Hospital pharmacists as part of the Drug & Therapeutics Committee I

EAHP Academy Seminar
20 May, Belgrade – Serbia
Mag. Gunar Stemer
Vienna General Hospital, Pharmacy Department

Nothing to disclose.

Agenda for this afternoon…

Concepts & principles of D&T committees

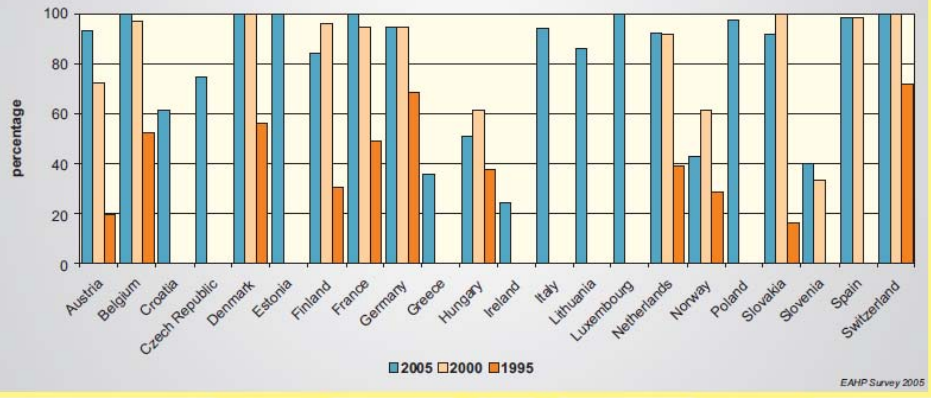
Workshop, presentation and discussion of results

Learning Objectives

- Knowledge about the **process of choosing members** of the committee
- Ability to know how to **create** and **update a formulary** or drug list according to **pharmacoeconomic** and **therapeutic principles**
- Knowledge about the **dissemination** of the results of the meetings
- Knowledge how to evaluate the **adherence** to the formulary
- Development of a local **implementation plan** for evolving pharmacy services in support of D&T committees

Drug formulary in the hospital

n_{2005}=789



1700s–1800s	First formularies introduced in the U.S. (the *Lititz Pharmacopoeia* and the *United States Pharmacopeia)*
1930s	Initial guiding principles of a formulary system introduced
1950s	Recognition of the value of formularies and P&T committees by JCAH
1960s	Requirement by JCAHO that every hospital establish its own P&T committee
1970s	Early emergence of managed care organizations and their adoption of formularies
1980s–present	Changing nature and functions of P&T committees in response to rising costs

Balu S et al. P&T 2004

Hatcher RA et al. JAMA 1933

Years	Purpose and Role
1960s	• to ensure inventory control • to maximize rational medication use
Early 1980s	• to identify preferred drugs • to evaluate the safety and efficacy of available medications • to minimize therapeutic duplication • to achieve cost savings
1990s	• to continue improving processes to ensure that safe and effective pharmaceuticals are available for an organization's patients and health plan members • to control pharmacy-related costs through aggressive contracting and utilization of control mechanisms

Drugs & Therapeutics Committee

- An advisory committee that is responsible for **developing, managing, updating,** and **administering** the drug formulary system (ASHP)
- The committee that **evaluates** the clinical **use** of medicines, develops **policies** for managing medicine use and administration, and manages the formulary system (WHO)

Drugs & Therapeutics Committee

- Decision to launch
- Selection of Committee members
- Bylaws

Duran-Garcia E et al. Int J Clin Pharm 2011

Table 4 Main characteristics of Pharmacy and Therapeutics Committees

Author	P&TC members[a]	P&TC members[b]	Pharmacist in P&TC[a]	P&TC include Pharmacist (%)	Pharmacist as P&TC secretary (%)	P&TC with subcommittees (%)	P&TC with SOP (%)
Cooke et al. [5]		6[c]	2[d]				90
Willems et al. [6]		8 (3–14)		95.6		10.2	
Pedersen et al. [8]						95.2	
Mannebach et al. [9]	19.3[d]		3.2[d]		69.5		
Shalanski et al. [10]	10.7 ± 5		2.2 ± 1.3				
Fijn et al. [11]		8 (3–14)		100	95	61	
Fijn et al. [12]							89

EAHP Academy Seminar – 20 May, Belgrade
Hospital pharmacists as part of the D&T committee

