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Medication Safety in Hospital Pharmacy

FIP 2015, Düsseldorf, Germany



Agenda

- Structure and Organisation
 - Supply of drugs into German hospitals
- Safety issues
 - Purchase for safety, supply for safety
 - Drug shortages
 - Hospital pharmacy: Measurements and actions to provide drug safety in hospital patients
 - Current actions in the field of drug safety

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Conflict of Interest Declaration

- In 2014/2015 THT received honorarium for presentations and advisory board meetings from
 - Basilea, Roche, Cogora, SANA, Limbach, ICON, Otsuka, Novartis, Sanofi, B.Braun, BioQuiddity

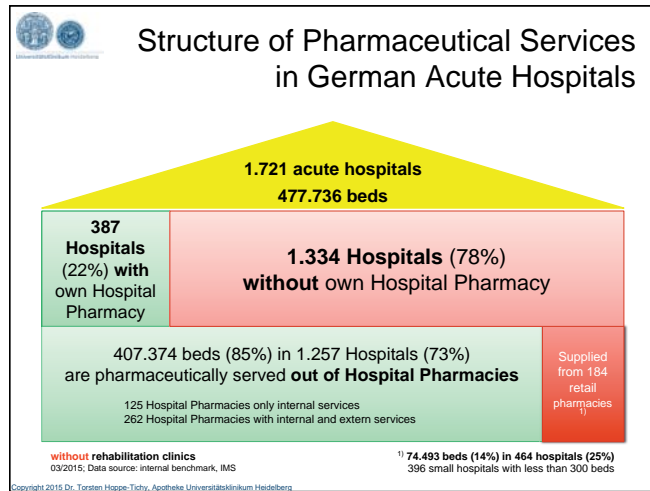
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- Structure and Organisation
 - Supply of drugs into German hospitals
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 - Hospital pharmacy: Measurements and actions to provide drug safety in hospital patients
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- One open question („→ *health economics*“)

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Drug Safety Issues

- Formulary decisions
 - efficacy
 - in clinical studies, literature
 - safety
 - adverse events rate, interaction profile, safety issues regarding drug preparation, staff safety, risk for mix-ups,
 - pharmacoeconomics

New safety issues:
drug shortages, counterfeit drugs, pricing of drugs (?)

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- ### Germany: Who brings the Drugs to the Hospital?
- Summary
 - A hospital can run an own hospital pharmacy
 - A hospital can be supplied by another hospital pharmacy by contract
 - A hospital can be supplied by a retail pharmacy by contract
 - Ward stock system in most hospitals
 - Unit-dose-system only in few hospital pharmacies
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The Problem of Drug Shortages

- Pharmaceutical industry is not legally forced to announce drug shortages
- The legal basic for stockpiling by pharmaceutical industry does not respect hospital pharmacy consumption numbers
 - i.v.-drugs (!)
- There is not even an announcement process for hospital pharmacies in place

Medicines shortages in European hospitals

- 99% of hospital pharmacists report experiencing problems with medicines shortages in the past year
- 63% of hospital pharmacists report that medicines shortages are a weekly, sometimes daily, occurrence
- 77% of hospital pharmacists report that medicines shortages have become worse over the past year

Survey by the European Association of Hospital Pharmacists on medicines shortages, September 2013-February 2014

2015 examples:
ampicillin/sulbactam,
flucloxacillin, melphalan,
... ..

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Purchase for Safety

- Avoid drug shortages
 - BUT HOW?
 - Price negotiations vs. budgetary constraints
 - Contracting with fees, penalties if no supply: But will this help the patient?
 - Choosing the right supplier: But do we know who will have no shortage?
- Avoid mix-ups of drugs
 - look-alike, sound-alike
- Avoid errors in usage
 - iv, ith, sc, dosages, calculations (concentration) ...
 - ...

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Purchase for Safety

- The problem of look-alike drug packages

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Purchase for Safety: Counterfeit Drugs

- Problem used to be a problem of third-world countries
- But higher ROI than dealing in illicit drugs
- Buying drugs or raw substances for drug production in certain countries may be risky

Kurzmitteilungen

Stippen-Präparat: Falscher in Wasser auflöslicher Arzneistoff

Am 12. September 2015 wurde ein Stippen-Präparat (Kapselchen) in der Apotheke Universitätsklinikum Heidelberg als Original eingekauft. Bei der Prüfung wurde festgestellt, dass es sich um ein Fälschprodukt handelt. Die Verpackung ist identisch mit der des Originals, jedoch enthält das Präparat einen anderen Wirkstoff. Die Fälschung ist als 'Stippen-Präparat' bezeichnet. Die Fälschung ist als 'Stippen-Präparat' bezeichnet. Die Fälschung ist als 'Stippen-Präparat' bezeichnet.

