Package Design Affects Accuracy Recognition for Medications

IMSN, October 30th, 2018
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NOMA

Norwegian Medicines Agency


rwin
Hipolixan
Lipistad
Enturion
Atorva
Lipitor
Lipomax
Lipodar
Lipiterol
ty
Ato
Lipomet
Jia
Litorva
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Truvaz
Tulip
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Bestatin
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Rotaqor
Speetin
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Lipinon
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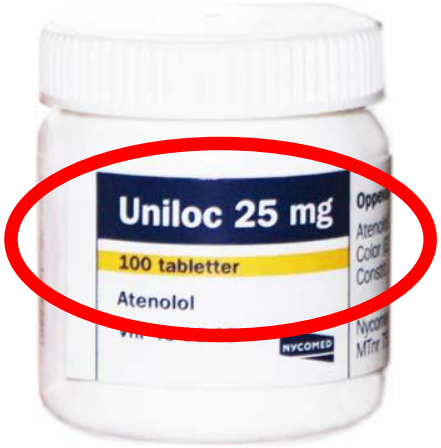
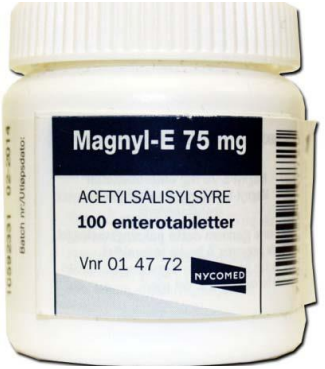
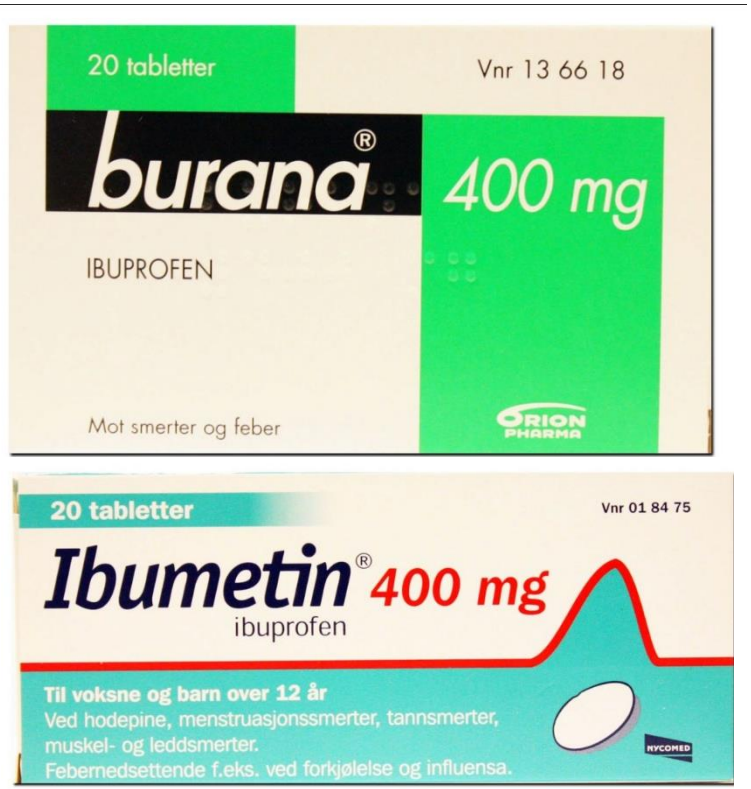
Ato

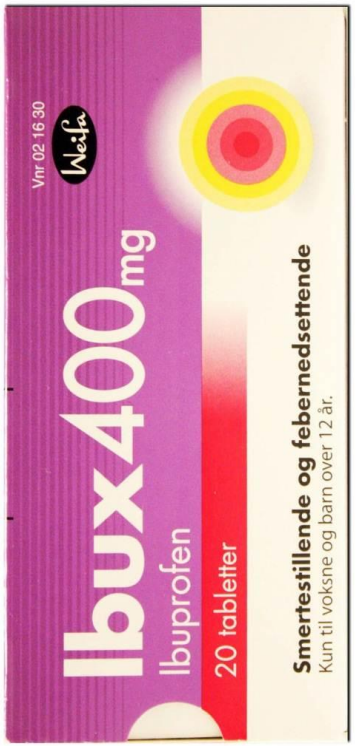
Peters drawer





Generic substitution in Norway: The pharmacy shall offer you the cheapest alternative.