Drugs & Therapeutics Committee

- **Organisational issues**
  - Regular meetings with agenda
    - VGH: 4 times p.a. legally required
  - Regular attendance needed
  - Dissemination
  - Minutes, including
    - Decisions
    - Deadlines
    - Votes
    - Comments and statements

Drugs & Therapeutics Committee

- **Guiding principles**
  - Transparent and unbiased decision-making
  - Objectivity
  - Consistency
  - Impact orientation

EAHP Academy Seminar – 20 May, Belgrade
Hospital pharmacists as part of the D&T committee

Drugs & Therapeutics Committee

Indicators

- **Process**
- **Impact**
- **Outcome**

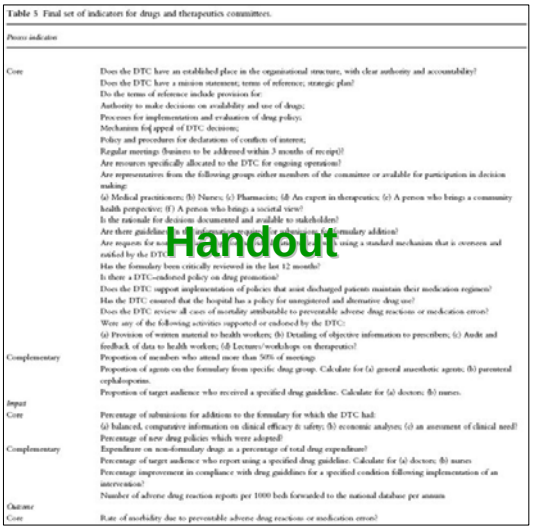


Table 3 Final set of indicators for drugs and therapeutics committees.

Process indicator	
Core	Does the DTC have an established place in the organizational structure, with clear authority and accountability?
	Does the DTC have a mission statement; terms of reference; strategic plan?
	Do the terms of reference include provision for:
	Authority to make decisions on availability and use of drugs;
	Processes for implementation and evaluation of drug policy;
	Mechanism for appeal of DTC decisions;
	Policy and procedures for declarations of conflicts of interest;
	Regular meetings (business to be addressed within 3 months of receipt)?
	Are resources specifically allocated to the DTC for ongoing operation?
	Are representatives from the following groups either members of the committee or available for participation in decision making:
	(a) Medical practitioners; (b) Nurses; (c) Pharmacists; (d) An expert in therapeutics; (e) A person who brings a community health perspective; (f) A person who brings a societal view?
	Is the rationale for decisions documented and available to stakeholders?
	Are there guidelines for [illegible] (formulary addition)?
	Are requests for non-[illegible] using a standard mechanism that is overseen and ratified by the DTC?
	Has the formulary been critically reviewed in the last 12 months?
	Is there a DTC-endorsed policy on drug promotion?
	Does the DTC support implementation of policies that assist discharged patients maintain their medication regimen?
	Has the DTC ensured that the hospital has a policy for unregistered and alternative drug use?
	Does the DTC review all cases of mortality attributable to preventable adverse drug reactions or medication errors?
	Were any of the following activities supported or endorsed by the DTC:
	(a) Provision of written material to health workers; (b) Detailing of objective information to prescribers; (c) Audit and feedback of data to health workers; (d) Lectures/workshops on therapeutics?
Complementary	Proportion of members who attend more than 50% of meetings
	Proportion of agents on the formulary from specific drug group. Calculate for (a) general anaesthetic agents; (b) parenteral cephalosporins.
	Proportion of target audience who received a specified drug guideline. Calculate for (a) doctors; (b) nurses.
Impact	
Core	Percentage of submissions for addition to the formulary for which the DTC had:
	(a) balanced, comparative information on clinical efficacy & safety; (b) economic analyses; (c) an assessment of clinical need?
	Percentage of new drug policies which were adopted?
Complementary	Expenditure on non-formulary drugs as a percentage of total drug expenditure?
	Percentage of target audience who report using a specified drug guideline. Calculate for (a) doctors; (b) nurses
	Percentage improvement in compliance with drug guidelines for a specified condition following implementation of an intervention?
	Number of adverse drug reaction reports per 1000 beds forwarded to the national database per annum
Outcome	
Core	Rate of morbidity due to preventable adverse drug reactions or medication errors?