• FDA Warns About Prescription Tablets (JANUARY)
 • FDA Warns Consumers about Counterfeit AD (JANUARY)
 • Internal Pharmacy Sold Counterfeit Vials, Misbranded Drugs
 • Belgian Citizen Sentenced for Selling Counterfeit, Misbranded Drugs
 • Chinese National Sentenced to Federal Prison for Trafficking Counterfeit Pharmaceutical Weight Loss Drug
 • Two Arrested for Illegally Trafficking Counterfeit Weight Loss Medication

[View News and Alerts](#)

Other Counterfeit Products

• FDA warns about counterfeit Extended-release supplements (MARCH)
 • FDA Issues Warning on Counterfeit Surgical Mesh (MARCH)
 • FDA Issues its National Alert on Counterfeit One Touch Blood Glucose Test Strips (MARCH)

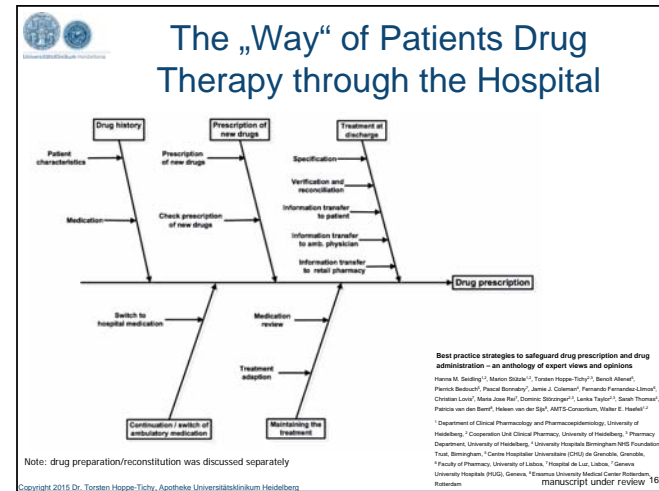
Consumer Information

• The Possible Dangers of Buying Medicines over the Internet
 • Questions and Answers about Counterfeit Drugs
 • Educational Resources: Counterfeit Medicines

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MORGEN MITTAG ABEND NACHT

look-alike problems in pharmacy shelf and on the ward level



Single Dose Package

ADKA requirements for single dose packages

- Compatibility of the content against environmental influences
- Compatibility with the content
- Free weight
- Measurement-friendly in regard to production and disposal
- Additional labeling needs to be possible and easy

Size and form

- Single dose packs for single application in a standardized size, comparable to sachet packs, size for example 3x10x3 cm or in other packs optimized into single dose
- At least one side transparent
- Easy to open
- Drug should be made to be use via further handling necessary
- Open packs to easily apply labels with patient name (max. 10x3 cm)
- Availability of further packaging for automatic dispensing systems

Information on the primary packs

- Easy to read (character, font)
- Health name
- Name of the manufacturer
- Manufacturer's name of the drug and strength per single dose in legible position for each
- Enough of dose in mg for each single dosage form, in case of liquid the additional information "in a ml" (in 100 amount of liquid)
- Storage form
- Valid administration dosage instructions
- Expiry date (approximate and exact)
- Batch number (approximate and exact)
- EU/US code (approximate and exact)

Information on secondary packaging

- Use primary packaging in case
- Usable to replace the lid of the box
- Labeling according to the box
- Expiry date (approximate and exact)
- Batch number (approximate and exact)
- EU/US code (approximate and exact)
- Labeling from barcodes of the batch number

Pharmacy Practice

German Society of Hospital Pharmacists (ADKA) initiative: single unit drug packs

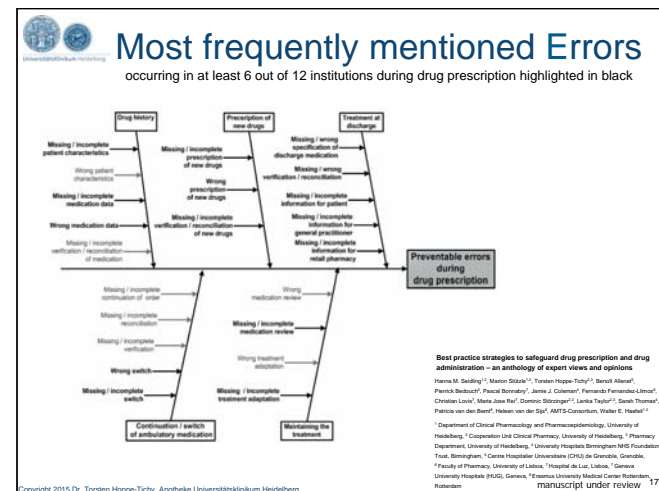
European Association of Hospital Pharmacists

EAHP: essential for the protection of patient's interests

To improve patients safety in drug therapy and to ensure the highest quality in medical treatment in European hospitals, the General Assembly of the European Association of Hospital Pharmacists (EAHP) demands:

- the production of single dose packed drugs from the pharmaceutical industry
- the mandatory inclusion of a barcode on each single dose.

