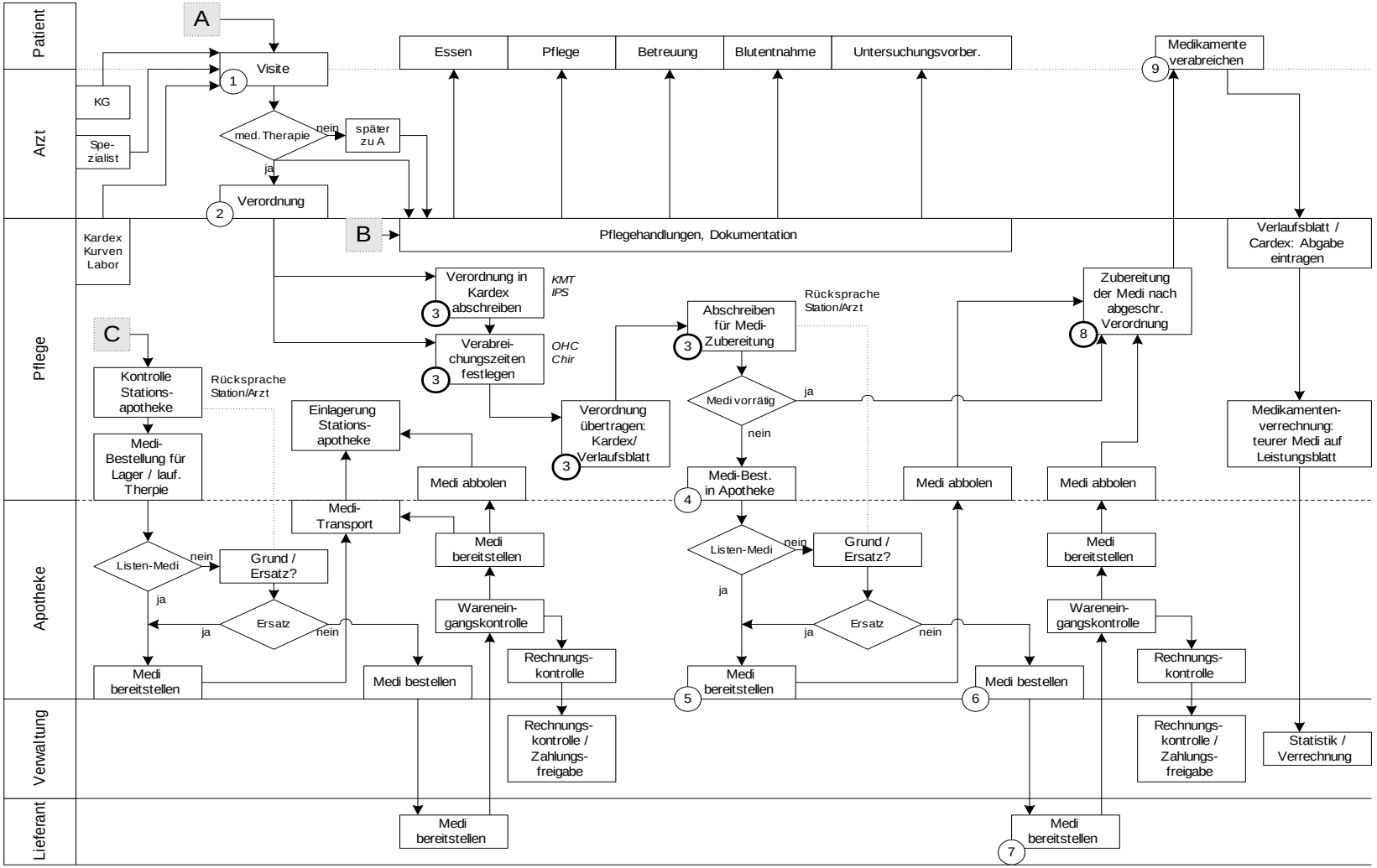
- **Joint recommendations for the avoidance of confusion concerning the primary packaging and labelling of several pharmaceutical dosage forms – the swiss way**

Dr. pharm. Enea Martinelli; Head of Pharmacy
Head of the working-group „look alike – sound alike“
(Science Industries, Interpharma, Intergenerika,
Patient Safety foundation, GSASA)

3rd annual Pharma Packaging and Labelling Forum
Global Conferences, Vienna 11.9.2014

- Policy and requirements
- Challenges
- Actions and achievements

The medication process in hospitals



Dr. J. Götte; Diplomarbeit NDS Wirtschaft 10/1999

Dr. Enea Martinelli, Joint recommendations for the avoidance of confusion concerning the primary packaging and labelling of several pharmaceutical dosage forms – the swiss way
3rd annual Pharma Packaging and Labelling Forum Global Conferences, Vienna 11.9.2014

Medication process

Optimised pharmacotherapy		„real“ pharmacotherapy
Right medication / form	→	Wrong medication (form) Contraindication not considered Interaction not considered Wrong order entry, transcription error
Right dosage	→	Wrong dosage (too much/ not enough) Wrong order entry, transcription error Error of calculation (Calculation error)
Right patient	→	Wrong Patient Bad (Poor?) communication
Right quality	→	Wrong application Incorrect handling Wrong preparation
Right time	→	Wrong time Late delivery (supply chain) Wrong order entry, transcription error

Medication errors

Kind of error	Share (Occurrence?)	Country	Source: author (year)
Perscription errors	14.4%	NL	Van den Bemt (2000)
	39%	UK, US	Leape (1999)
	48%	US	Pepper (2006)
	15-21%	US	MedMarx (2004)
Transcription errors	11%	US	Leape, Bates (1995)
	23-26%	US	MedMarx (2004)
Dispensing errors	12.5%	US	Kistner (1994)
	14%	US	Leape, Bates (1995)
	21-22%	US	MedMarx (2004)
Errors of use (including preparation)	3%	UK	Taxis (2003)
	38%	US	Leape, Bates (1995)
	33-37%	US	Medmarx (2004)