Handout

Weekes LM et al. Br J Clin Pharmacol 1998

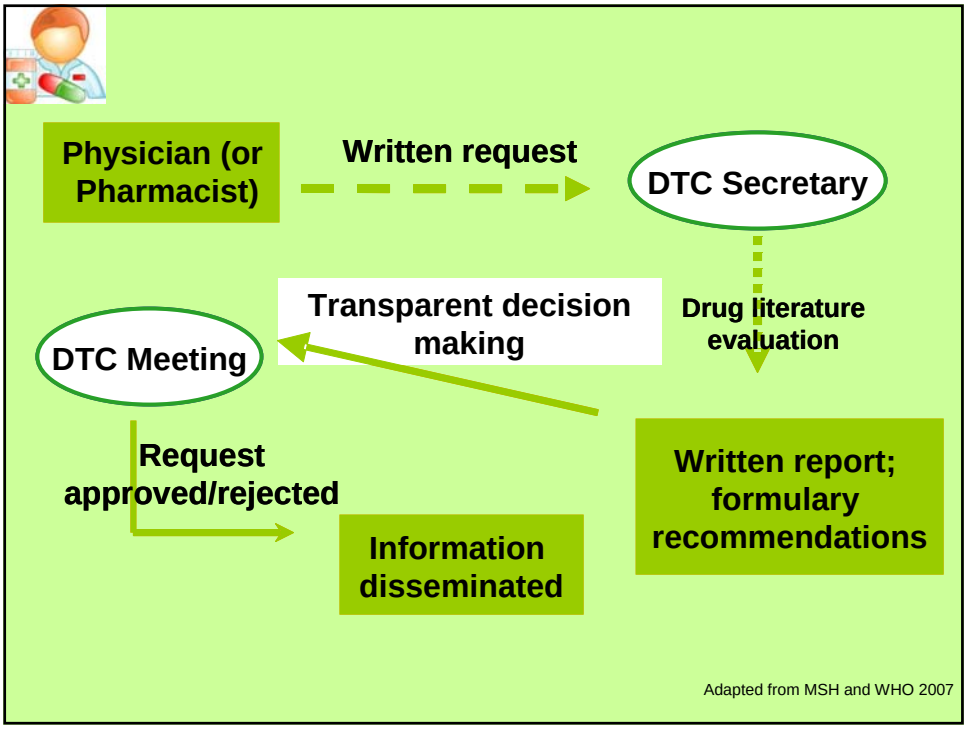
Drug formulary (system)

- A **continually updated list of medications** and related information, representing the clinical judgement of physicians, pharmacists, and other experts in the diagnosis and/or treatment of disease and promotion of health (ASHP)
- An ongoing process whereby a health care organization […] establishes **policies on the use of drug products and therapies** that are the most medically appropriate and cost effective to best serve the health interests of a given patient population (ASHP)

EAHP Academy Seminar – 20 May, Belgrade
Hospital pharmacists as part of the D&T committee

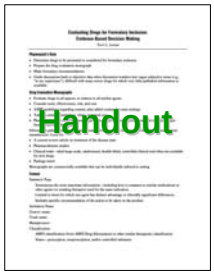
Drug formulary

- **Explicit evaluation, selection, and process criteria**
  - Efficacy
  - Safety
  - Quality
  - Cost and cost-effectiveness
  - *Update and maintenance*
- **Consistent decision-making**
  - EBM
  - Local context
  - Transparency



