

What scientific considerations arise from evaluating a medication error intervention?

Examples from a Swedish study of change in design in medication packaging.



Presentation

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# Is the problem well known in literature?

- WHO/Joint Commission Patient Safety Solutions :  
nr 1 Look Alike and Sound Alike Medications (2007)
- Council of Europe report on Medication Safety 2007
- NPSA England New design of packaging 2007-2008
- Denmark new design SAD 2008
- MMC/KI Research report 2010 incl Adverse Drug Events
- Läkartidningen  
nr 28-29 2008 study on S:t Görans sjukhus,  
nr 20 2009 injury at KS that went to court  
nr 16-17 2011 elektrolytes

# Well known case Astrid Lindgrens childrens hospital



# Generic names are often similar in the beginning and the end



The strength could be difficult to see clearly



# How important is the problem?

6000 injured, 750 of them seriously in Sweden

- **Socialstyrelsen study on medical injuries 2007**
- 8,6% had a medical injury = 105 000 patients
- Out of them were
  - 27 % caused by medication treatment
  - - 8 % side effects of the drugs
  - =19 % medical treatment in hospitals
- 1/3 of them were mix up of medicines NPSA 2008
- = 6% mix up of medicines out of 105 000 patients=6000
- 6% of the total 8,6 % is 0,5% of all admissions
- Incident reporting systems in Sweden show 1/3 of this

# The Swedish health care started the project

Started by a network for patient safety with:

*The national unions of doctors, nurses, auxiliary nurses*

*The federations for public and private hospitals*

*The medical injury insurance company*

The aims of the project:

- To develop principles for standardised medicines packages
- To use the principles as demands in public purchasing of medicines for Swedish hospitals.

# Based on influence from health care

- Questionnaire to regional committees for better use of medicines and to chief medical officers in hospitals
- Working party developed proposal for principles (cefalosporines och electrolytes)
- Questionnaire to the Hospital regions if they could approve our proposal for principles – very positive response



# Good discussions with the regulatory body



The Medical Products Agency accepts that our proposals:

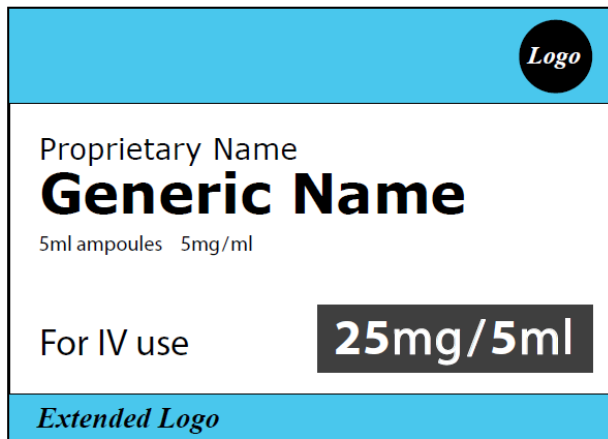
- could be web-tested by Linné University and with adjustments according to the test
- could be tested in a pilot public tendering in some hospital regions

# Positive responses on our proposals from medication industry's national organisations



# Starting point

Inspiration from England och Danmark



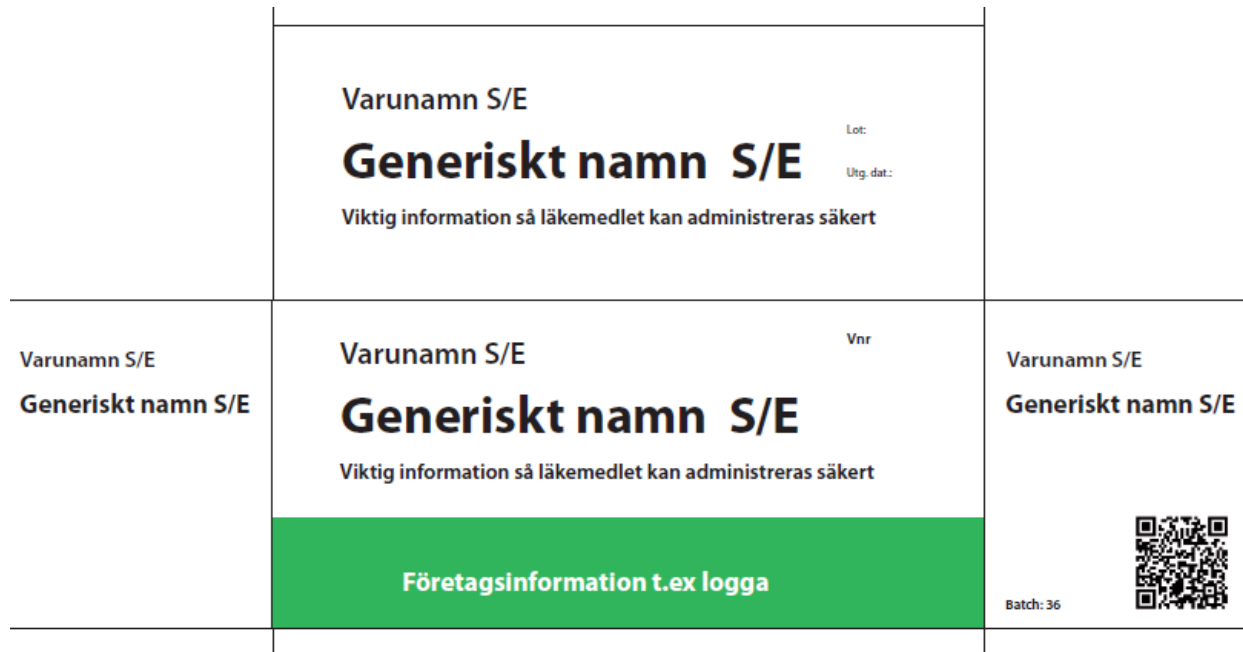
NPSA 2008



Denmark 2008

# Principles (based on NPSA 2008)

- Label in two parts
- Standardised places on the label for information.
- Generic name larger
- Only important information for administration of the medicine on front side



# Principles

If a company has different strengths of a medicine:  
Not standardised\* colour backgrounds should be used  
behind the figure for strength



\* It is important that there is no pattern in  
the colour scheme NPSA 2008

# Principles

A special broken line should be applied around the sides of the package for medicines that must be diluted



# Principles

A special colour (red) for a **one or a few high risk medicines**



In Denmark they used yellow and also for Adrenalin and Celokurin (high speed muscle relaxantia)

# Principles

## Tallman lettering





# Principles

....and capital letters for certain added ingredients or methods



# Principles

- Labels of ampoules/small bottles should have similar design as the medication packaging
- Labels should not be transparent\*



\*AstraZeneca has changed to not transparent labels in Sweden now



# Web-test by the e-health Institute at Linné University in Kalmar

- - During spring 2012 the e-health institute will test the proposals of changing the design:
    - Generic name largest
    - Coloured background for strength (not standardised)
    - Broken line for medicines that must be diluted
    - Easy to read type-face and large enough
    - Tall Man Lettering



## Web-test by the e-health Institute at Linné University in Kalmar

A pilot study will be performed in virtual laboratory environment. A small group of nurses will test different layouts shown on a computer screen.

The test will include both quantitative and qualitative data collection by interviews and observations.

The result will be used as background for a larger study where the risk of mix up will be tested both in laboratory and in real work environment.

# Coming steps

- After web-test adjustments of the proposal
- Discussions with regional committees for better use of medicines and public purchasing staff
- Discussions with the medication companies
- Test in reality by pilot public purchasing from 2014? for cefalosporines and electrolytes



**Comments are welcome to:**

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