Action Plan for Medication Safety
2013-2015

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Action Plans for Medication Safety

  – 49 measures

• 2nd Action Plan for Medication Safety 2010-2012
  – 59 measures

  – 39 measures
Overall Goal - Relevance

• About 5% of all hospital admissions are based on adverse drug events (Lazarou et al, 1998)

• For Germany it is assumed that about 5% of all hospital admissions come from adverse drug events, approximately 25% of those are considered avoidable (Schneeweiss et al, 2001; Dormann et al, 2003)

• Goal: Reduction / avoidance of medication errors to prevent harm from patients
Definitions of Medication error

Medication errors are unintentional errors in the prescribing, dispensing, administration or monitoring of a medicine while under the control of a healthcare professional, patient or consumer.
(EMA Proposal, GVP annex I – Definitions, 2/2012)

A failure in the drug treatment process, whether through omission or commission, that leads to, or has the potential to lead to, harm to the patient.
(Aronson, Ferner: EMA Workshop 3/2013)
Medication process

- Drug history including self-medication
- Prescription/ordinance
- Information of the patient
- Distribution/delivery
- Application
- Documentation
- Therapy monitoring/medication reconciliation
- Communication/coordination - evaluation of results
Errors in the medication process

![Bar chart showing errors in medication process stages]

**Fig 1.** Percent of all errors by stage in the medication use process in adult patients (blue) and pediatric patients (gold).

*Walsh et al. (2009). Journal of clinical oncology 27; 891-896*
Medication errors are errors in the process of medication order distribution, application, transcription, and support of the hospital information system.

- Prescriber knows about co-medication?
- Support of the hospital information system?
- Patient knows or understands his medication?
- Risk minimization (colours, connectors)

Reason, BMJ 2000;320:768–70
Action Plan of the BMG for Medication Safety

The coordination group controls the Action Plan and advises the Federal Ministry of Health

Formation:
- Federal Ministry of Health (BMG), 2 participants
- The Drug Commission of the German Medical Association (DCGMA), 3 medical doctors
- The German Society of Hospital Pharmacists, Federal Union of German Associations of Pharmacists (ADKA, ABDA), 2 pharmacists
- Patient representatives, 2 participants
- Aktionsbündnis Patientensicherheit (APS), 1 participant
- Deutscher Pflegerat, 2 participants
Priorities of the Action plan for Medication Safety

1. Patient awareness
2. Improving information on medicines
3. Improving intersectoral/interprofessional communication
4. Using technical support for Medication safety
5. Medication safety research
Involvement of patients in the drug therapy safety management

• What contribution can the patient afford for safe drug therapy?
• What messages need to be conveyed?
• What is feasible in everyday life?

-> active role of the patient!
Drug therapy during pregnancy and lactation

Public funding of the database

Pharmacovigilance and consultation center for embryonic toxicology
Charité - University Berlin


Indikation: Bakterielle Infektionen

Erfahrungen in der Schwangerschaft

Erfahrungsumfang: HGCH


2.-3. Trimenon / Perinatal: Bisherige Beobachtungen sprechen gegen ein fetotoxisches Risiko.

Empfehlungen zur Schwangerschaft

Planung einer Therapie oder Planung einer Schwangerschaft unter Therapie: Norfloxacin ist ein...
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High-alert medications

• Drugs that bear a heightened risk of causing significant patient harm when used in error.

• Although mistakes may or may not be more common with these drugs, the consequences of an error are clearly more devastating to patients.
Recommendations for the Use of High-Alert Medications

- Vincristine
- MTX

...to be continued..
Example Vincristine
Approaches to Minimize Errors

• No small-volume solutions
  (Use minibags with a volume of 50 ml, for children <20 ml)

• Contrasting striking label

• Positively worded warnings
  (vincristine - for intravenous application only)
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Medication List

- information tool
- should be complete and correct
- should provide information for patient, physician, pharmacist, health care giver
- should be under control of the patient (paper based)
- should be handled electronically by health care providers
- should be updated/completed by all physicians as well as pharmacists
# German Medication list