Drug formulary

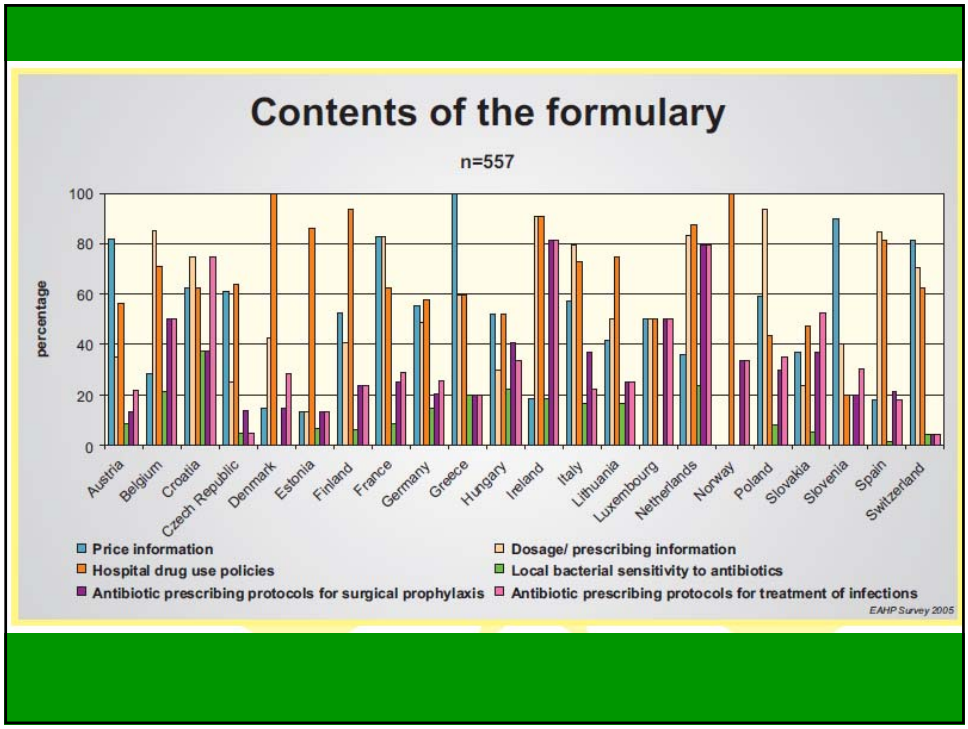
- Evidence-based evaluation
  - thorough, accurate, and unbiased review and analysis
- Types of drug reviews
  - New drug monograph
  - Reevaluations of previous formulary decisions
  - Therapeutic class reviews
  - Expedited review
- Pharmacoeconomic assessments
- Formulary exceptions



Drug formulary

- **Conduct a systematic review of therapeutic groups or classes (e.g. WHO-ATC-Code)**
  - Analysis of current situation (drug use in time period, new drugs applied, comparison, main consumer)
  - Analysis of indications drugs are used in
  - Literature/Evidence regarding unlicensed indications?
  - Request for addition to formulary necessary?
  - Analysis of changes in drug use – deletions?

EAHP Academy Seminar – 20 May, Belgrade
Hospital pharmacists as part of the D&T committee



Drug Formulary

Adherence

- Patient safety comprised due to unfamiliarity with non-formulary drugs regarding prescribing, administration, dispensing
  - Reasons: Cost- and efficacy issues
  - Assessment of adherences to formulary
    - ~90% of formulary adherence
    - CV drugs with the highest proportion of non-adherence
    - Indicator for non-adherence:
      - existing pre-admission drug therapy, propriertary drug, drug age, number of me-too drugs, restrictiveness of formulary
    - Non-adherence **not** linked to:
      - prescriber characteristics, gender, dosage form

Fijn R et al. Eur J clin Pharmacol 2001

Drug formulary system

Risk management

- Decisions only based on acquisition costs
  - ➔ clinical and economic effectiveness to consider
- Lack of systems to ensure safe and effective use of potentially problematic formulary drugs and drugs with need of special protocols
  - ➔ checklists, dose limits, preprinted orders, special packaging, special labeling, double checks, specific written guidelines, prerequisites for prescribing (e.g., pregnancy check, ECG check)

Raber JH. Pharmacotherapy 2010

Drug formulary system

Risk management

- Failure to restrict the use of problematic drugs to certain subspecialities
  - ➔ special training, specific monitoring requirements, guided-use strategies (cardiology, infectious disease)
- Failure to monitor the use of drugs
  - ➔ clinical pharmacy services

Raber JH. Pharmacotherapy 2010

The decision-making process

- Domains of importance for decisions
  - **Patient safety!!**
  - Ensure EBM practice
  - Costs
  - Adherence to legal requirements
- **Priorisation** of decisions necessary due to lack of resources
- Prediction of local **effectiveness**
  - consideration of patient care and unbiased reviews of the biomedical literature

Jenkings KN et al. Soc Science Med 2004, Tan EL et al. Pharm World Sci 2007

Table 4 Importance-urgency grid (suggested by respondent)

	High importance	Low importance
High urgency	Do NOW!	Do if have time
Low urgency	Plan and then do later	Set aside

Tan EL et al. Pharm World Sci 2007

Pharmacoeconomics

CME Clinical pharmacology

Pharmacoeconomics: principles and relevance to the activities of drug and therapeutics committees