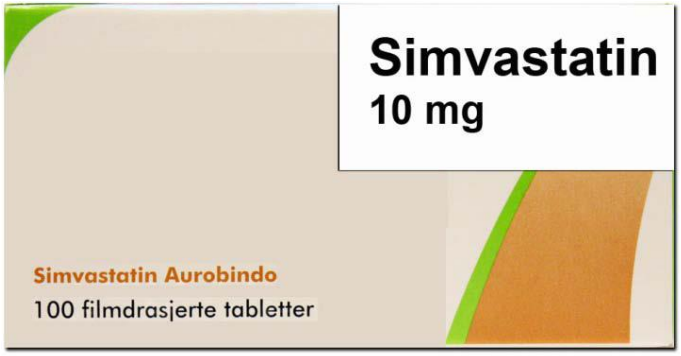


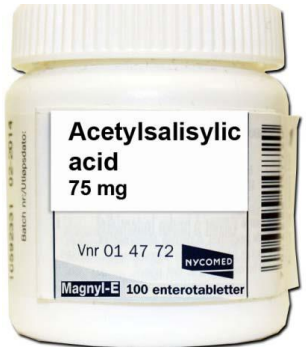
Peter is not the only one. Home visits after generic substitution in pharmacy

In an interview study of 174 Norwegian hypertensive patients, Hakonsen et al. (2009) found that

- 5% of the patients used more than one equivalent generic product at the same time.

Can a modified design help Peter?





Proposed new packaging design

Figure 1 New structured labelling as suggested by Endestad *et al.*[19]

- In the new design, the active ingredient and dose is prominently displayed in the upper right hand corner of the package.

