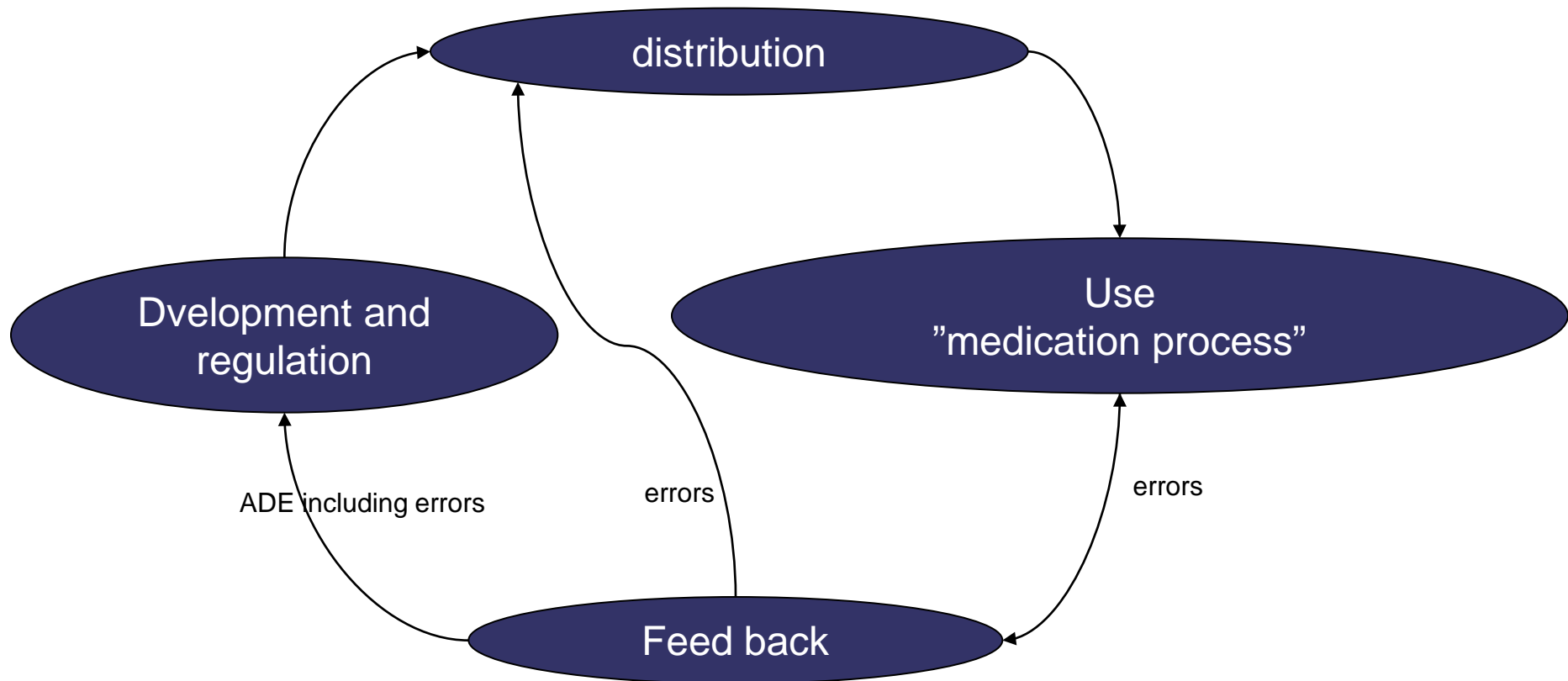
# Errors

- Systematically working on error prevention is important for health care
- In my region in the last year
  - One patient without diabetes almost died due to administration of 140 units of insulin
    - Mix up with heparin vial
  - One patient was ordered double dose warfarin for three days at the start of treatment. The patient died – hopefully due to cancer
    - Mix up number of tablets and dose in mg

# Medication cycle - now



# Medication cycle - now



# Agenda

- Overview - Definitions and epidemiology
- Tools and examples
  - Analysis of single serious errors
  - Analysis of large scale errors
  - Risk management





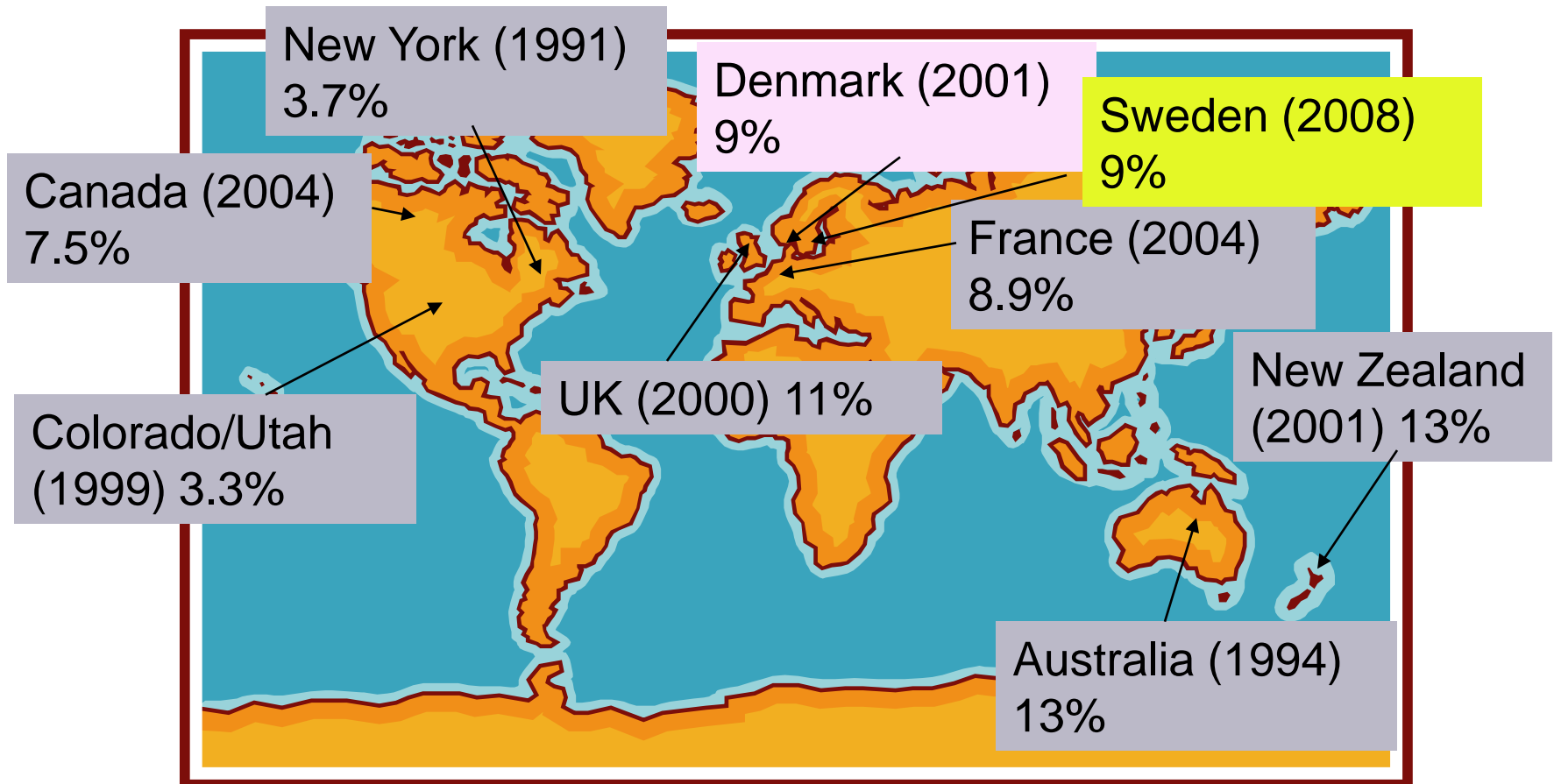
# Adverse Event

13 definitions!