SECTION 1
FOUNDATION ISSUES

CHAPTER 1

Pharmacoeconomics: Principles, Methods, and Applications

KEY CONCEPTS

Hughes D. Clin Med 2009; DiPiro JT et al. Pharmacotherapy: a pathophysiologic approach

The decision-making process

- Formal **rationality of science** vs. local **rationality of healthcare provision**
- Supplementary evidence
  - pharmaceutical company activities
  - clinicians‘ excitement
  - patient demand
  - pre-existing prescribing of a new drug
  - decisions of other D&T committees
  - personality of the applicant
  - prediction of the future
  - dealing with uncertanties

Jenkings KN et al. Soc Science Med 2004, Tan EL et al. Pharm World Sci 2007

The decision-making process

Outcomes

- Structure – Process – **OUTCOME**
- ECHO-Model by KOZMA
  - economic
  - clinical
  - humanistic outcomes (patient-reported outcomes)

Evaluation of the introduction of an antimicrobial drugs formulary in a general hospital in Slovenia

• Jure Peklar, Franci Tratar and Aleš Mrhar

➔ **Clinical and economic outcomes reported!**

Peklar J et al. Pharm World Sci, 2004; DiPiro JT et al.

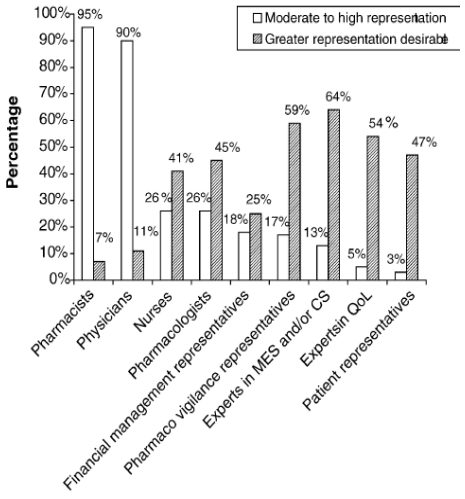


Fig. 1. Level of involvement in the decision-making process and opinion about this level of involvement. CS: clinical studies; MES: medico-economic studies; QoL: quality of life.

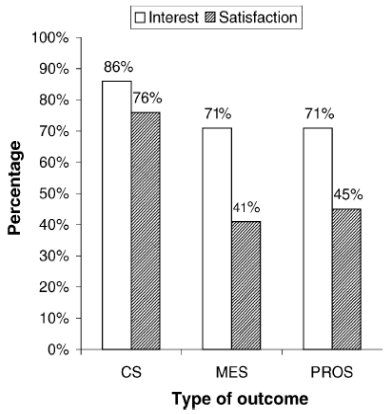


Fig. 3. Interest of the respondents in clinical studies, medico-economic studies and patient-reported outcomes studies and satisfaction with information available on these studies. CS: clinical studies; MES: medico-economic studies; PROS: patient-reported outcome studies. *Y*-axis gives the percentage of respondents having ticked the response modalities "Yes, moderately" or "Yes, very interested" for interest in the studies and "Yes, moderately" or "Yes, very satisfied" for information available on these studies.

Role of clinical, patient-reported outcome and medico-economic studies in the public hospital drug formulary decision-making process: results of a European survey. Health Policy 2005; 71:205-212