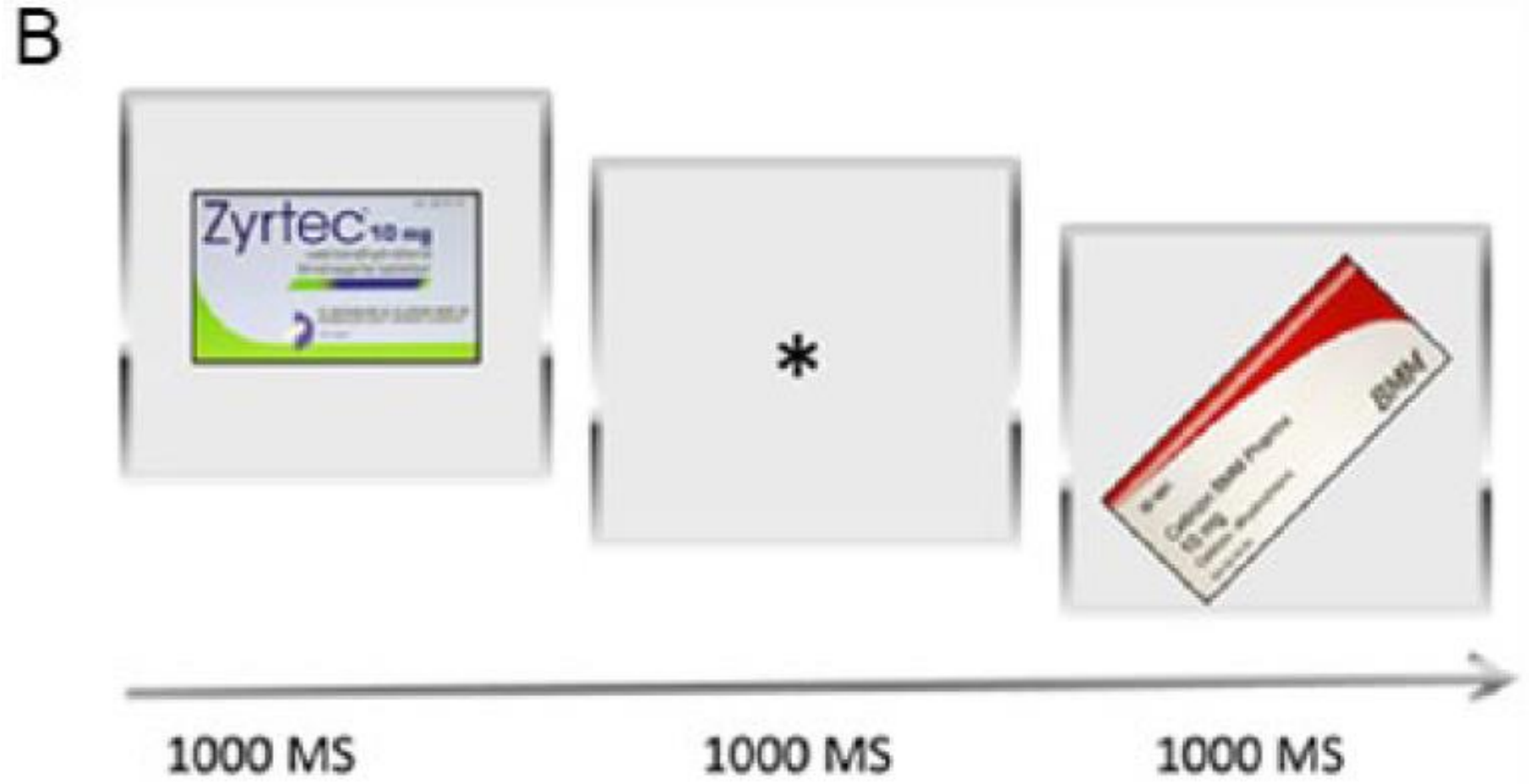
A

Example of original (left) and redesigned (right) packages.

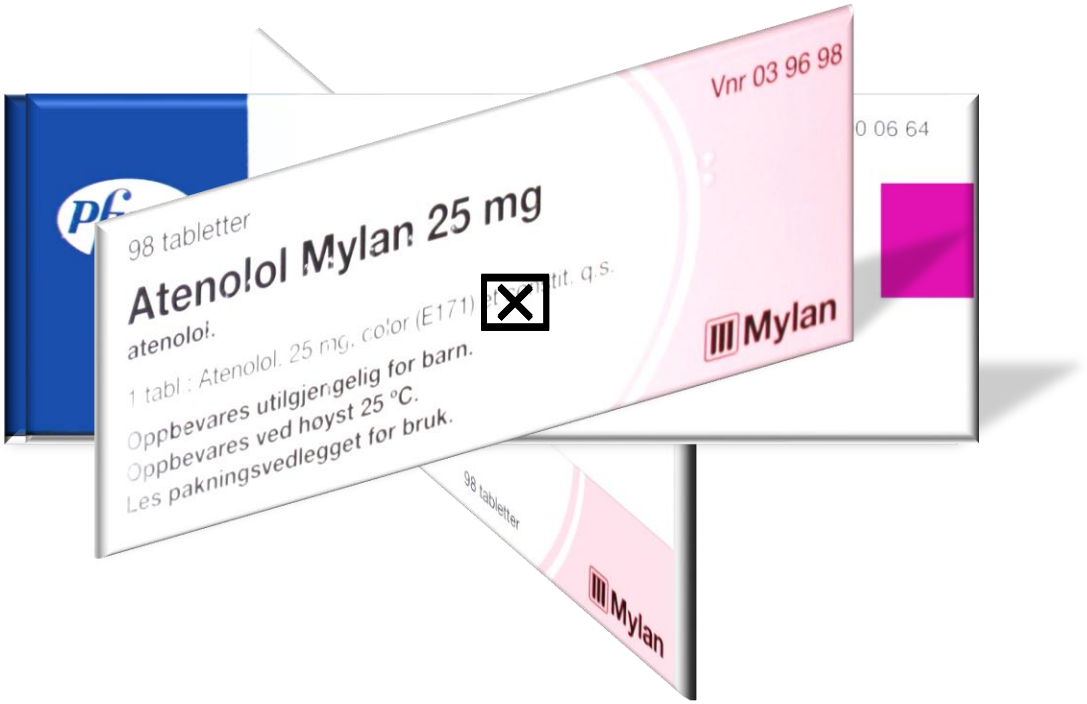
- We wanted to provide empirical support for the use of substance name and dose as the main source of information and for more consistent placement of this information.