Undesired incident involving harm or potential harm to the patient, caused by medical management rather than by the underlying disease or condition of the patient

The major difference in definitions is whether or not harm/injury is required

## Frequency of admissions with adverse events with harm





# Adverse drug event and medication errors

- ADE can be divided into preventable and not preventable
- Not preventable
  - Caused by pharmacology
- Preventable
  - Caused by human being mistake
    - Caused by known allergy
    - Dose-miscalculation
- Preventable ADE are harmful medication errors



Fig. 1. Forside  
(øverst) og bagside  
af henholdsvis 100  
digoxin (til venstre)  
og 100. Mirevan.

# Epidemiology of Preventable ADE

## Research

- 10-40% of adverse events are drug related adverse events
- 30-50% of these are preventable

## Reporting systems

- Preventable adverse drug events in 0,4-7,3% of all hospital stays
  - In my region 3000 medication errors are reported every year – still rising! We have approximately 30 serious adverse drug events per year caused by medication errors.
- Preventable adverse drug events in primary care cause 0,9-4,7% of admissions to internal medicine or intensive care
  - In one hospital routine data indicates 35 warfarin admissions per year (covers 300000 inhabitants)

## Relation to Pharmacovigilance

- Epidemiologic studies indicate same frequency of serious not preventable ADE and serious preventable ADEs

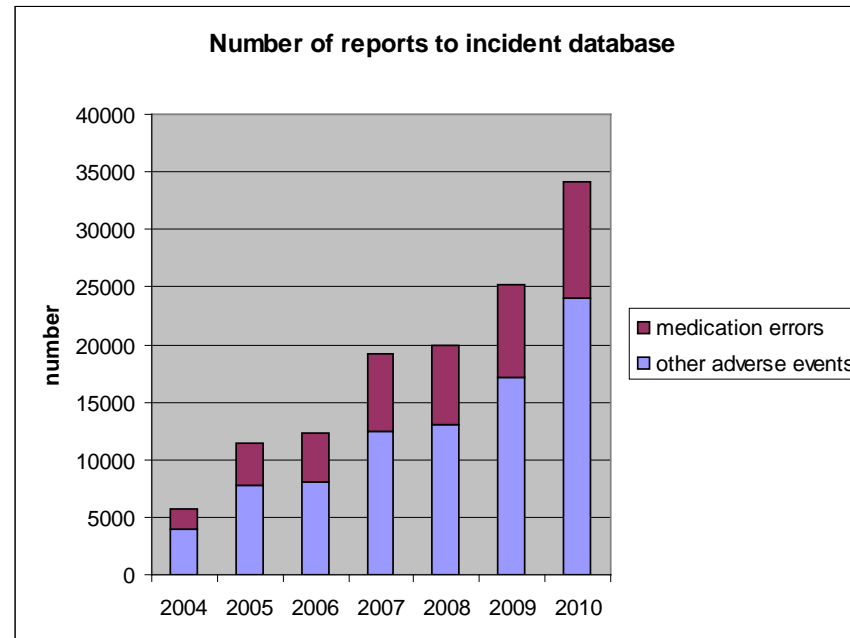
# Test your own epidemiology

- Global trigger tool – audit on patient records
- 20 records every months, count possible errors, harm and admission days
- 6 preventable medication incidents in 640 admission days.
  - 2 of these were serious
    - Stopped antibiotics before time – readmission with infection
    - Medication list not checked with home care and therefore patient did not get anti convulsive treatment – readmission with convulsions.
- 3 promille of admission days with severe medication errors
- Compared with data from reporting database Global trigger tools identifies more errors with harm

# Reporting systems for ME

- Voluntary reporting systems
  - "ISMP"
- Mandatory reporting systems as part of general adverse event reporting
  - UK
  - Denmark
- Reporting as part of pharmacovigilance system
  - Marocco

# Danish Patient Safety Database



- Some reporting systems receive most dispensing errors others most prescribing errors.
  - Depends on focus and feedback
- Most frequent error reported with severe consequence is always overdose
- 7-20% of reported medication errors relate to name and package (inner and outer)

# Reporting systems – is it worth the effort?

- Does not provide a true incidence rate
- When hospitals have tried it – they want to continue
- Provides information for analysis

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# Methods for analysis

- Root cause analysis, London protocol etc
- Detailed
- Typically one incident
- In depth knowledge about incident among team members in addition to reports
- Analysis based on reports only
- Less detailed
- Look at more errors at the same time
- Knowledge on normal process and medication risks among team members

