



5th PCNE Working Conference 21 – 24 February 2007

PCNE quality standards in systematic medication review

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Workshop structure first day



- Presentation of the participants
- Presentation of current models (UK, USA, Australia)
 of conducting systematic medication reviews (SMR)
- Participants' experiences
- Defining objectives for the workshop
- Presentation of a German model

Workshop participants



Beckins	Jennie
de Smit	Denhard
De Wulf	Isabelle
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Heeres	Leendert
Larsen	Anna Bira
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van Mil	Foppe J.W.
van Tongelen	Inge
Verheyen	Frank
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Introduction



- Various different models for medication management review
- Overall aims
 - To optimize outcomes from drug therapy
 - → To reduce medication related problems
- Different providers
 - → Community and hospital pharmacists, GPs, nurses and collaborative multi-disciplinary teams

Terms



- Many different terms in the literature
 - Drug/medication regimen review (DRR/MRR)
 - Drug use process (DUP)
 - Patient medication management service
 - Comprehensive medication review
 - Clinical medication review
 - → Home medication review (HMR)
 - Medication use review (MUR)

PCNE Working Conference 2007, Workshop 5

Settings



- GP clinics, hospital outpatient clinics, residential aged care facilities, pharmacy and the home
- Mostly literature about the institutional/hospital setting
- Many principles can be applied in the community setting
- Differences
 - → Limited access to clinical data
 - Medical care and prescriptions from multiple prescribers

Process



- Interrogation of data sources such as GP databases or patients medication charts in institutional settings
- Face-to-face interview with the patient in the pharmacy or at home
 - Without prescription and/or medical history
 - → With prescription and/or medical history

Workshop focus



- Ambulatory care setting
 - At the pharmacy and in the patient's home
- Reference lists:
 - SMR in the community
 - Inappropriate medication, drug related problems (DRP) in the elderly
- pdf files (with and without abstracts) and reference manager files:
 - http://www.abda.de/83.html (at the end of the side)

SMR-types with remuneration



- Medication therapy management services – USA
- → Medication use review

 (advanced service) and
 full clinical medication review
 (supplementary enhanced service) UK
- Home Medicines Review Australia





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Medication Review - Current Models:

Example USA



Beginnings/Development



- Broad range of services, ranging from
 2-minute conversation to an hour consultation
- Since 1990 retrospective and prospective drug utilization review (DUR) in many states
- Medication therapy management in outpatient clinics and other primary care sites for many years

Medication Therapy Management (MTM)



- New reimbursement opportunity, beginning 2006 for Medicare
- Medicare Prescription Drug, Improvement and Modernization Act 2003
- Medicare: health insurance program for people 65 years of age and older
- Insurers that offer a Medicare prescription drug plan must develop MTM services for certain beneficiaries

Medication Therapy Management (2)



- Target beneficiaries (no clear definition):
 - Taking multiple medications
 - Several chronic diseases
 - → Likely to spend more than \$4,000 on those medications by the end of the year

Goals:

- → To improve medication use and thereby to optimize therapeutic outcomes
- → To reduce the risk of adverse events, including adverse drug interactions

Medication Therapy Management (3)



- MTM services can include pharmacists or other providers
- No Medicare's MTM guideline, insurers determine the education, skills, and experience of the MTM providers
- Evaluation should identify best practice models
- Pharmacies must market their programs to patients and providers

Medication Therapy Management (4)



- Pharmacy Profession Stakeholder Conference 2004
- Consensus definition of MTM:
 - → Distinct service or group of services that optimizes therapeutic outcomes for individual patients
 - → MTM services are independent of dispensing, but can occur in conjunction with dispensing

Core objectives



- To engage all national professional pharmacy organizations in developing consensus MTM definition
- To ensure that the MTM definition was inclusive of the types of services that are or can be provided in diverse pharmacy practice segments
- To include a description of examples of services that can be implemented by a majority of pharmacy practitioners

Medication Therapy Management (5)