Ethnographic study of incidence and severity of intravenous drug errors

Katja Taxis, Nick Barber

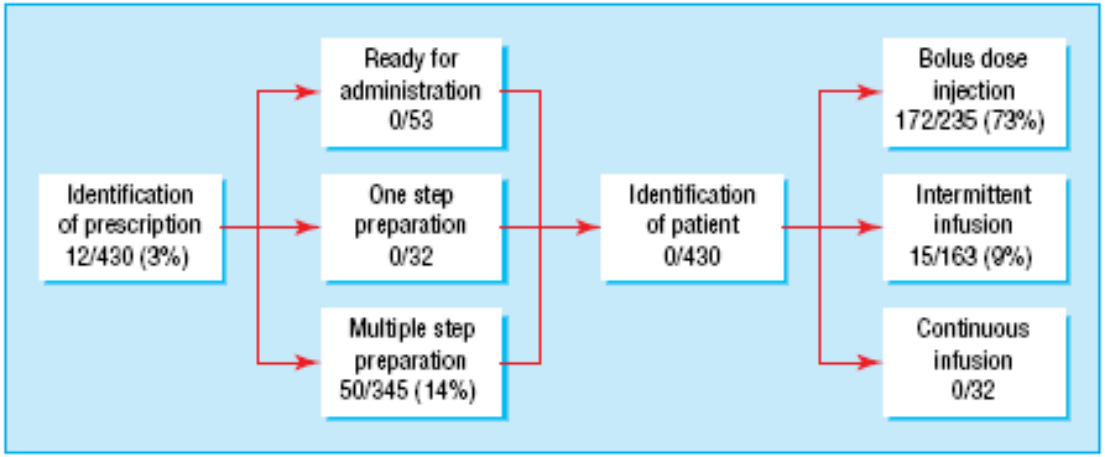
BMJ VOLUME 326 29 MARCH 2003

What this study adds

Errors occurred in about half of the intravenous drug doses observed

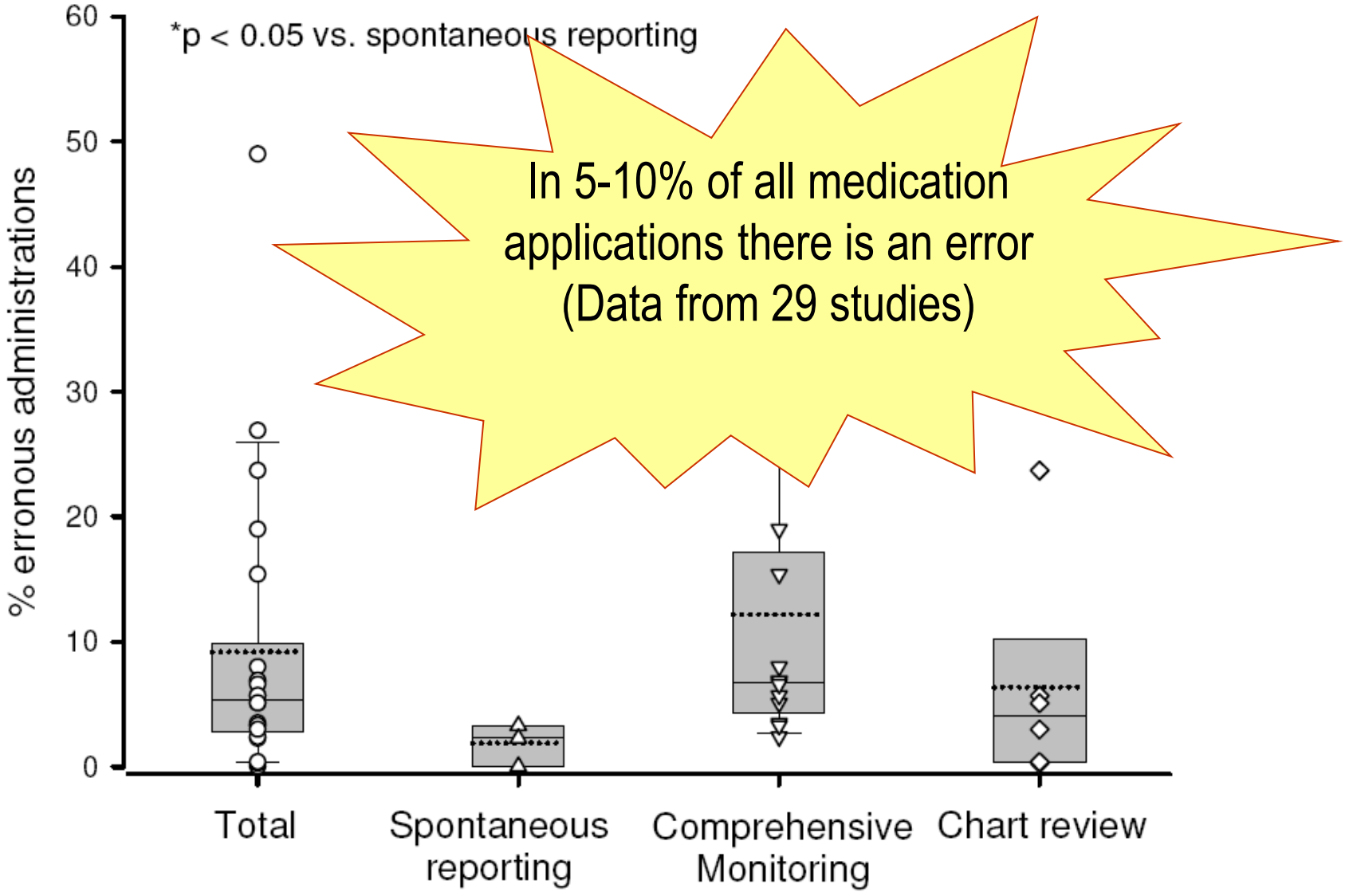
Errors were potentially harmful in about a third of cases

The most common errors were giving bolus doses too quickly and mistakes in preparing drugs that required multiple steps