Experiment 1

- **Aim of study** To test if highlighting and placement of substance name (and dose) on medication package have the potential to reduce patient errors.
  - To compare the redesigned packages with the original packages, we used a modified version of the Shepard and Metzler “Mental rotation task”.
  - Participants: 59 volunteers.
    - 30 elderly users (69–86 years, mean 75.9; 20 females)
    - 29 young students (18–38 years, mean 25.9; 18 females).



A trial consisted of a reference image, a fixation cross, and the target image. By pressing a key, participants indicated whether the target image contained the same or a different active ingredient as the reference image.


Vnr 03 96 98
98 tabletter
Atenolol Mylan 25 mg
atenolol.
Oppbevares utilgjengelig for barn.
Oppbevares ved høyst 25 °C.
Les pakningsvedlegget før bruk.
Mylan
0 06 64
98 tabletter
Mylan

Package Design Affects Accuracy Recognition for Medications

Tor Endestad, **Laura A. Wortinger**, University of Oslo, Norway, **Steinar Madsen**, and **Sigurd Hortemo**, Norwegian Medicines Agency, Oslo, Norway

Objective: Our aim was to test if highlighting and placement of substance name on medication package have the potential to reduce patient errors.

Background: An unintentional overdose of medication is a large health issue that might be linked to medication package design. In two experiments, placement, background color, and the active ingredient of generic medication packages were manipulated according to best human factors guidelines to reduce causes of labeling-related patient errors.

Method: In two experiments, we compared the original packaging with packages where we varied placement of the name, dose, and background of the active ingredient. Age-relevant differences and the effect of color on medication recognition error were tested. In Experiment 1, 59 volunteers (30 elderly and 29 young students), participated. In Experiment 2, 25 volunteers participated.

Results: The most common error was the inability to identify that two different packages contained the same active ingredient (young, 41%, and elderly, 68%). This kind of error decreased with the redesigned packages (young, 8%, and elderly, 16%). Confusion errors related to color design were reduced by two thirds in the redesigned packages compared with original generic medications.

Conclusion: Prominent placement of substance name and dose with a band of high-contrast color support recognition of the active substance in medications.

Application: A simple modification including high-

INTRODUCTION

Medication error is a major patient safety issue in the United States with 1.5 million adverse drug events reported annually, over one third of which occur in the outpatient setting, at an annual estimated cost approaching $1 billion. Over-the-counter (OTC; i.e., nonprescription) drug use is increasing; almost one half of U.S. adults take at least one OTC medication regularly. Almost one fifth of U.S. adults take acetaminophen in any given week (Wolf et al., 2012). Acetaminophen overdose is the leading cause of liver failure in the United States, and the package labeling of acetaminophen-containing OTC medications is a likely contributor to many unintentional overdoses (Wolf et al., 2007, 2012). A substantial number of medication errors may be related to name confusion due to inadequate labeling on medication packaging. Labeling effectiveness may be influenced by placement of the drug name and dosage

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Results experiment 1

- The most common error with original packages was the inability to identify that two different packages contained the same active ingredient
- This kind of error decreased with the redesigned packages

Results experiment 1: Reaction time and Accuracy (percentage correct responses)

TABLE 1: Mean Reaction Times, Accuracy, Standard Errors, and Confidence Intervals (CI) for the Different Versions of Packages

	Young		Elderly		
Variable	*M* (*SE*)	95% CI	*M* Correct (*SE*)	95% CI	*p*
Reaction time in milliseconds					
Original same substance	981 (37)	[907, 1055]	1282 (35)	[1212, 1352]	***
Original different substance	1036 (42)	[951, 1121]	1344 (36)	[1273, 1416]	***
Redesigned same substance	779 (33)	[713, 844]	1152 (31)	[1090, 1214]	***
Redesigned different substance	894 (38)	[819, 970]	1318 (40)	[1237, 1398]	***
Accuracy in percentages					
Original same substance	65 (4)	[56, 73]	44 (3)	[38, 50]	***
Original different substance	95 (1)	[94, 96]	77 (4)	[69, 84]	***
Redesigned same substance	92 (2)	[89, 96]	85 (2)	[81, 90]	**
Redesigned different substance	95 (1)	[93, 96]	78 (3)	[71, 85]	***

*$p \leq .05$. **$p \leq .01$. ***$p \leq .001$.