## From individual error and blame to

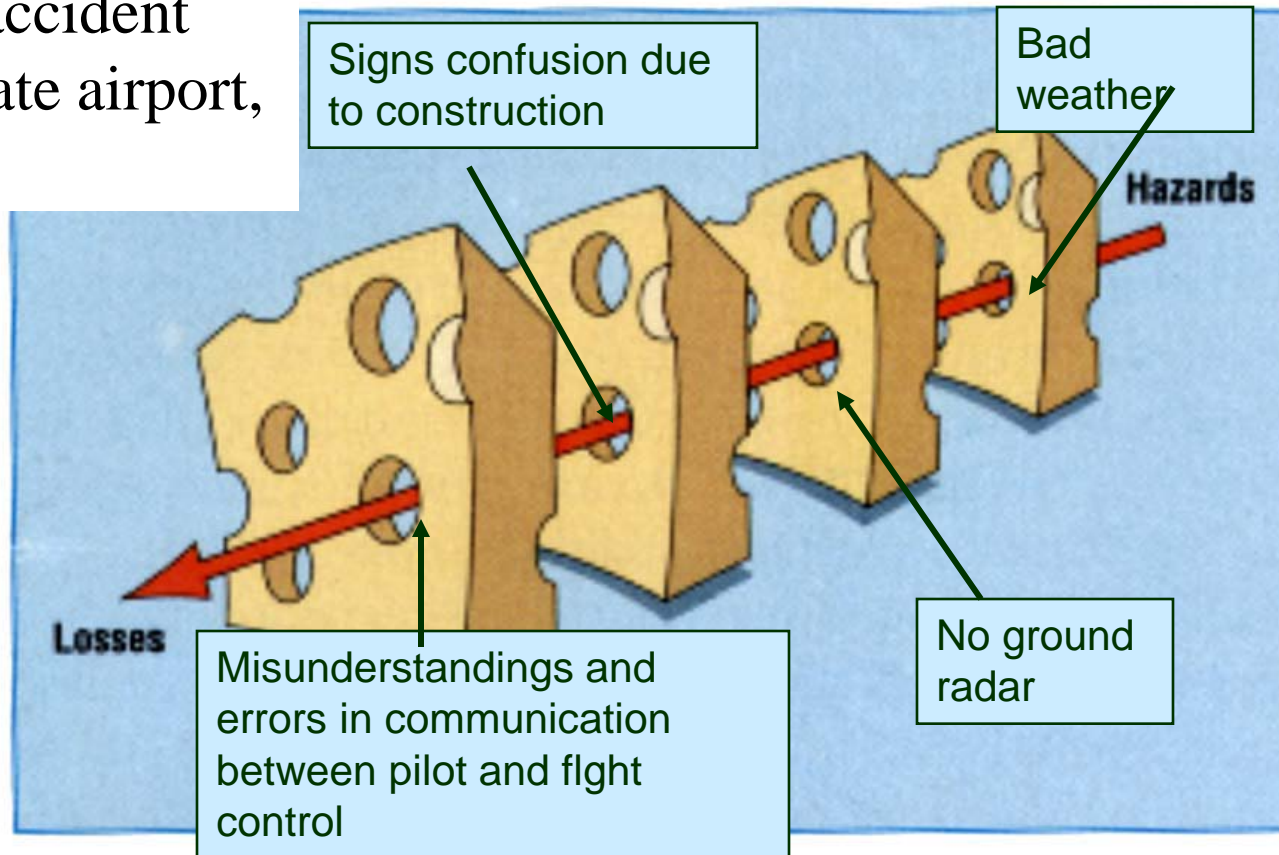


**Me?**



# Systems analysis

SAS flight accident  
2006 in Linate airport,  
Italy





# Analysis of medication errors

## Work flow

- Order and information
- Documentation
- Dispensing
- Administration
- Monitoring

## Facilities vary

- Storage areas
- System for documentation
- Systems for control
- Distribution and supply
- Guidelines

Healthcare professionals  
make heuristics

## Patients

- Seek information in many places
- Have poor sight
- Do not understand generic substitution

## Drug

- Name
- Strength
- Pharmacology
- Effect
- Side effect
- Inner package
- Outer package
- Device
- Information
- Price



# Analysis and Solutions

**Wulffmorgenthaler**

af Mikael Wulff & Anders Morgenthaler

wm@politiken.dk

Vi har specialiseret dit tastatur, så det lige præcis kun indeholder de knapper, der er nødvendige for at udfylde din jobfunktion. Smart, ikke?





# Problem: Wrong choice with electronic prescribing



# Solution: Focus on human factor

- Change of unit for strength



MedWin - [TH @ Læge Torben Hellebek] - Medicinskema

Arkiv Rediger Patient Tidstyring Afregning Bogholderi Kartoteker Kommunikation Hjælp

### Præparatsøgning

Handelsnavn | Indikation

Valgt ordination:

Søg:	Dispensering:	Styke:	Importer:	Tilsk./d dis
Idigo	Tabletter	0.25 mg		A D
Digoxin 'DAK'	Tabletter	62.5 µg		A D

Pakning:

Indhold:	BGP:	ESP:	Prisgrupper:
			G P O
100 stk.	78.65	78.65	- . -

Indikation:

for hjertet  
mod uregelmæssig hjerterytme  
mod uregelmæssig hjerterytme

Dosering:

1 dg  
1\*2  
skiftlig

Vis tekst  Vis kun dosisdispensering præparater

Synonympakninger:  
**Generisk substitution:**  
Grp: Præparat: Pris:  
Ingen synonympakninger i denne kategori

**Parallel substitution:**  
Grp: Præparat: Pris:  
Ingen synonympakninger i denne kategori

**Original substitution:**  
Grp: Præparat: Pris:  
Ingen synonympakninger i denne kategori

Vis recepter Udskrift Annuller Narko Pens. Gravid Ammer

Tryk F1 for hjælp. Læge: TH NT: 22-10-03 11.30 01-10-2003 21:34

# Problem: Poor handwriting

			GIVES KL.				
T	Poldi	50mg x 4	.	8	12	18	22
T	Parodol	1gr x 4	.	8	12	18	22
T	Magnyl	150mg x 1	.	8			
Inj	Mitford 20/80	16 i.p. mand	.	8			
Inj	Insulatard	61.p. vds	.			18	
T	Magnesia	1gr x 1	.	<del>8</del>			22

# Solution : Electronic prescribing

			DAGES KL.				
T	Poldi	50mg x 4	.	8	12	18	22
T	Panodil	1gr x 4	.	8	12	18	22
T	Magnyl	150mg x 1	.	8			
lmj	Mitford 20/80	16 i.p. mand	.	8			
lmj	Insulatard	61.p. vds	.			18	
T	Magnesia	1gr x 1	.				22



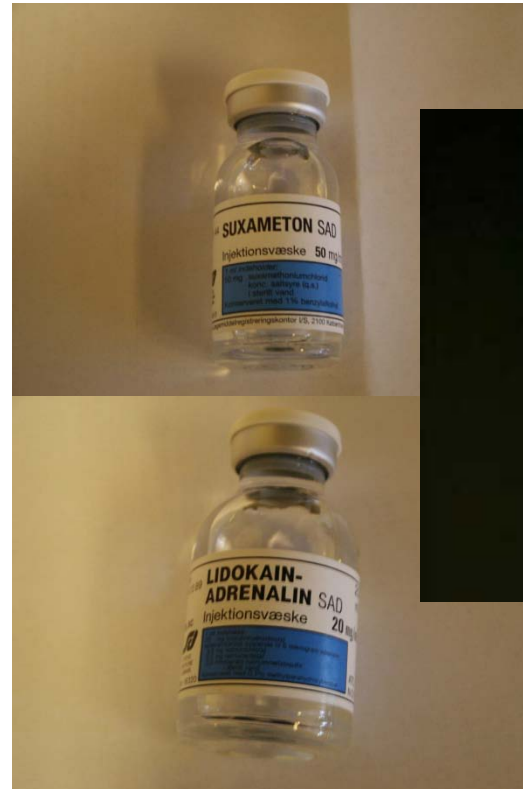
## Problem Look alike with many drugs from same company

Look alike suxamethonium

Medicinal company owned by state

Large number of different medicines

Few money for design



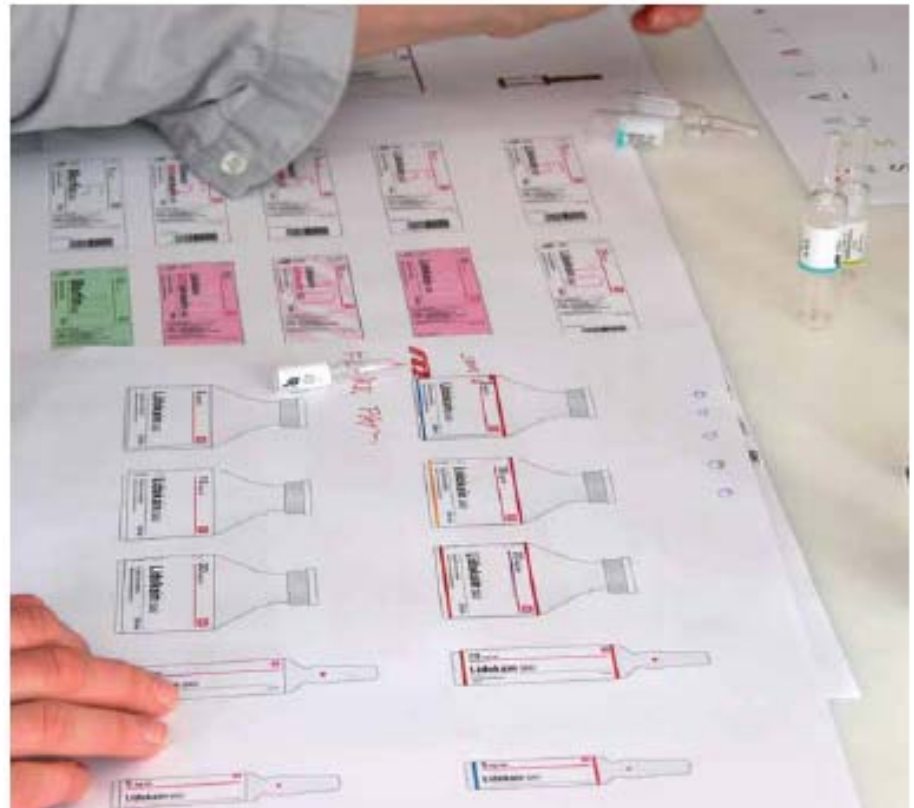
# Solution. Patient safety in design

## Denmark

- Three large graphic bureaus were invited to make a new design for medicines in a publicly owned company
- They should focus on patient safety only
- Medical staff were at service to help