APhA/National Association of Chain Drug Stores Association Foundation

- → Model framework for conducting MTM visits based on the consensus definition
- Service distinct from dispensing
- Core elements, not all possible services

http://www.ashp.org/s_ashp/docs/files/MMA_MTMCommRxPractice.pdf

Model framework - aims

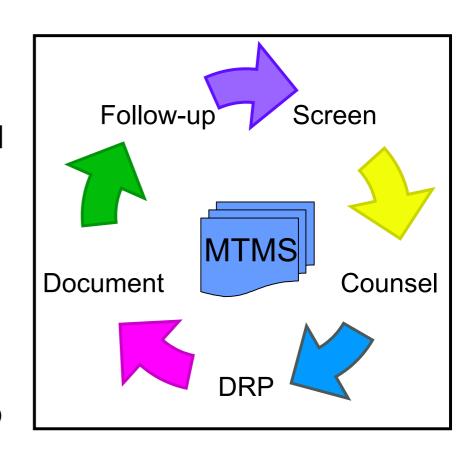


- → To improve care
- → To enhance communication among patients and providers
- → To improve collaboration among providers
- → To optimize medication use that leads to improved patient outcomes

Model framework – core elements



- Medication therapy review
- A personal medication record
- → A medication action plan
- Intervention and referral
- Documentation and follow-up



Medication Therapy Review (MTR)



- Preferably face-to-face
- Recommendation: one annual comprehensive MTR and targeted MTRs
 - → Comprehensive MTR: Assessment of medication therapy appropriateness, "ideally brown bag", education and information to improve patients' selfmanagement
 - → Targeted MTR to address new DRP or for ongoing medication monitoring

Medication Therapy Review (2)



- Tailored to individual needs
- Therefore different contents possible
 - Assessing the patients physical and overall health status
 - → Assessing, identifying, and resolving DRP
 - → Interpreting, monitoring, and assessing patient laboratory results, when available
 - **>**

Remuneration



- > Set fees for specific services
- Sample payment rates ranges
 - → From US\$75 \$120 for an initial visit at an independent pharmacy
 - → to \$40 for an initial visit at a supermarket pharmacy
- Mostly to the organization or pharmacy

Lewin Group, Medication therapy management services: a critical review. J Am Pharm Assoc (Wash DC). 2005;45:580-587

Implementation



- Most drug plan sponsors offer MTM services
- Delivery methods from telephone call center counseling to face-to-face meetings
- 53 % planned to employ managed care pharmacists,8 % to use a "traditional" pharmacist
- Characteristics required for a patient to be enrolled in MTM programs
 - → Number of diseases 3 (range 2-5)
 - Type of chronic condition
 - → Number of medications 6 (range 2-24)

Boyd ST, et al. Medication therapy management survey of the prescription drug plans. *J Am Pharm Assoc (Wash DC)*. 2006;46:692-699.

Touchette DR, et al. Survey of medication therapy management programs under Medicare part D. J Am Pharm Assoc (Wash DC). 2006;46:683-691.





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Medication Review - Current Models: Example UK

Purpose of the Service Medicines Use Review (MUR)



The 1st Advanced Service (New Community Pharmacy Contract, 2005)

AIMS:

- To help the patients use their medicines more effectively
- To assist prescribers in opting for the most clinical or cost effective treatment

OBJECTIVES:

To improve patient knowledge, concordance and use of medicines by: establishing actual use, understanding and experience of taking their medicines; identifying, discussing and resolving poor or ineffective use of their medicines; identifying side effects and drug interactions that may affect patient compliance; improving the clinical and cost effectiveness of prescribed medicines and reducing medicine wastage.

Rx intervention & MUR



- > Rx intervention & MUR part of the same service.
- Rx intervention: a medicines use review is carried out in response to a particular problem with a patient's medicines, which may be highlighted during the dispensing of a regular prescription
- MUR: a medicines use review which is part of the on-going care of a patient with a long-term condition who is taking a number of medicines.

Service specifications: MUR



- In the community pharmacy (if elsewhere, prior approval of the NHS Primary Care Organisation must be sought)
- Only when needed should be made by telephone
- PCTs may identify specific pt groups appropriate for targeting the service based on the needs of the local health economy.
- Pharmacists may accept referrals for MUR from other HCPs and requests from pts (if meeting criteria)

Service requirements: MUR



- > Patients on multiple medicines
- Patients with long term conditions
- Every 12 months
- If initiated by the pharmacist -> only for pts using the pharmacy ≥ 3 months.
- Private consultation area (requirements included in the regulations for accreditation of premises). Note: the PCT may monitor maintenance of requirements
- Accredited pharmacists (assessment based on the nationally agreed competencies; training is optional based on experience and perceived needs).