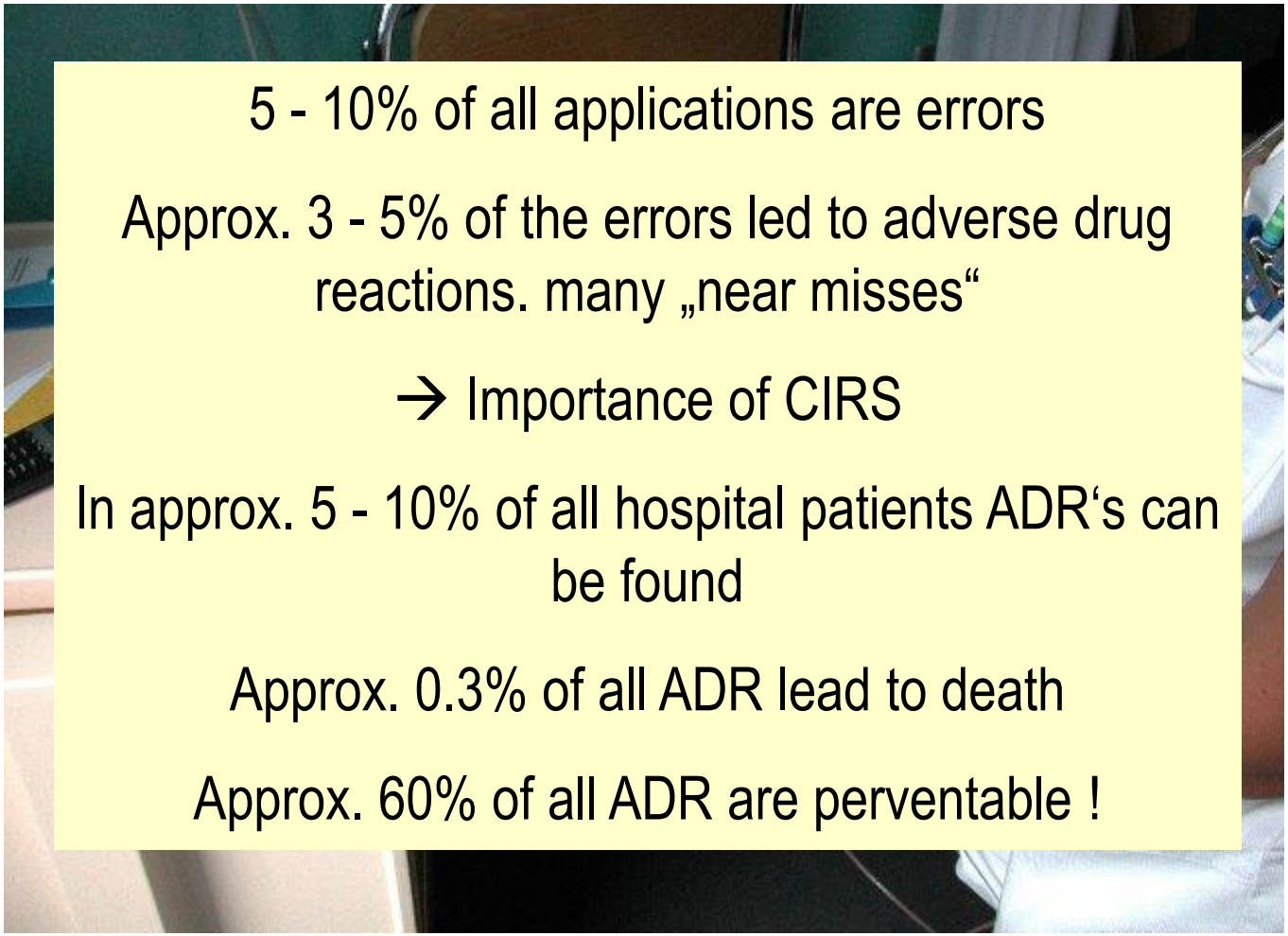
Stages and errors in preparation and administration of intravenous drugs (numbers of errors/number of observations of each stage)

How often do medication errors occur ?



Krähenbühl A, Schlienger R, Lampert M et al. Drug Safety 2007; 30 (5): 379-407

Medication errors and consequences



5 - 10% of all applications are errors

Approx. 3 - 5% of the errors led to adverse drug reactions. many „near misses“

→ Importance of CIRS

In approx. 5 - 10% of all hospital patients ADR‘s can be found

Approx. 0.3% of all ADR lead to death

Approx. 60% of all ADR are perventable !

- Classen DC.; Adverse drug events and medication errors : the scientific perspective. In: Proceedings of Enhancing Patient Safety Foundation; 1998: 56 – 60
- Oertle M., Schweizerische Aerztezeitung 84, 41 (2003) 2136 – 2138
- Leape LL et al.; N Engl J Med 24, 6 (1991) 377 - 384

Impact of these errors

- in over 5% of all applications in a hospital a medication error is found
- In an average hospitalisation of 7 days and a treatment with 7 drugs = approx. 50 applications per hospitalisation

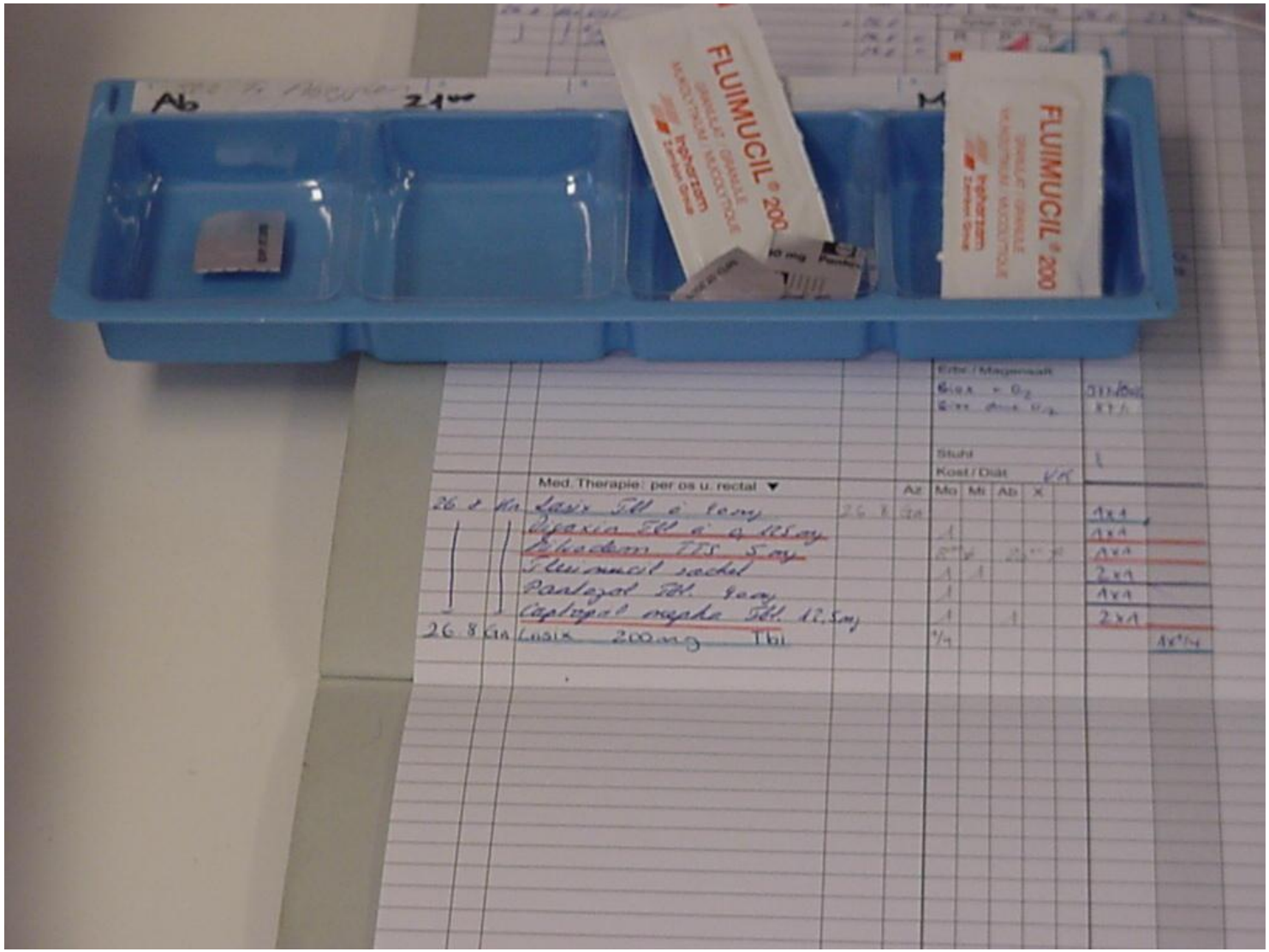
  → ≥ 2 medication errors / hospitalisation
- Empirical data show that 6% of all patients have an ADR during hospitalisation.
- 3-5% of all medications lead to a ADR → every 10. - 20. patient (5-10%) is exposed to an ADR
- 3% of ADR lead to death → 0.15 - 0.3% of all medication errors are fatal
- 1 ADR costs Ø $4000 and prolongs hospital stay Ø 3 days. With 7'000 patients/ year this results in 14'000 errors a year (Basis = 3 sources)
- 3% of the 14'000 equal 420 ADR's / year. 60% are preventable = 250 UAW's / Jahr
- 420 x 4000.- Fr. = 1.7 Mio Fr. extra cost with 7'000 patients / year