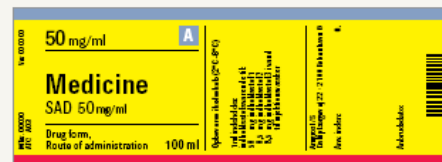
## UK

- The British Patient safety agency used designer-students to develop two brochures on design for safety
  - <http://www.npsa.nhs.uk/nrls/medication-zone/design-for-patient-safety-medication-topics/>



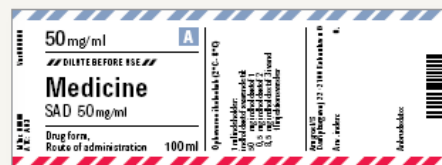
## Dangerous Drugs

Particularly dangerous drugs have a yellow label. The yellow background is a warning and a reminder to the user to take extra care: Read the label one more time.



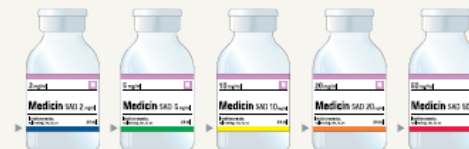
## Dilution

Products that have to be diluted are marked with a diagonally-striped band of colour and text "dilute before use". When a product is available only in one strength, the label is marked with a diagonally-striped band of colour at the top edge.



## Strength

Medicinal products that are available in several strengths are marked with a band of colour at the bottom edge. The colour spectrum goes from blue to red, where blue is the weakest concentration and red the strongest. Medical products available in one strength only have no band of colour at the bottom edge.









# Problem: No proper reaction to known side effects

Mabthera

- Problem
  - Increased risk of infections
  - Infections may have blunt symptoms
  - We did a root cause analysis in 2006
  - - No "always carry with you card"

# **Problem: No proper reaction to known side effects**

Mabthera

Solution

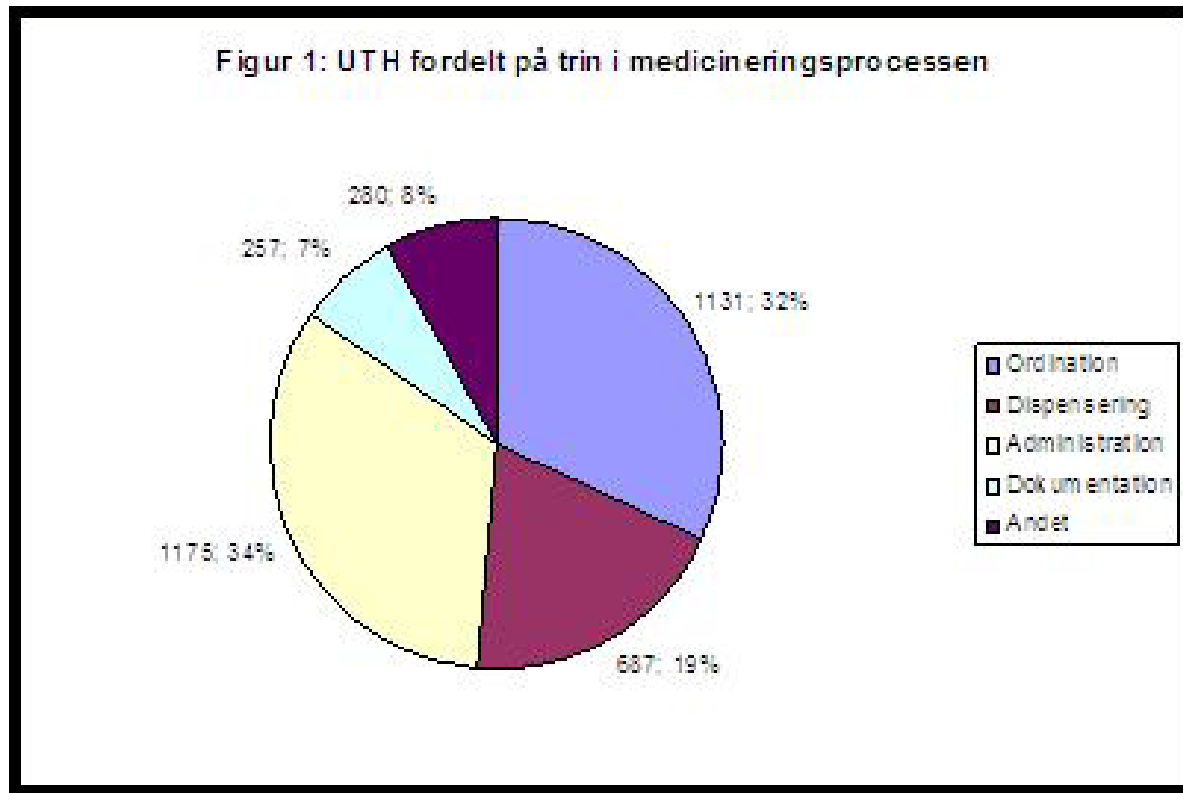
- We made a card – but we did not circulate it to other hospitals
- Now there has been a similar incident in another hospital in Denmark!

# Agenda

- Overview - Definitions and epidemiology
- Tools and examples
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  - Risk management



# Large scale: 3520 medication errors



Stud Health Technol Inform Binzer and Hellebek 2011

Lægemiddelgruppe	Århus	Blechnholm	Frederiksberg	Frederiksberg	Helsingør	Østfås	Østfås	Hørås	Hvdsås	Blpsås	Hllersås	Rjgås	Psyklsås
Antibloska (J01)	14,7	23,6	11,1	20,3	22,8	7,5	14,2	21,4	17,3	12,6	24,4	16,5	
Antitrombosensler (B01A)	18,7	11,1	20,6	15,9	15,2	6,2	12,5	10,3	8,2	29,7	9,4	6,0	
Insuliner (A10A)	8,0	13,9		7,2			7,8	5,3	8,5	2,7	6,2		
Opioids (N02A)	14,7		7,9	11,6	5,1	4,6		3,9	5,2	7,2	4,2		
Infusionsvæsker og koncenterter (B05)			6,3					4,8				7,1	
Antineoplastiske stoffer (L01)								7,2				18,1	
Smerestillende, ikke specificeret (N02)								6,4	5,2				
Antipsykotika (N05A)													32,0
Anxiolytika (N05B)													5,5
Antidepressiva (N06A)													5,5
Ikke oplyst	14,7	18,1	20,6	5,8	15,2	47,1	11,6	10,3	12,3	10,8	17,1	6,2	26,7

# The frequent medicines- and the worst

- Error types with insulin, warfarin, opioides, cytostatics
- Staff identified 11 serious cases
- We identified 12 more..