Accuracy (percentage correct responses)

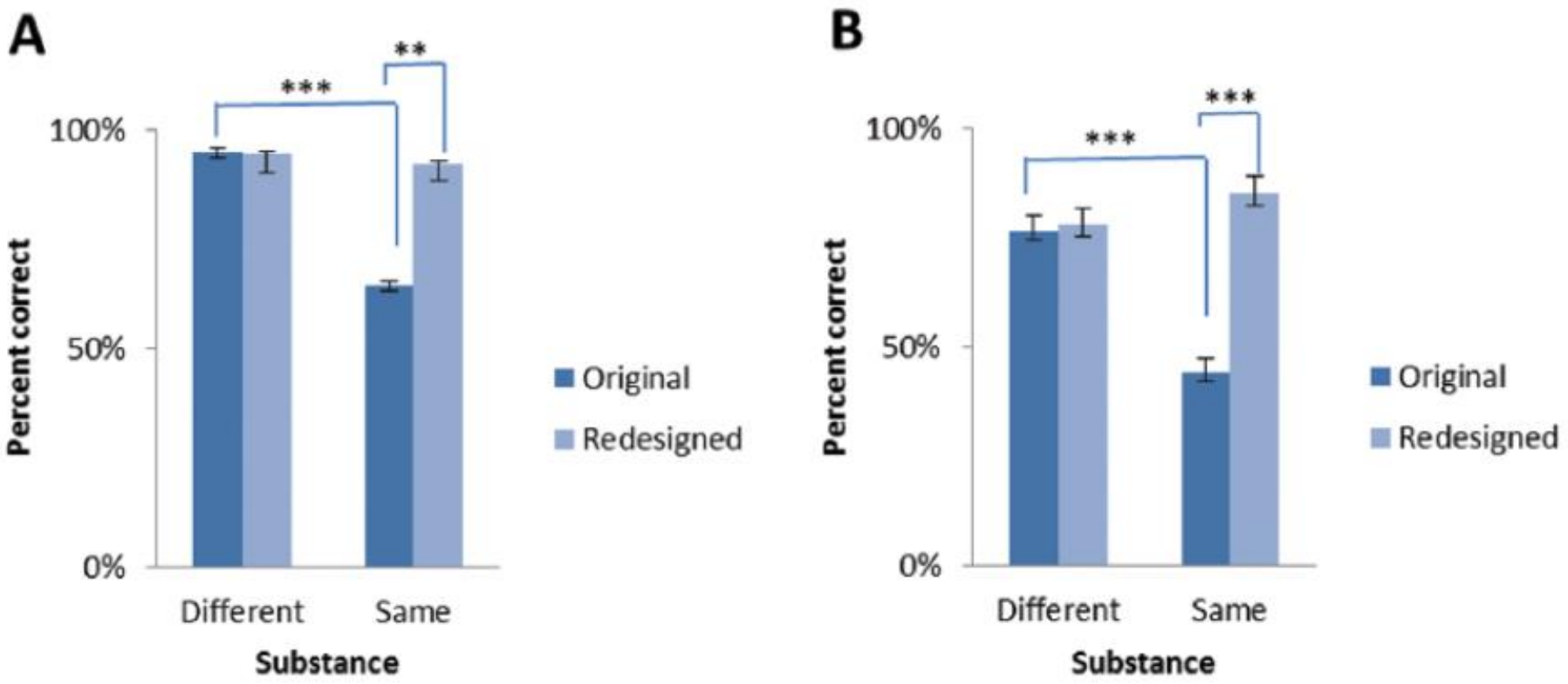


Figure 2. (A) Overall percentage correct responses for the two designs for the young group. (B) Overall percentage correct responses for the two designs for the elderly group.

Main findings experiment 1

- Our main findings indicate that there are advantages related to both effort (reaction times) and accuracy (percentage correct responses) for the redesigned packages compared to original packages.