Packaging and medication errors

- Packaging is not the only problem in the process, there are many more to work on
- **Packaging is one of the solutions for improving the process (or one of the problems leading to many errors).**

Dr. Enea Martinelli, Joint recommendations for the avoidance of confusion concerning the primary packaging and labelling of several pharmaceutical dosage forms – the swiss way
3rd annual Pharma Packaging and Labelling Forum Global Conferences, Vienna 11.9.2014


5%
5%



Dr. Enea Martinelli, Joint recommendations for the avoidance of confusion concerning the primary packaging and labelling of several pharmaceutical dosage forms – the swiss way
3rd annual Pharma Packaging and Labelling Forum Global Conferences, Vienna 11.9.2014

Dr. Enea Martinelli, Joint recommendations for the avoidance of confusion concerning the primary packaging and labelling of several pharmaceutical dosage forms – the swiss way
3rd annual Pharma Packaging and Labelling Forum Global Conferences, Vienna 11.9.2014

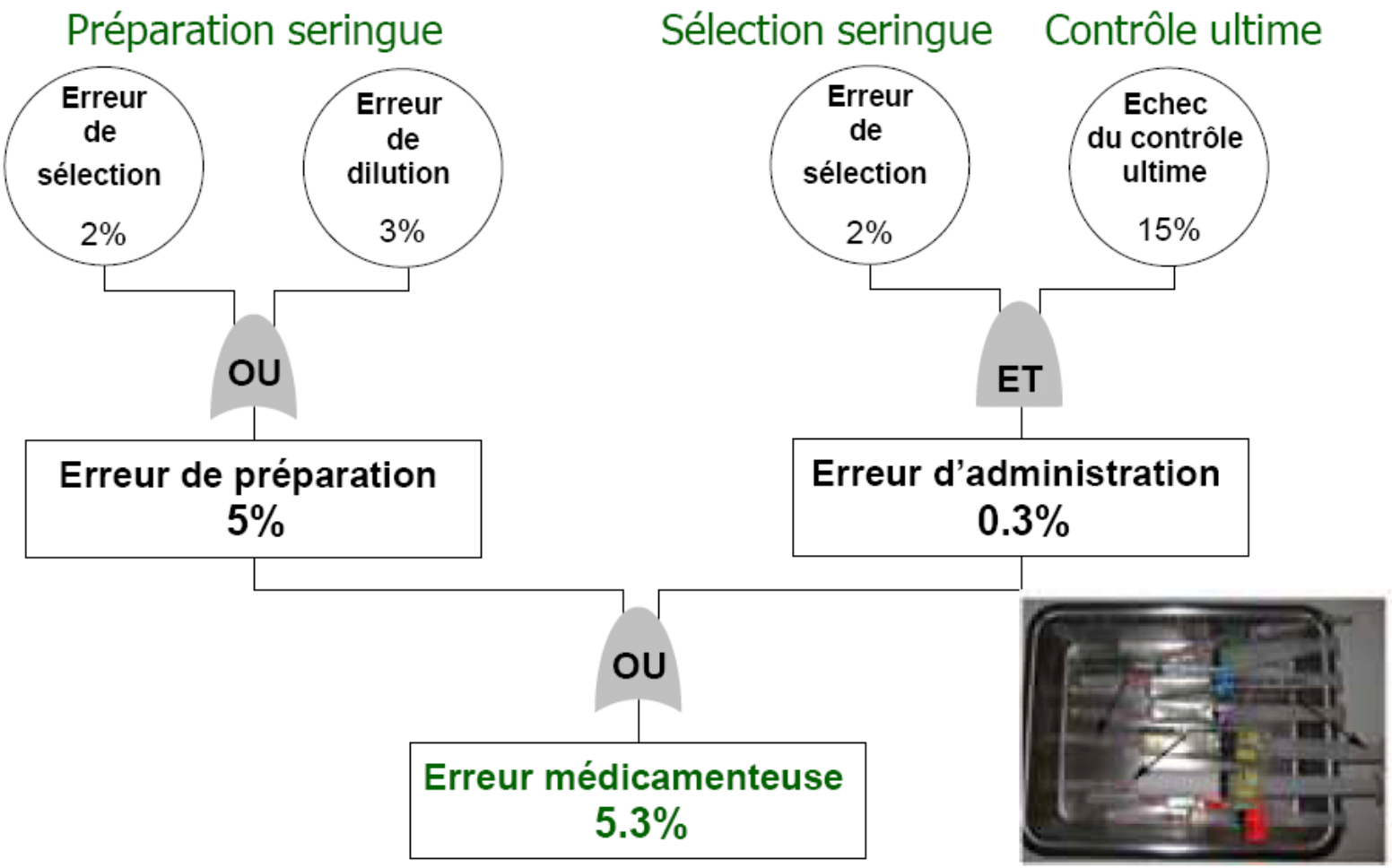
„Tree of breakdowns“

- Experimentally generated results
  - Dispensing errors 3%
  - Picking errors 2%
  - Diluting errors 3%
  - Errors in calculation 10%