Stud Health Technol Inform Binzer and Hellebek 2011

# Follow up - Novo mix 30

## Autumn 2007

- Letter to Novo CEO from Hospital CEO regarding "concern on mix ups"
- Telephone call to me from previous colleague now working in Novo
- Letter in return saying we must report as adverse events
  - But adverse drug event form include data on involved parties

## Spring 2008

- Letter from company pharmacovigilance office based on newspaper article
- But – we still cannot disclose details
- Letter in return from me asking for working together and offer on presentation
- No reply

## Spring 2009

- Meeting with all Danish Pharmacovigilance offices in companies
- Invitation to Novo-Nordisk to talk at international conference on medication errors in Sept 2009
- Now we work together



# Follow up – vaccines/immunisation



# 69 root cause analyses

- Harm
  - 33 % of patients died
  - 20 % had to be removed to higher degree of care
  
- Some errors came back indicating that analyses and action plans in departments were not good enough

# Medicines

- Oral potassium
- Electrolytes
- Insulin
- Digoxin
- Warfarin
- Antibiotics
- Cytostatics
- NSAID
- Metotrexat
- Barbiturate
- Phosfenytoin
- Anaesthesia
- Pain killers
- N acetylcystein

# High alert medicine

- Certain classes of medications that have consistently been identified as particularly serious threats to patient safety.

Gandhi TK, Shojania KG, Bates DW. Protocols for high-risk drugs: Reducing adverse drug events related to anticoagulants. In: Making Health Care Safer: A Critical Analysis of Patient Safety Practices. Evidence Report/Technology Assessment, Number 43. Rockville, MD: Agency for Healthcare Research and Quality, 2001.

- Average drugs cause harm in 3,8% of reported medication errors
- High risk drugs cause harm in 6% or more of reported medication errors (USP)

# Medicines- situations

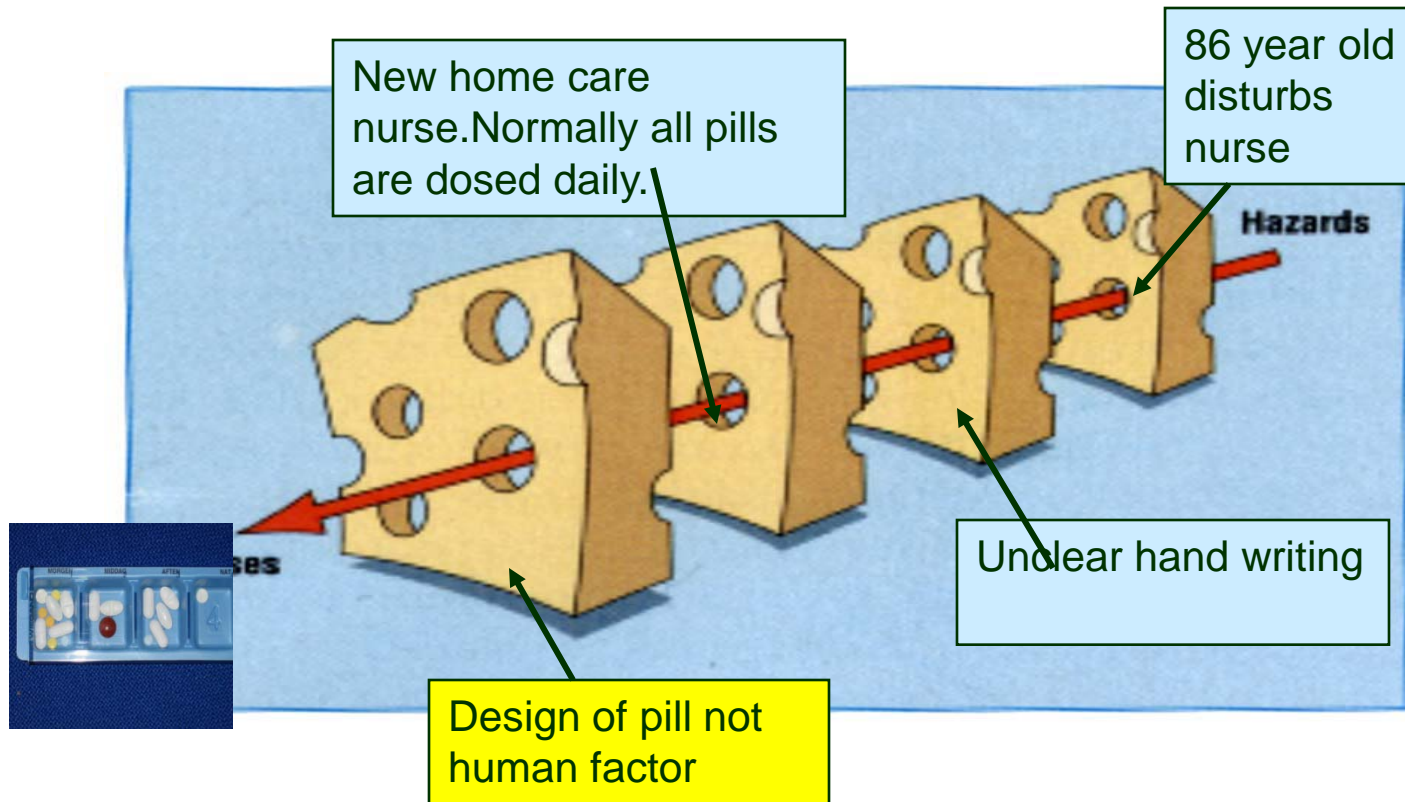
- **Double order/documentation/administration**
  - Gentamycin
  - NSAID
  - Insulin, warfarin, barbiturate
- **Mix up mg og and dispensible units**
  - Warfarin
  - Morphine
- **Mix up day, week, every third day**
  - Metotrexat
  - Medicine adhesives
- **Visual mix ups**
  - New medication due to normal drug not available in anaesthesia (concentrated iv potassium)
- **Saturation/wrong infusion speed**
  - Digoxin
  - N-acetylcystein
  - Phenytoin
- **Wrong way**
  - Oral potassium
  - Cytostatics
- **Calculation error**
  - Cytostatics
  - Morphine
  - Digoxin