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Error-Prevention Approaches

Projects

- not only BPMH but also Medication Reconciliation in the same step
- time consuming
- WHO-High-5s-study in GER: MedRec only successful when hospital pharmacy on board
- switch to formulary drugs: qualification needed even if IT in background

Best practice strategies to safeguard drug prescription and drug administration – an anthology of expert views and opinions
 Hanna M. Sieding¹, Marco Stizza², Torsten Hoppe-Tichy³, Berndt Albrecht⁴, Patrick Bedouch⁵, Pascal Bonnyard⁶, James J. Colomer⁷, Fernando Fernandez-Linera⁸, Christian Lovat⁹, Maria Jose Ruf¹⁰, Dominic Störzinger¹¹, Lenka Taylor¹², Sarah Thomas¹³, Patricia van den Bergh¹⁴, Heleen van der Spijl¹⁵, AMTS-Consortium, Walter E. Haefliger¹⁶

¹ Department of Clinical Pharmacology and Pharmacoepidemiology, University of Heidelberg, ² Cooperation Unit Clinical Pharmacy, University of Heidelberg, ³ Pharmacy Department, University of Heidelberg, ⁴ University Hospitals Birmingham NHS Foundation Trust, Birmingham, ⁵ Centre Hospitalier Universitaire CHU de Grenoble, Grenoble, ⁶ Faculty of Pharmacy, University of Liège, ⁷ Hospital de Luz, Lisbon, ⁸ Geneva University Hospitals (HUG), Geneva, ⁹ Erasmus University Medical Center Rotterdam, Rotterdam

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Most frequently mentioned Errors

occurring in at least 6 out of 12 institutions during drug prescription highlighted in black

Preventable errors during drug prescription

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Errors in Switching Patients Drug Therapy

data from ADKAs anonymous medication error reporting system (DokuCIRS)

- Background: electronic drug information system in place but wrong use
 - switch of budesonid for inhalation (COPD) to budesonid tablets/capsules (M. Crohn)
 - prescription of cyclokaprone per os instead of cyclosporine (Sandimmun® intolerance, kidney transplantation)
 - switch of an unknown product of a generic company to candesartan in the highest dosage of same company (no indication)
- ward pharmacists corrected errors
- electronic ordering software called attention to wrong prescription
- reasons for errors: lack of knowledge

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Error-Prevention Approaches

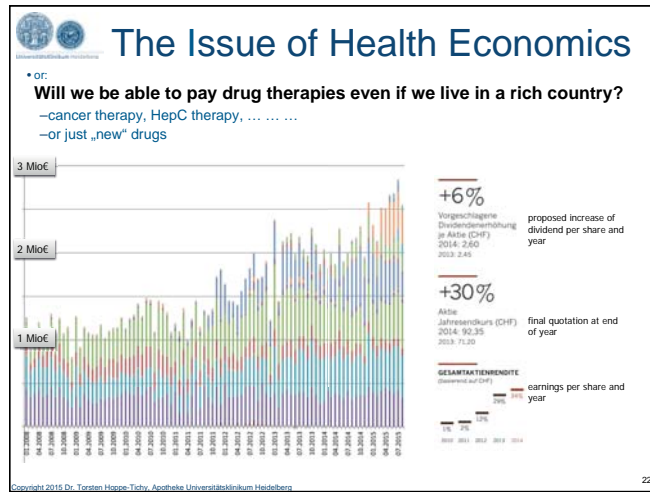
New legislation in 2016

- patients rights
- information on medication at discharge is mandatory
- medication plan has to be given to the patients at discharge
- IT, barcode

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- ### Summary
- There are numerous approaches to improve patient safety through drug safety in hospitals with positive results but mostly only on a local level and in certain local projects
 - Projects suffer from differences in
 - local situations like supply chain, staffing or IT environment
 - monetary constraints
 - recognizing the positive role of a hospital pharmacy or of hospital pharmacists
 - and from missing legal regulations
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