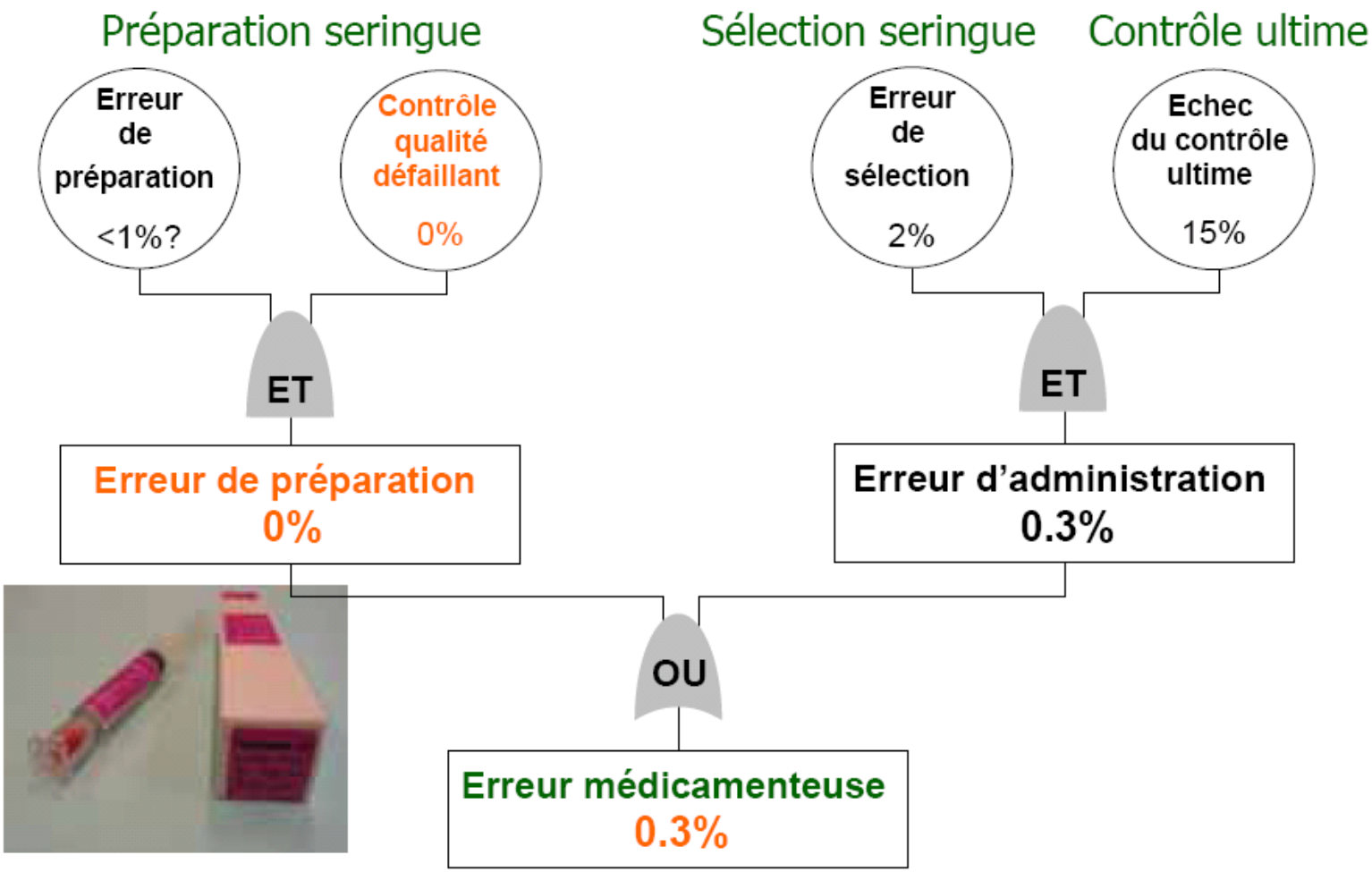
  - Performance of double-checks 85%

Garnerin Ph, Eur J Clin Pharmacol 2007;63:769

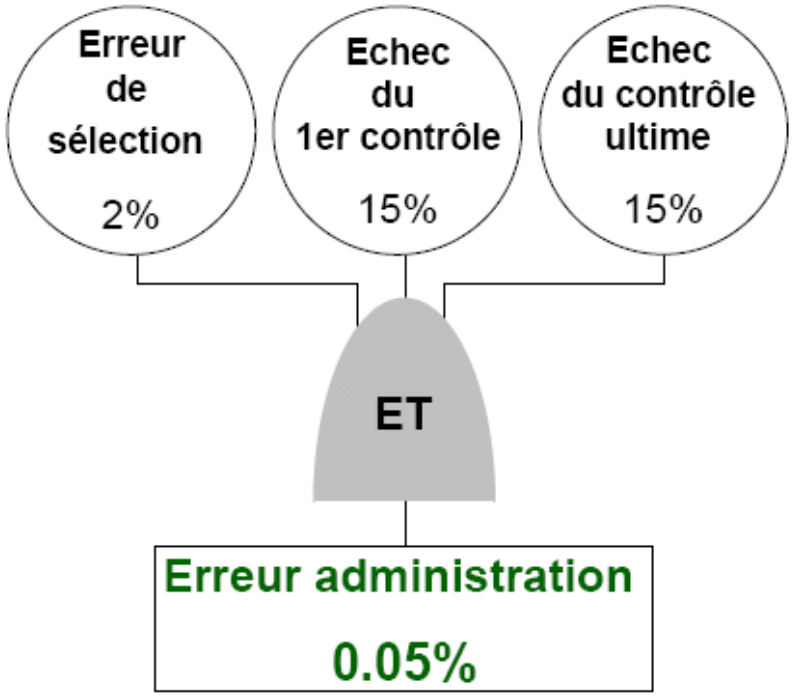
Baalbaki R, HUG, 2006

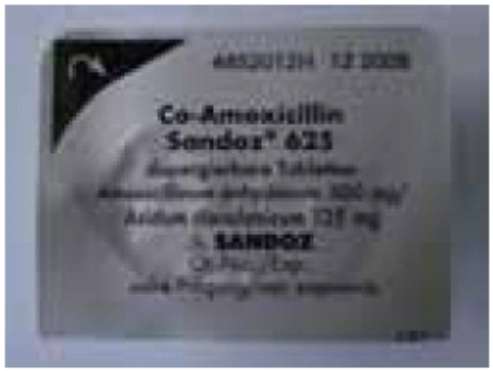


Slides presented with the kind permission of © Prof. P. Bonnabry, Head of Pharmacy, University-hospital Geneva