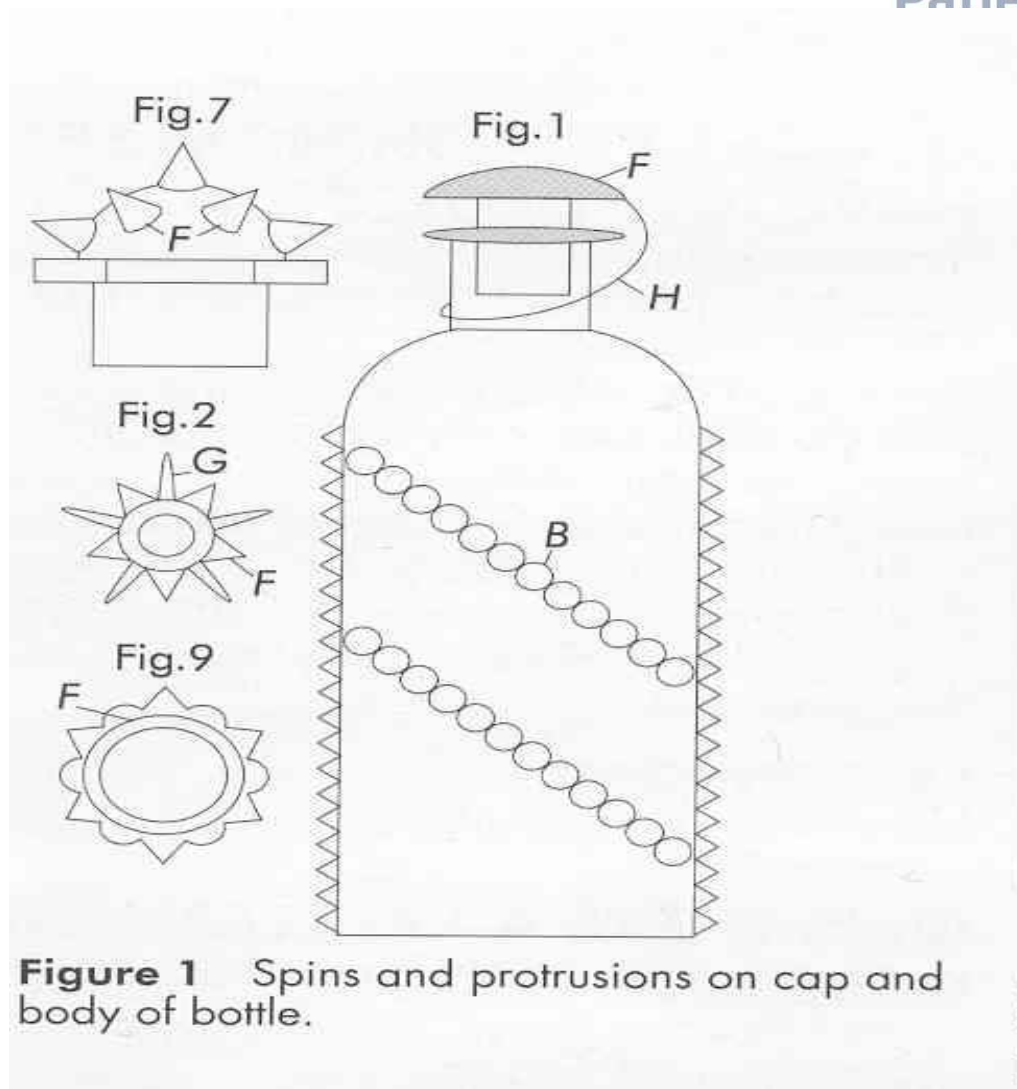
# Follow up

- Oral potassium -Implementation of oral syringes
- Medications in which dose is variable- - increased focus including IT system
- Decision support for Saturation calculation

# Unsolved problems

## Woman dies from medication error







# Agenda

- Overview - Definitions and epidemiology
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# Use of risk minimization plan

Make it easy to do it right – checklist for consideration of basal medication safety "tricks"

- Inspect the package/vial/tablets/device – use common sense
- Run a google test of the name – using small spelling errors
- More strengths - avoid "factor 10"
- May concentration and total content easily be mixed up
- How is strength marked for combination drugs – especially multi language packages
- Is label information on all sides of package information
- Is information on package of any practical use for patient and provider
- Weight or surface based dose: Include dosing aid ~ table with weight-dose
- Is name marked on single unit dose
- Is blister package child proof



# Use of risk minimization plan

Make it easy to do it right!

- Demand discussion on specific risk for medication errors
  - consider high risk population
    - patients whose medicine is administered by others (methotrexat)
  - high risk situation
    - wrong administration route (vincristine)
  
- Demand database searches for medication errors with similar products/similar dispensing situation
  - Ionsys- patient administered pain relief drugs known to be high risk
  - Concentrated iv fluids and medicines – need to highlight dilution
  - Name mix up lists (ISMP)
  
- Demand change of package if ADEs occur (page 4 in notes)

# Use of risk minimization plan

## *Product specific surveillance*

In addition to routine pharmacovigilance surveillance, product-specific surveillance activities will be performed to address AEs of special interest. The product-specific surveillance plan is a comprehensive program utilizing multiple databases from different sources, each of which was selected based on the capability to detect, characterize and monitor over time the identified key safety risks associated with IONSYS™. The objectives are to monitor the following AEs: overdose, death, abuse, addiction or misuse (use inconsistent with labeling whether intentional or unintentional), misuse in health care providers, reports suggesting diversion, medication errors, and respiratory depression.

There will be an education program for health care professionals on launch of the product. Training will be provided to Physicians, Nurses and Pharmacists prior to the use of IONSYS. These may include, but not be limited to representative in-services, videos, web casts, CD-ROMs, demonstration units and printed brochures. Physician and nurse training will focus on the appropriate use of IONSYS. Brochures devoted to pharmacists will concentrate on system testing and proper disposal.



# Agenda

- Want to know more?



# NHS in UK

## **Medication Zone**

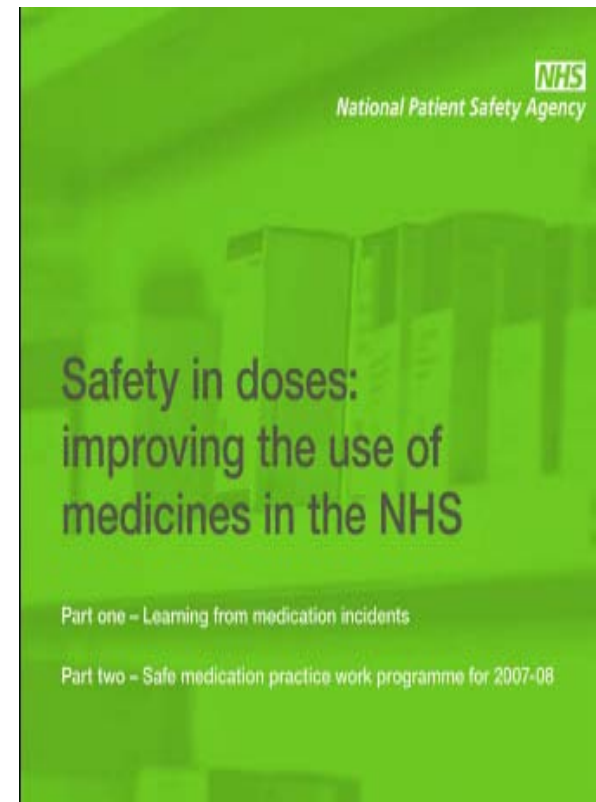
Heparin solutions, oral anticancer medicines, paraffin based skin products

## **Design For Patient Safety Booklets**

Dispensed medicines and the dispensing environment

## **Medication Publications**

Several reports. The last on safety in doses  
Solutions on methotrexate



# ISMP

**Table 1** – Examples of confused drug name pairs in selected countries  
*Brand name is shown in italics—Nonproprietary name is shown in bold*