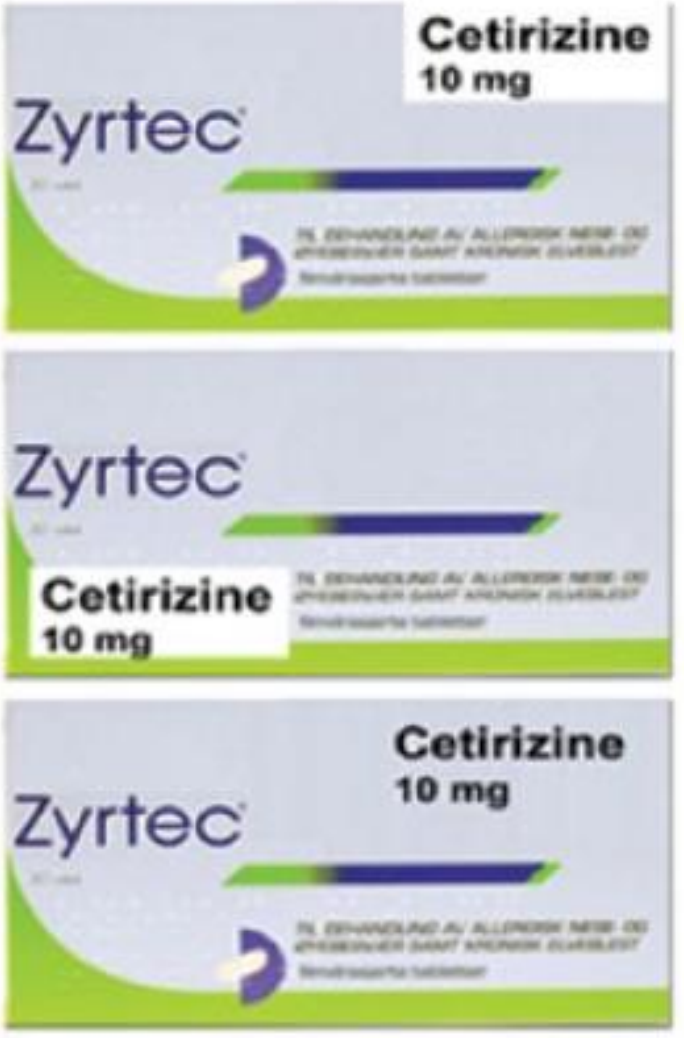
- However, since we made several changes
  - highlighted the substance name with a prominent font
  - provided a distinct contrast background and
  - standardized placement of this information

  we could not discern the role of these three manipulations in experiment 1

Experiment 2 compared three conditions

Twenty-five students participated in this study

- **The redesigned condition** Same packages as in Experiment 1.
- **The placement condition** Same design, but the critical information randomly placed in either the upper right or the lower left corner.
- **The transparent condition** Substance names were placed in the upper right corner but without the contrasted background.



Results experiment 2

Reaction time

- We found a significantly longer reaction time for the transparent condition compared with the others, $p < 0.001$.
- There were no differences between the redesigned and placement conditions.

Accuracy.

- We found more errors for the transparent condition compared with the other two conditions, $p = 0.005$.
- The redesigned and placement conditions were not significantly different.

Details experiment 2

TABLE 3: Mean Reaction Times in Milliseconds, Errors in Percentages, Standard Errors, and Confidence Intervals (CI) for the Different Conditions

	Reaction Time		Errors	
Condition	*M* (*SE*)	95% CI	% (*SE*)	95% CI
Redesigned	1017 (40)	[934, 1100]	6 (1)	[4, 8]
Substance	1131 (47)	[1035, 1227]	12 (2)	[8, 15]
Placement	1035 (50)	[932, 1138]	7 (1)	[5, 9]

Conclusions

- A redesign of medication packages decreased recognition errors.
  - The most prominent improvement occurred when different packages contained the same substance.
  - The results of experiment 2 suggest that the key to error reduction is the highlighted substance name placed in a high-contrast area (band or box).
- The present study suggests that minor changes in packaging design significantly improves users' ability to determine whether or not two different drugs contain the same active ingredient.

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BMJ

Safety and efficiency of a new generic package labelling: a before and after study in a simulated setting

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Kjell Hermann Halvorsen,[1] Sigurd Hortemo,[3] Steinar Madsen[3]

- **Conclusions** A new labelling of medication packages with prominent placement of the active substance(s) and strength(s) in the front of the medication package may reduce time for nurses when preparing medications, without increasing medication errors.

PS

- If FDA or EMA or WHO adapts these design principles, we recommend that «form» is highlighted together with the name of active sunstance and dose.

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