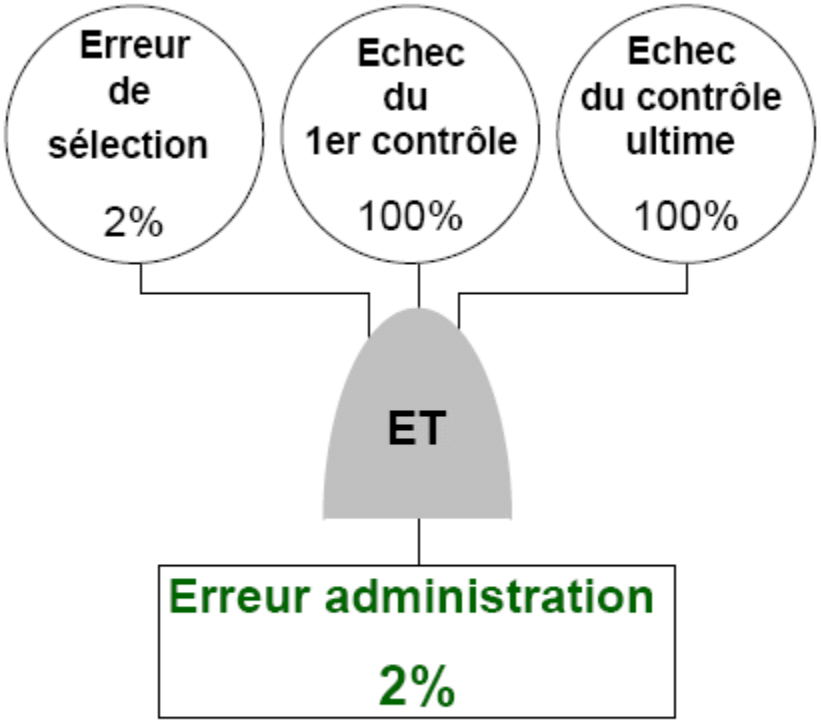


Slides presented with the kind permission of © Prof. P. Bonnabry, Head of Pharmacy, University-hospital Geneva





Slides presented with the kind permission of © Prof. P. Bonnabry, Head of Pharmacy, University-hospital Geneva



Slides presented with the kind permission of © Prof. P. Bonnabry, Head of Pharmacy, University-hospital Geneva

which one would you choose ?

Dr. Enea Martinelli, Joint recommendations for the avoidance of confusion concerning the primary packaging and labelling of several pharmaceutical dosage forms – the swiss way
3rd annual Pharma Packaging and Labelling Forum Global Conferences, Vienna 11.9.2014

250 or 500 mg per pill ?

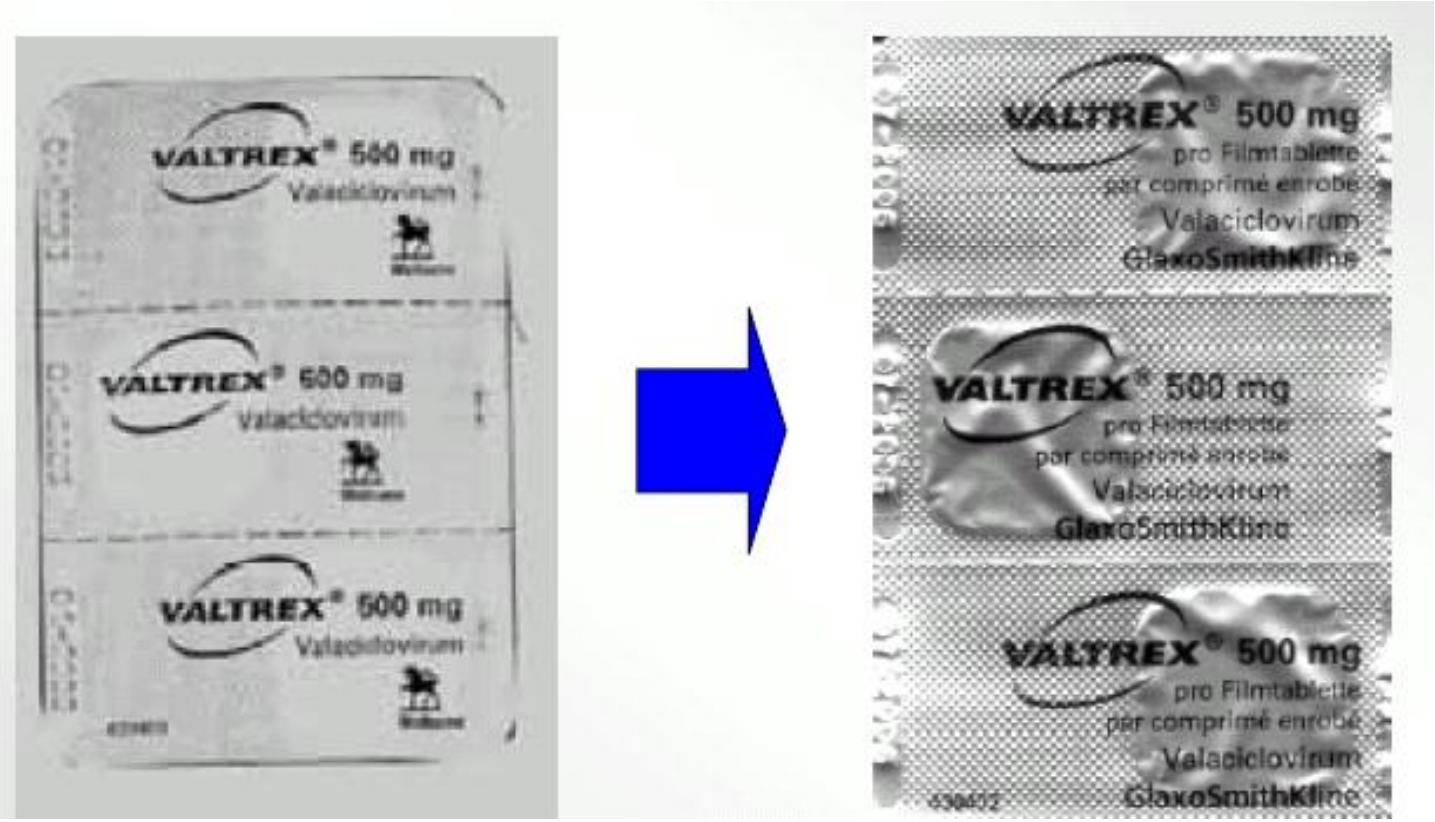
Dr. Enea Martinelli, Joint recommendations for the avoidance of confusion concerning the primary packaging and labelling of several pharmaceutical dosage forms – the swiss way
3rd annual Pharma Packaging and Labelling Forum Global Conferences, Vienna 11.9.2014

9 in 11 nurses judged that the content of one pill is 250 mg Valacyclovir.

In fact it‘s 500 mg per pill .....