Country	Brand name (Nonproprietary name)	Brand name (Nonproprietary name)
Australia	<i>Avanza</i> ( <b>mirtazapine</b> )	<i>Avandia</i> ( <b>rosiglitazone</b> )
	<i>Losec</i> ( <b>omeprazole</b> )	<i>Lasix</i> ( <b>furosemide</b> )
Brazil	<i>Losec</i> ( <b>omeprazol</b> )	<i>Lasix</i> ( <b>furosemida</b> )
	<i>Quelicin</i> ( <b>succinilcolina</b> )	<i>Keflin</i> ( <b>cefalotina</b> )
Canada	<i>Celebrex</i> ( <b>celecoxib</b> )	<i>Cerebyx</i> ( <b>fosphenytoin</b> )
	<i>Losec</i> ( <b>omeprazole</b> )	<i>Lasix</i> ( <b>furosemide</b> )
France	<b>fluoxétine</b>	<i>Fluvoxamine</i>
	<i>Reminyl</i> ( <b>galantamine hydrobromide</b> )	<i>Amarel</i> ( <b>glimepiride</b> )
Ireland	<i>Losec</i> ( <b>omeprazole</b> )	<i>Lasix</i> ( <b>furosemide</b> )
	<b>morphine</b>	<b>hydromorphone</b>
Italy	<i>Diamox</i> ( <b>acetazolamide</b> )	<i>Zimox</i> ( <b>amoxicillina triidrato</b> )
	<i>Flomax</i> ( <b>morniflumato</b> )	<i>Volmax</i> ( <b>salbutamolo solfato</b> )
Japan	<i>Almarl</i> ( <b>arotinolol</b> )	<i>Amaryl</i> ( <b>glimepiride</b> )
	<i>Taxotere</i> ( <b>docetaxel</b> )	<i>Taxol</i> ( <b>paclitaxel</b> )
Spain	<i>Dianben</i> ( <b>metformin</b> )	<i>Diovan</i> ( <b>valsartan</b> )
	<i>Ecazide</i> ( <b>captopril/hydrochlorothiazide</b> )	<i>Eskazine</i> ( <b>trifluoperazine</b> )
Sweden	<i>Avastin</i> ( <b>bvacizumab</b> )	<i>Avaxim</i> ( <b>hepatitis A vaccine</b> )
	<i>Lantus</i> ( <b>insulin glargine</b> )	<i>Lanvis</i> ( <b>toguanine</b> )



# WHO

- Curriculum for students
- Warnings



# Example vincristine (warning from WHO)

- Fatal errors in Hong Kong, Spain, USA, Australia and Denmark

## WHO recommendations

The WHO World Alliance for Patient Safety has consulted expert opinion widely and recommends:

- 1) The labelling of vincristine should include a clear warning label that reads: 'FOR INTRAVENOUS USE ONLY - **FATAL IF GIVEN BY OTHER ROUTES**'.
- 2) Syringes should not be used for vincristine administration.
- 3) Vincristine should where possible be prepared by dilution in small volume intravenous bags (the 'minibag' technique), rather than in a syringe, to protect against accidental administration via a spinal route.

# International Medication Safety Network

- Medication-error- freaks
- Meeting once a year
- 2011 in the middel east or Hong Kong
- WHO collaborators- hearings

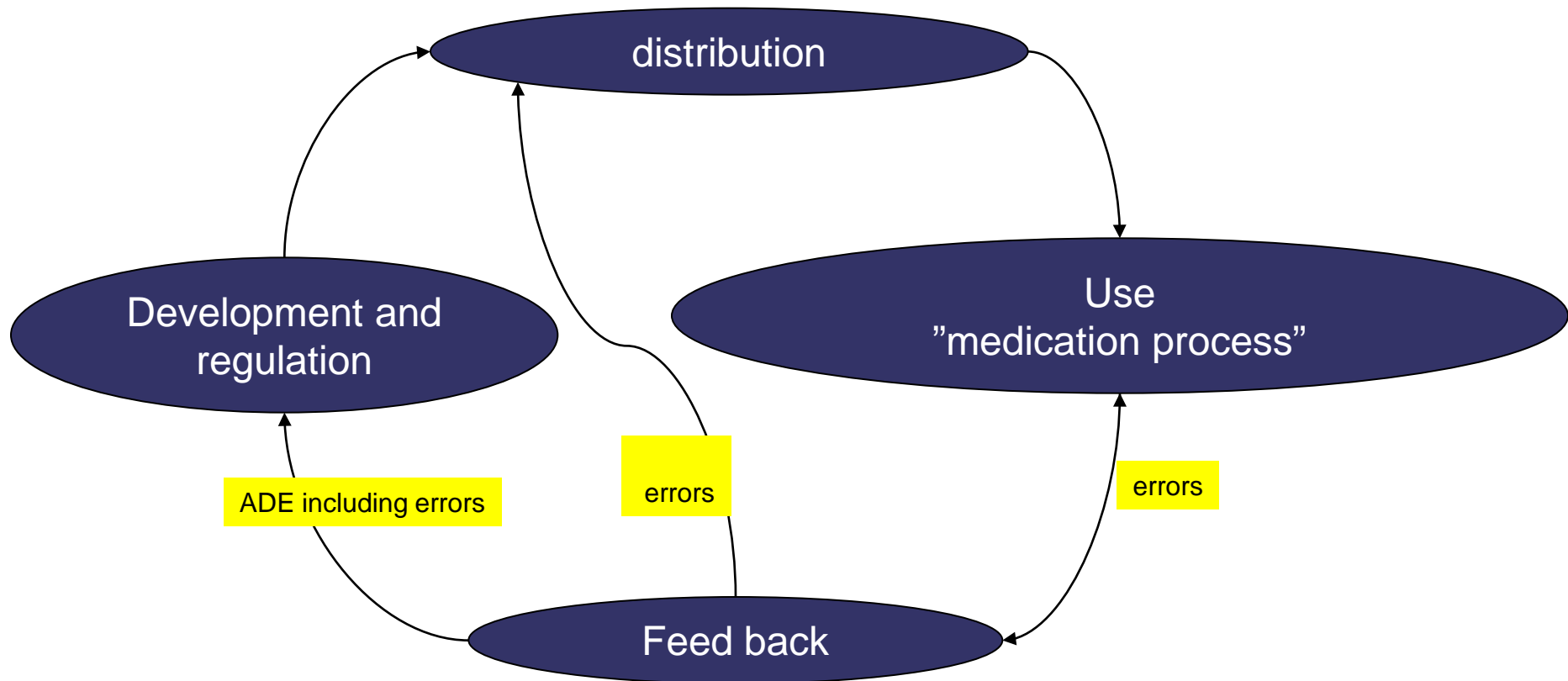


# Agenda

- Summary



# Medication cycle - now



# Analysis of medication errors

## - be broad minded

### Work flow

- Order and information
- Documentation
- Dispensing
- Administration
- Monitoring

### Facilities vary

- Storage areas
- System for documentation
- Systems for control
- Distribution and supply
- Guidelines