MUR: process



Pharmacist identifies a significant problem during the dispensing of regular prescriptions

Unravel the need for a more detailed examination of the patient's medication regimen

1

Discussion with the patient & communication to the patient's GP.

MUR: interventions



To the patient:

- Advice on medicines usage (prescribed and OTC), aiming to develop compliance and concordance;
- Effective use of 'when required' medication;
- Ensuring appropriate use of different medicine dosage forms
- Advice on tolerability and side effects; dealing with practical problems in ordering, obtaining, taking and using medicines;

To the prescriber:

- Identification of items without adequate dosage instructions.
- Identification of unwanted medicines
- Identification of the need for a change of dosage form;
- Proposals on changing branded medicines to generics or vice-versa;
- Proposals for dose optimisation;
- Suggestions to improve clinical effectiveness.

MUR: tools



- Reporting template (nationally agreed for pharmacists to make recommendations to the GP).
- Template to record the MUR on the patient's pharmacy record.
- Template to record the summary of the MUR and any recommendations to be sent to the GP (copy given to the patient).

Community Pharmacy MUR & Rx Intervention Service



- Patient details (incl. GP contact)
- Patient's informed consent
- Reason for review
- Basic health data (e.g. medical history)
- Location & Outcome of review
- Rx medicine
- Dosage regimen
- > Pt knowledge
- Compliance

- Appropriateness of formulation
- Effectiveness
- Safety
- Medicines use issue
- Priority
- Proposed action
- Outcome (dates)





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Medication Review - Current Models:

Example Australia



Home Medicines Review (HMR)



- Introduction of HMR 2001
- Part of the Third Community Pharmacy Agreement between the Pharmacy Guild of Australia and the Commonwealth Department of Health and Ageing
- > Structured and collaborative health care service

Home Medicines Review



- Systematic evaluation of patient's complete medication treatment regimen in the context of other clinical information and the patient's health status
- Collaboration between GPs, pharmacists and 'consumers' (patients)
- Face—to—face
- In the patient's home

Core objectives



- Achieve safe, effective and appropriate use of medication by detecting and addressing DRP
- Improve patients' quality of life and health outcomes
- Improve patients' and health professionals' knowledge about medicines
- Facilitate co-operative working relationships between members of the health care team

How were HMRs developed?



International	& National	published	evidence
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1995 - 1998

5 HMR projects commissioned by Pharmacy Guild

1999

Chen research used to justify savings of around €185 p.a. in medication cost to Government

Early 2000

Guild lobbied Government and politicians for inclusion in next Community Pharmacy Agreement

1999 - 2000

Budget allocation of €30m, of which €10m for implementation (leads to €10m cost saving)

May 2000

17 months development through collaborative working group – GPs, pharmacy, patients, government, etc..