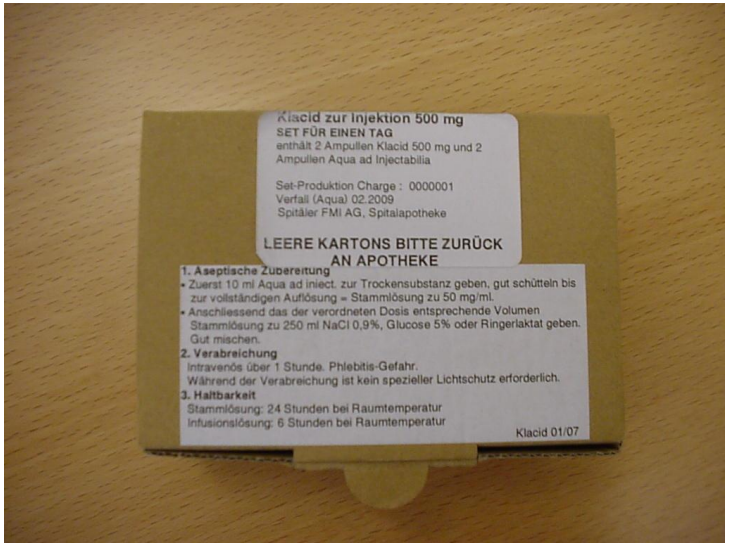
Guchelaar HJ, Kalmeijer MD, Jansen ME. Medication error due to ambiguous labelling of a commercial product Pharm World Sci. 2004 Feb;26(1):10-1.

the easy solution



Multiple step preparation

„dilute in x ml Aqua, mix the solution with normal saline“



95% of all dilutions are made by normal saline.
Find easy solutions for the exceptions !

Actions and achievements

- Working group „look alike – sound alike“ :

Interpharma, Intergenerika, SGCI, VIPS, ASSGP, GSASA

- Worked first on parenterals -> Adopted in 2010

- Guidelines on look alike and sound alike were definitively adopted in November 2012.

- Guidelines are published on :
  http://www.en.scienceindustries.ch/involvement/recommendations-for-pharmaceuticals

ASSGP Intergenerika interpharmaph scienceINDUSTRIES SWITZERLAND vips

Stiftung für Patientensicherheit
Fondation pour la Sécurité des Patients
Fondazione per la Sicurezza dei Pazienti
Patient Safety Foundation

GSASA
Verein Schweizerischer Amts- und Spitalapotheker
Association suisse des pharmaciens de l'administration et des hôpitaux
Swiss Association of Public Health Administration and Hospital Pharmacists

Joint recommendations[1]

for the avoidance of confusion concerning the primary packaging and labelling of *solid* pharmaceutical dosage forms

Companies in the pharmaceutical industry will endeavour, in so far as this is technically feasible and compatible with the internationally standardized regulatory framework[2], to improve the labelling and identification of individual blister pack cavities on the basis of the following recommendations:

Improvements of the primary packaging and its labelling

Graduated based on safety aspects and importance	*Objectives*
1. Primary packaging of pharmaceuticals in blisters (instead of bulk, i.e. open in cans, bottles etc.), if at all possible with perforations between the individual blister cavities	Safety
2. Labelling of the individual blister cavities (readable by the human eye) with • Brand name • active pharmaceutical ingredient (INN / DCI) • dosage Sans serif characters are recommended, min. character height 1.4 mm.	Safety
3. Labelling of individual blister cavities (readable by the human eye), additionally to the preceding with: • expiry date and batch number (EXP/LOT) • [Optional: indication of the manufacturer name]	Safety, traceability
4. Labelling of individual blister cavities (readable electronically), additionally to the preceding with: • data matrix with Global Trade Item Number (GTIN)[3]	Safety, traceability
5. Labelling of individual blister cavities (electronically readable), additionally to the preceding with: • data matrix with GTIN, plus expiry date and batch number (EXP/LOT)	Safety, traceability

Dr. E
prima
3rd a

ASSGP Intergenerika interpharma ph scienceINDUSTRIES SWITZERLAND vips VEREINIGUNG PHARMAFIRMEN IN DER SCHWEIZ ASSOCIATION DES ENTREPRISES PHARMACEUTIQUES EN SUISSE

STIFTUNG FÜR PATIENTENSICHERHEIT
FONDATION POUR LA SÉCURITÉ DES PATIENTS
FONDAZIONE PER LA SICUREZZA DEI PAZIENTI
PATIENT SAFETY FOUNDATION

GSASA Verein Schweizerischer Amts- und Spitalapotheker
Association suisse des pharmaciens de l'administration et des hôpitaux
Associazione svizzera dei farmacisti dell'amministrazione e degli ospedali
Swiss Association of Public Health Administration and Hospital Pharmacists

Joint recommendations[1]

for the avoidance of confusion affecting the primary package and labelling of *liquid* pharmaceutical dosage forms

Companies in the pharmaceutical industry will endeavour, in so far as this is technically feasible and compatible with the internationally standardized regulatory framework, to improve the primary packaging and labelling of liquid forms of pharmaceuticals on the basis of the following recommendations:

4. *Non-essential information in the hospital context:*
(AMZV Annex 1: Point 1 Para. 1 Letter h)

The warning statement to keep medicines out of reach of children and the instruction to observe the information given in the patient information leaflet are essentially superfluous for parenteral preparations used in hospitals. As a general rule, these particulars may be omitted in favour of information relevant to safety following the above Priorities 1 to 3, provided that the corresponding comments appear on the secondary packaging[8].

B. Design appearance of the label

- ***Imprint:*** The particulars should not be printed on the container itself. The contrast between the label background and the print colour should make it easy to read.
- ***Font size:*** The text should be printed in a font size of at least 1.4 mm and in a "sans serif" font (e.g. "Arial"). "Times New Roman" and similar fonts in particular should not be used.
- ***Text alignement:*** It should not be necessary to turn the container to be able to read all the particulars on one line of the label at a glance. Basically, we recommend that the text be printed parallel to the longitudinal axis of the container. Printing at right angles to this axis should be chosen only if the container is large enough.
- ***"Tall Man Letters":*** To make a clearer distinction between different active pharmaceutical ingredients whose names are similar in appearance and sound, we recommend printing the distinguishing elements of the words in "Tall Man Letters"[9]. – *Example:* DOPamine / DOBUTamine.
- ***Colours:*** Where colours are used on the label, they should serve primarily to distinguish between active pharmaceutical ingredients and dosages. Their use to differentiate between therapeutic groups within the product range of one company should be avoided to prevent the risk of confusion.

  Colour codes (e.g. for individual groups of high-alert drugs) should be guided by the principles of any ISO standards in existence (e.g. for anaesthetics[10]).

ASSGP Intergenerika interpharma ph scienceINDUSTRIES SWITZERLAND vips VEREINIGUNG PHARMAFIRMEN IN DER SCHWEIZ ASSOCIATION DES ENTREPRISES PHARMACEUTIQUES EN SUISSE

STIFTUNG FÜR PATIENTENSICHERHEIT
FONDATION POUR LA SÉCURITÉ DES PATIENTS
FONDAZIONE PER LA SICUREZZA DEI PAZIENTI
PATIENT SAFETY FOUNDATION

GSASA Verein Schweizerischer Amts- und Spitalapotheker
Association suisse des pharmaciens de l'administration et des hôpitaux
Associazione svizzera dei farmacisti dell'amministrazione e degli ospedali
Swiss Association of Public Health Administration and Hospital Pharmacists

Joint recommendations[1]

for the avoidance of confusion caused by pharmaceutical packaging and labelling which look similar ("look alike")

Companies in the pharmaceutical industry will endeavour, in so far as this is technically feasible and compatible with the internationally standardized regulatory framework, to improve the packaging and labelling of their pharmaceutical products so as to avoid confusion caused by pharmaceutical packages and labels which look similar ("look alike"), on the basis of the following recommendations.