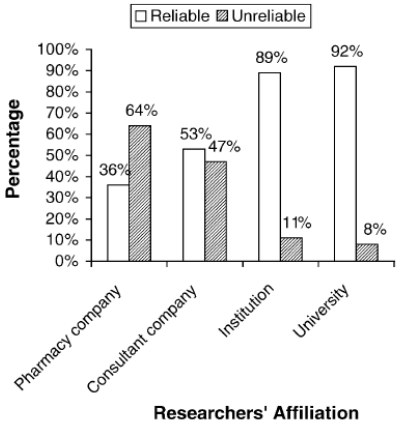


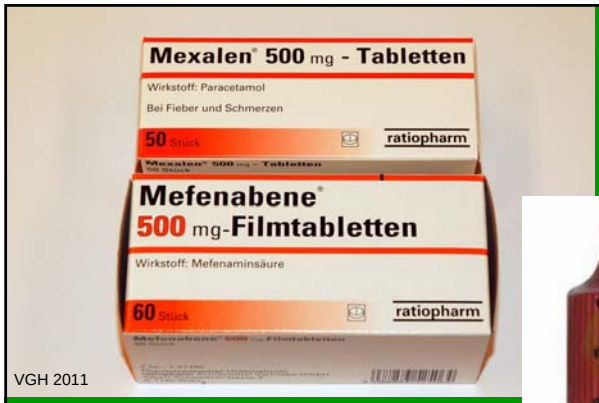
Fig. 4. Reliability of the study conclusions according to their researchers' affiliation. *Y*-axis gives the percentage of respondents having ticked the response modalities "Never" or "No, in general" and "Yes, in general" or "Yes, always" for studies issued from a pharmacy company, a consultant company, an institution (e.g. European Union, Ministry of Health) or an university.

Role of clinical, patient-reported outcome and medico-economic studies in the public hospital drug formulary decision-making process: results of a European survey. Health Policy 2005; 71:205-212

The decision-making process

Patient-Safety Issues

- Inclusion of new drugs
  - To consider: look alikes - sound alikes (LASAs), adverse effects, dosing and administration issues
- Proactive assessments of risks in medication-use process
- Review of medication-event data
  - Incl. near misses
  - Deduce recommendations for prevention
- Quality improvement projects
- Enforcement of evidence-based fail-safe techniques



VGH 2011

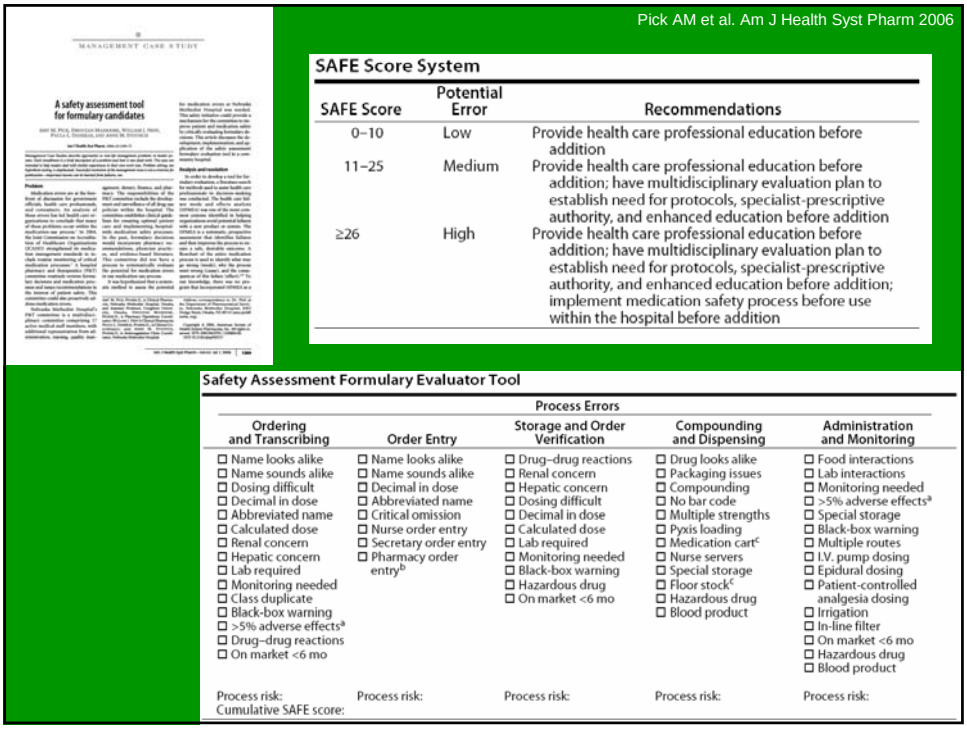
Look alike – sound alike drugs

ISMP 2008

Table 1 – Examples of confused drug name pairs in selected countries
Brand name is shown in italics—Nonproprietary name is shown in bold