**Medikationsplan**

<table>
<thead>
<tr>
<th>Wirkstoff</th>
<th>Handelsname</th>
<th>Stärke</th>
<th>Form</th>
<th>Mo</th>
<th>Mi</th>
<th>Ab</th>
<th>ZN</th>
<th>Einheit</th>
<th>Hinweise</th>
<th>Grund</th>
</tr>
</thead>
<tbody>
<tr>
<td>Metoprololsuccinat</td>
<td>Metoprololsuccinat 1A Pharma® 95 mg retard</td>
<td>95 mg</td>
<td>TAB</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>Stck</td>
<td>Mit 1 Glas Wasser</td>
<td>Herz/Blutdruck</td>
</tr>
<tr>
<td>Ramipril</td>
<td>Ramipril-ratiopharm®</td>
<td>5 mg</td>
<td>TAB</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>Stck</td>
<td>Mit ausreichend Flüssigkeit</td>
<td>Blutdruck</td>
</tr>
<tr>
<td>Clopidogrel</td>
<td>Clopidogrel Zentiva®</td>
<td>75 mg</td>
<td>FTA</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>Stck</td>
<td></td>
<td>Herz</td>
</tr>
<tr>
<td>Pantoprazol</td>
<td>Pantoprazol dura®</td>
<td>20 mg</td>
<td>TMR</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>Stck</td>
<td>1 Stunde vor der Mahlzeit</td>
<td>Magen</td>
</tr>
<tr>
<td>Insulin aspart</td>
<td>NovoRapid® Penfill®</td>
<td>100 E/ml</td>
<td>PAT</td>
<td>20</td>
<td>0</td>
<td>20</td>
<td>0</td>
<td>I.E.</td>
<td>Wechseln der injektionsstellen, unmittelbar vor einer Mahlzeit</td>
<td>Diabetes</td>
</tr>
<tr>
<td>Simvastatin</td>
<td>Simva-Aristo®</td>
<td>40 mg</td>
<td>FTA</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>Stck</td>
<td>Mit ausreichend Flüssigkeit</td>
<td>Blutfette</td>
</tr>
<tr>
<td>Torasemid</td>
<td>Torsamid Hexal®</td>
<td>5 mg</td>
<td>TAB</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>Stck</td>
<td>Mit etwas Flüssigkeit</td>
<td>Blutdruck</td>
</tr>
</tbody>
</table>

**Zeitlich befristete Medikation**

| Clarithromycin   | Clarithromycin-TEVA®        | 250 mg | FTA | alle 12 Std. | Stck | von 1.4. bis 6.4. | Bronchitis |

**Selbstmedikation**

| Myrtol          | Gelomyrtol®                 | 120 mg | KPS | 2  | 2  | 2  | 0  | Stck    | Mind. 1/2 Stunde vor dem Essen mit einem großen Glas kaltem Wasser | Bronchitis |
| Johanniskraut   | Laif® Balance               | 900 mg | FTA | 1  | 0  | 0  | 0  | Stck    | Nach dem Frühstück                              | Stimmung       |

**Selbstmedikation bei Bedarf**

| Magnesium       | Magnesium® Verla            | 121,5 mg | BTA | bei Bedarf | Stck | Magen-Verla, stark | Wadenkrämpfe |
| Diphenhydramin-HCl | Hydroxyz® Sleep tablets, stark | 50 mg  | TAB | 0  | 0  | 0  | 1  | Stck    | b. Bed. 30 min vor dem Schlafengehen mit ausreichend Flüssigkeit | Schlafstörungen |
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Research - Medication List

• technical feasibility of 2D Barcode solution

• possibilities of correct coding of medicinal products

• practicability and acceptance of the medication list in everyday practice

• possibility of implementation in software solutions
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Research - Concept of Collection of Medication Errors in ADR Database

– Centralised Detection and Analysis of Medication Errors

• new European pharmacovigilance legislation (Directive 2010/84/EU): Definition of the term „adverse reaction“ extended:
  • „Adverse reaction: A response to a medicinal product which is noxious and unintended.“
  • transposed into national law 2012
Concept of Collection of Medication Errors as ADRs

- How many ME are reported?
- Can we use ADR reporting forms to detect errors related to medication process?
- Do we need additional information?
- How can quantity and quality of reporting be influenced?
Errors can happen in all stages in the process of care, from diagnosis, to treatment, to preventive care.

Building safety into processes of care is a more effective way to reduce errors than blaming individuals.
Thank you for your attention!

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