Secondary packaging:
Presentation of the information relevant to safe differentiation upon administration[2]

Information element	on 3 sides	on 1 side	Solid forms (Orals)[3]	Liquid forms (Parenterals)*
Brand name	☑		☑	☑
INN	☑		☑	☑
Dosage form	☑		☑	☑
Total quantity of active substance[4]	☑		☑	☑
Total volume of active substance[5]	☑			☑
Concentration[6]	☑			☑
Possible administration routes	☑			☑
Quantity of content (number of units)		☑	☑	☑
Medically essential information		☑	☑	☑
Storage instructions		☑	☑	☑
Period for allowed use after opening		☑	☑	☑
Children's Warning statement		☑	☑	☑
Reference to package insert		☑	☑	☑
Manufacturer / Marketing Authorisation Holder		☑	☑	☑
Exp. / Lot		☑	☑	☑
Marketing authorization number		☑	☑	☑
Machine-readable code		☑	☑	☑

ASSGP Intergenerika interpharma ph scienceINDUSTRIES SWITZERLAND vips VEREINIGUNG PHARMAFIRMEN IN DER SCHWEIZ ASSOCIATION DES ENTREPRISES PHARMACEUTIQUES EN SUISSE

STIFTUNG FÜR PATIENTENSICHERHEIT
FONDATION POUR LA SÉCURITÉ DES PATIENTS
FONDAZIONE PER LA SICUREZZA DEI PAZIENTI
PATIENT SAFETY FOUNDATION

GSASA Verein Schweizerischer Amts- und Spitalapotheker
Association suisse des pharmaciens de l'administration et des hôpitaux
Associazione svizzera dei farmacisti dell'amministrazione e degli ospedali
Swiss Association of Public Health Administration and Hospital Pharmacists

Joint recommendations[1]

for the avoidance of confusion caused by *similar sounding* designations of pharmaceuticals ("sound alike")

Companies in the pharmaceutical industry will endeavour, in so far as this is technically feasible and compatible with the internationally standardized regulatory framework, to improve the packaging and labelling of their pharmaceutical products so as to avoid confusion caused by similar sounding pharmaceutical packages and labels ("sound alike"), on the basis of the following recommendations.

The "*Guideline on package design to prevent labelling errors*" (Editor: UK National Patient Safety Agency, NPSA)[2] has proved expedient and practical as a basis.

C *Recommendations concerning the procedure for practical implementation*

Improvement steps, differentiated according to the degree of possible confusion of brand names and the information on the secondary package:

Avoiding confusions of brand names or active pharmaceutical ingredient designation forming part of brands	*Avoidance of confusion based on the information given on the outer package (secondary package)*
Primary: New pharmaceutical product Use of the algorithm (by companies and Swissmedic) to exclude confusion of brand names with other brand and active pharmaceutical ingredient names.	**Differentiate dosage indications** Font size, colour code and other suitable differentiation measures as part of the corporate design concept to distinguish between dosages.
Subsidiary: Pharmaceuticals already licensed Use of Tall Man Letters, especially for INN / DCI (including generic brand names). Example: DOPamine / DOBUTamine.	**Font size of dosage indication** At least equivalent to that of the brand designation.
	Arrangement for assured differentiation of information relevant to administration (pursuant to AMZV Annex 1 and the table in the Joint recommendations for the avoidance of confusion caused by pharmaceutical packaging and labelling which look similar, "look alike" of August 2012) On each of three sides of the package not facing one another as part of the corporate design concept to differentiate between dosages.
	GS1 Datamatrix and barcode Must not appear on the same side of the package.
	Individual dosing information Allow sufficient space on the package.
	Font size for indication of quantity of tablets, ampoules etc. in the package Clear differentiation from the dosage indication (as a rule use smaller type).

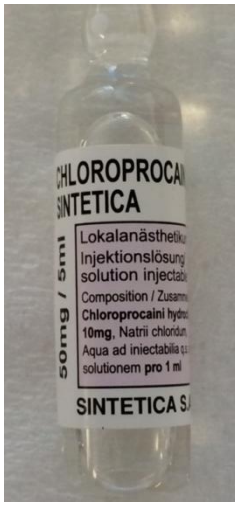
August 2012

Dr. Enea Marti
primary packa
3rd annual Pha

the ideal packaging

Dr. Enea Martinelli, Joint recommendations for the avoidance of confusion concerning the primary packaging and labelling of several pharmaceutical dosage forms – the swiss way
3rd annual Pharma Packaging and Labelling Forum Global Conferences, Vienna 11.9.2014

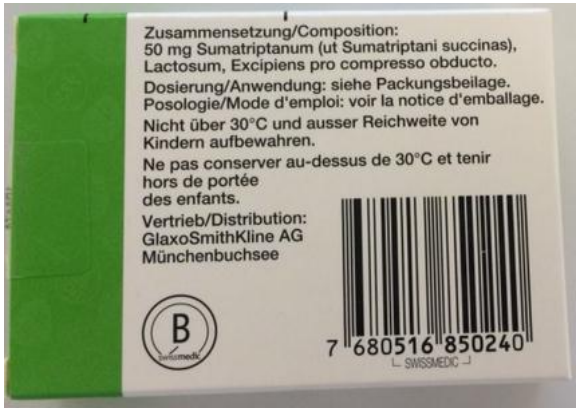
before



after

Dr. Enea Martinelli, Joint recommendations for the avoidance of confusion concerning the primary packaging and labelling of several pharmaceutical dosage forms – the swiss way
3rd annual Pharma Packaging and Labelling Forum Global Conferences, Vienna 11.9.2014

before



after

Dr. Enea Martinelli, Joint recommendations for the avoidance of confusion concerning the primary packaging and labelling of several pharmaceutical dosage forms – the swiss way
3rd annual Pharma Packaging and Labelling Forum Global Conferences, Vienna 11.9.2014

House of horrors.....

Dr. Enea Martinelli, Joint recommendations for the avoidance of confusion concerning the primary packaging and labelling of several pharmaceutical dosage forms – the swiss way
3rd annual Pharma Packaging and Labelling Forum Global Conferences, Vienna 11.9.2014

Conclusions

- Packaging is one of the risk factors in the medication process not only in hopsitals, but everywhere where a third party is prepearing medications for patients.
  -> hospitals, homes, home care

- With a good packaging concept many errors can be prevented

- Your good ideas may be good, but also may bring new risks

- Ask the professionals in the medication use process BEFORE you launch a medication.

Thank you for your attention !

interlaken
Schweiz · Switzerland · Suisse