Country	*Brand name* (Nonproprietary name)	*Brand name* (Nonproprietary name)
Australia	*Avanza* (**mirtazapine**)	*Avandia* (**rosiglitazone**)
	Losec (**omeprazole**)	*Lasix* (**frusemide**)
Brazil	*Losec* (**omeprazol**)	*Lasix* (**furosemida**)
	Quelicin (**succinilcolina**)	*Keflin* (**cefalotina**)
Canada	*Celebrex* (**celecoxib**)	*Cerebyx* (**fosphenytoin**)
	Losec (**omeprazole**)	*Lasix* (**furosemide**)
France	**fluoxétine**	*Fluvoxamine*
	Reminyl (**galantamine hydrobromide**)	*Amarel* (**glimepiride**)
Ireland	*Losec* (**omeprazole**)	*Lasix* (**furosemide**)
	morphine	**hydromorphone**
Italy	*Diamox* (**acetazolamide**)	*Zimox* (**amoxicillina triidrato**)
	Flomax (**morniflumato**)	*Volmax* (**salbutamolo solfato**)
Japan	*Almarl* (**arotinolol**)	*Amaryl* (**glimepiride**)
	Taxotere (**docetaxel**)	*Taxol* (**paclitaxel**)
Spain	*Dianben* (**metformin**)	*Diovan* (**valsartan**)
	Ecazide (**captopril/hydrochlorothiazide**)	*Eskazine* (**trifluoperazine**)
Sweden	*Avastin* (**bvacizumab**)	*Avaxim* (**hepatitis A vaccine**)
	Lantus (**insulin glargine**)	*Lanvis* (**toguanine**)

JCI, WHO. Patient Safety Solution 2007



MANAGEMENT CASE STUDY

A safety assessment tool for formulary candidates

Pick AM et al. Am J Health Syst Pharm 2006

SAFE Score System

SAFE Score	Potential Error	Recommendations
0–10	Low	Provide health care professional education before addition
11–25	Medium	Provide health care professional education before addition; have multidisciplinary evaluation plan to establish need for protocols, specialist-prescriptive authority, and enhanced education before addition
≥26	High	Provide health care professional education before addition; have multidisciplinary evaluation plan to establish need for protocols, specialist-prescriptive authority, and enhanced education before addition; implement medication safety process before use within the hospital before addition

Safety Assessment Formulary Evaluator Tool

Process Errors				
Ordering and Transcribing	Order Entry	Storage and Order Verification	Compounding and Dispensing	Administration and Monitoring
☐ Name looks alike	☐ Name looks alike	☐ Drug–drug reactions	☐ Drug looks alike	☐ Food interactions
☐ Name sounds alike	☐ Name sounds alike	☐ Renal concern	☐ Packaging issues	☐ Lab interactions
☐ Dosing difficult	☐ Decimal in dose	☐ Hepatic concern	☐ Compounding	☐ Monitoring needed
☐ Decimal in dose	☐ Abbreviated name	☐ Dosing difficult	☐ No bar code	☐ >5% adverse effects[a]
☐ Abbreviated name	☐ Critical omission	☐ Decimal in dose	☐ Multiple strengths	☐ Special storage
☐ Calculated dose	☐ Nurse order entry	☐ Calculated dose	☐ Pyxis loading	☐ Black-box warning
☐ Renal concern	☐ Secretary order entry	☐ Lab required	☐ Medication cart[c]	☐ Multiple routes
☐ Hepatic concern	☐ Pharmacy order entry[b]	☐ Monitoring needed	☐ Nurse servers	☐ I.V. pump dosing
☐ Lab required		☐ Black-box warning	☐ Special storage	☐ Epidural dosing
☐ Monitoring needed		☐ Hazardous drug	☐ Floor stock[c]	☐ Patient-controlled analgesia dosing
☐ Class duplicate		☐ On market <6 mo	☐ Hazardous drug	☐ Irrigation
☐ Black-box warning			☐ Blood product	☐ In-line filter
☐ >5% adverse effects[a]				☐ On market <6 mo
☐ Drug–drug reactions				☐ Hazardous drug
☐ On market <6 mo				☐ Blood product
Process risk:	Process risk:	Process risk:	Process risk:	Process risk:
Cumulative SAFE score:				

Medicine Use Problems

- Pharmaceutical procurement and availability
- Pharmaceutical distribution
- Medicine prescribing
- Administration and use
- ADR reports
- Medication error reports
- Antimicrobial resistance surveillance reports
- Drug use evaluation (DUE)

Learning Objectives – **Wrap up**

- Knowledge about the **process of choosing members** of the committee
- Ability to know how to **create** and **update a formulary** or drug list according to **pharmacoeconomic** and **therapeutic principles**
- Knowledge about the **dissemination** of the results of the meetings
- Knowledge how to evaluate the **adherence** to the formulary
- Development of a local **implementation plan** for evolving pharmacy services in support of D&T committees