Healthcare professionals  
make heuristics

### Patients

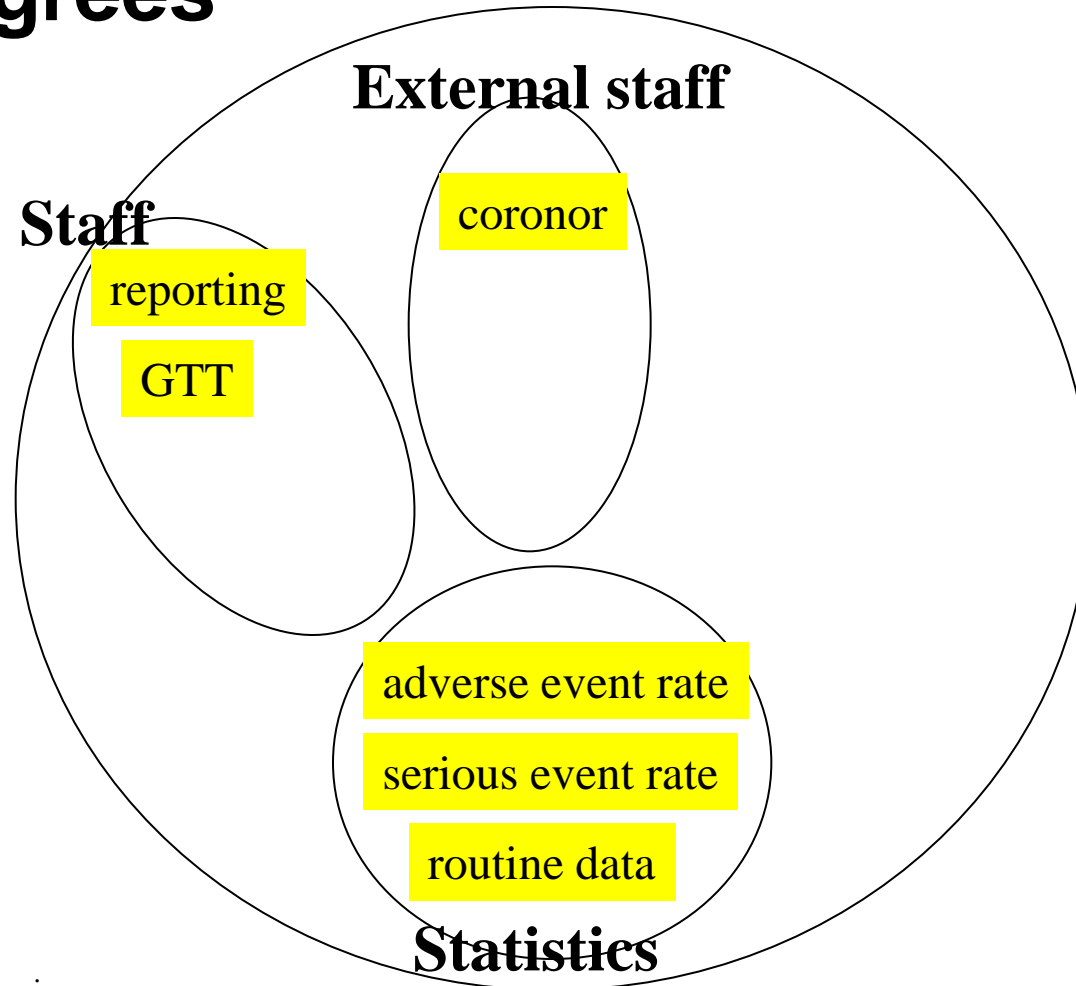
- Seek information in many places
- Have poor sight
- Do not understand generic substitution

### Drug

- Name
- Strength
- Pharmacology
- Effect
- Side effect
- **Kinetics**
- **Narrow therapeutic interval**
- **Variable dependent dose adjustment**
- Inner package
- Outer package
- Device
- Information
- Price

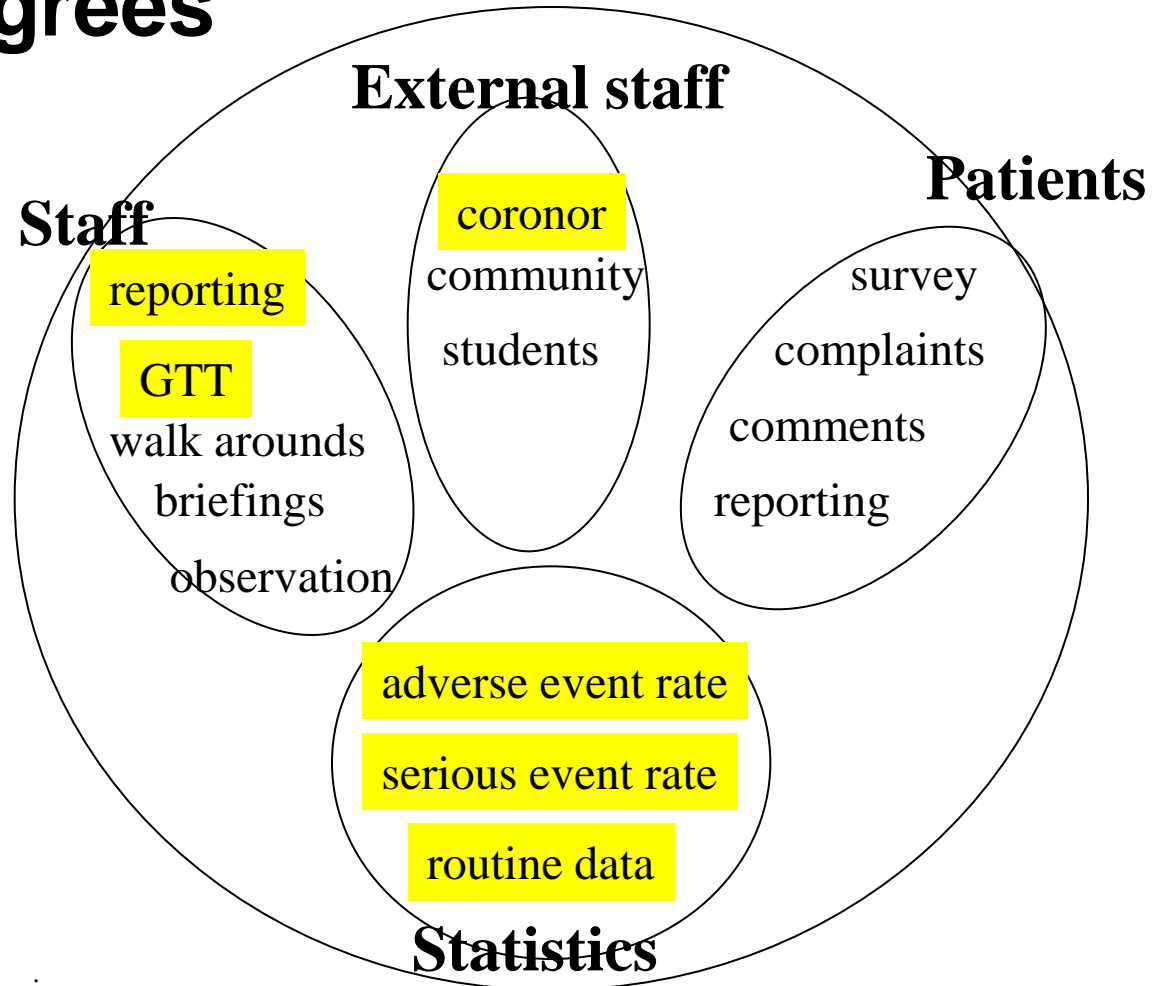


# Get to know the problems - 360 degrees



Manchester group on patient safety in primary care

# Get to know the problems - 360 degrees

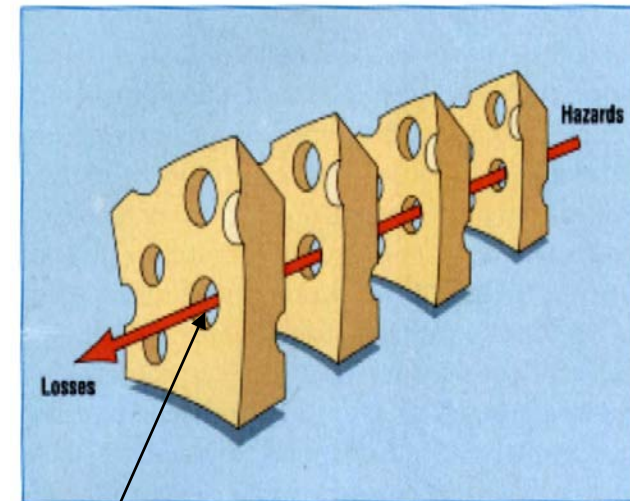


Manchester group on patient safety in primary care



# Remember

- Typical errors for specific medicines exist
- Medication errors and ADE due to medication errors can be prevented
- Prevention starts in the medicinal company
- Systematic analysis of different data can help change
- Systematic analysis of safety reports and risk minimization plans can help change
- In brief: think of yourselves as slices of swiss cheese – and stop the holes!



Lack of human factor thinking