May 00 - Sept 01

First HMR delivered

Nov 2001

Framework

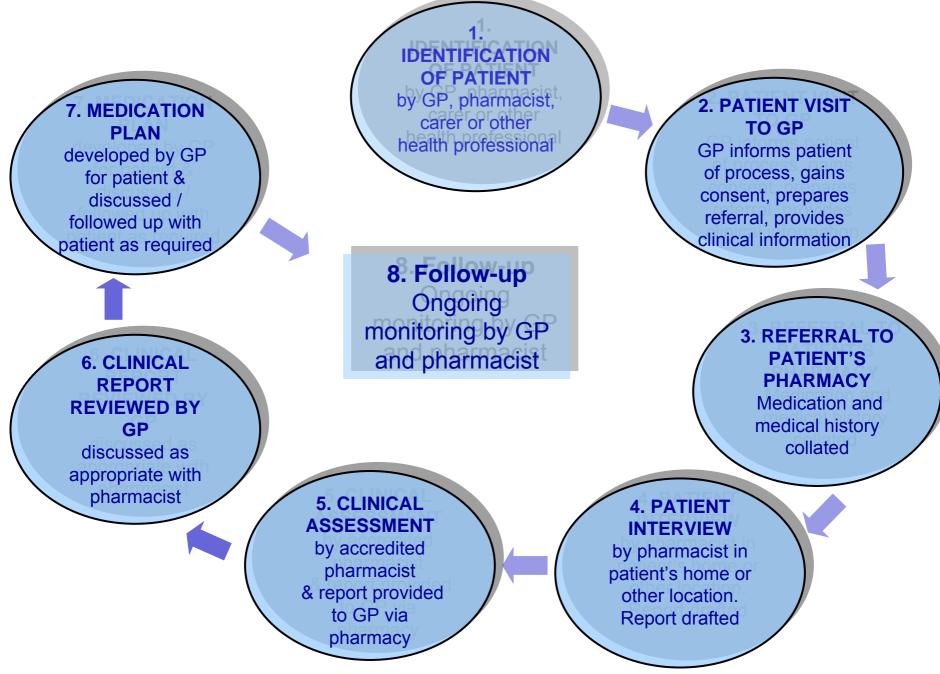


- Developed by the Medication Management Implementation Steering Group
- Representatives from key medical and pharmacy groups, along with nursing, consumer and government representation (see article in binder)
- http://www.psa.org.au/site.php?id=1090

Examples of criteria for an HMR



- The GP feels it is clinically necessary to ensure quality use of medicines or address patient's needs
- Five or more regular medications
- More than 12 doses of medication/day
- Medication with a narrow therapeutic index
- Symptoms suggestive of an adverse drug reaction
- Sub-therapeutic response to treatment with medicines
- Suspected non-compliance or inability to manage medication related therapeutic devices
- > Patient having difficulty managing their own medicines
- Patient attending a number of different doctors
- Recent discharge from a facility/hospital (in the last 4 weeks)



Dr. L. Emerson, Symposium "Medication Review for the Elderly with Polypharmacy", 7 February 2006, Berlin

'Consumer' interview



- Home as preferred setting
 - Opportunity to holistic assessment
- Assessment of
 - Consumer's understanding and acceptance of their medication regimen
 - Consumer's health beliefs and attitudes
 - → Barriers to compliance
 - Use of devices and aids
 - → Need for information and education about use of medications and self-care activities

Medication profile



- To identify and assess medication-related issues and problems
- Developed by collating information from the GP, the patient interview (see interview guide in the binder) and the examination of medicines at home
- Type of information (exact definition, see binder)
 - Demographic/personal detail
 - Relevant social history
 - Health and medical history
 - Medication history

Payment



- Medicare Australia pays AUS\$180 (108 €) to the approved service provider for each HMR undertaken after a referral by a general practitioner
- Medical practitioners (including general practitioners, but not a specialist or consultant physician) receives AUS\$134.10

Quality Control Processes



- Pharmacy QC process:
 - → Pharmacy and pharmacist standards
 - Pharmacies must apply to Government to become an Approved
 HMR Service Provider agree to adhere to standards
 - → Pharmacist accreditation to conduct clinical audit stage
 - Pharmacists must re-accredit educational requirements
 - → All paperwork auditable by Government
- > Doctor QC process:
 - → No specific GP standards only guidelines
 - Patient signs letter of agreement

Guidelines/Reports



- Pharmaceutical Society of Australia (PSA)
 - → Guidelines for Pharmacists: Domiciliary Medication Management Review http://www.psa.org.au/site.php?id=1090
- Professional Practice Standards
 - → PSA standard Home Medicines Review http://www.psa.org.au/site.php?id=1089
 - → Quality Care Pharmacy Program standards beta.guild.org.au/mmr/content.asp?id=413
- Evaluation of the Home Medicines Review Program – Pharmacy Component
 - → http://beta.guild.org.au/mmr/content.asp?id=406

Three possibilities for owners



- Become accredited yourself
- Employ an accredited pharmacist
- Obtain the service of an accredited pharmacist on a contract basis
- > 85.7 % of all pharmacies are registered
- > But: The budget for pharmacy services has been underspent

Implementation



- > Survey 2004*
 - → 39 % have accredited pharmacist on their staff
 - → 54 % obtain the service of an accredited pharmacist on a contract basis
- ➤ Nov. 2001 Sep. 2006: 115,121 HMR claims
 - Approximately 22 HMR per community pharmacy and
 5.2 per reviews for every 1,000 Australians
 - Only a minority of GPs have so far made referrals
- > What might accelerate the uptake of HMR?

^{*} Roberts AS et al. Implementation of home medicines review (HMR) in community pharmacy. *Aust Pharm.* 2005;24:808-813.

Facilitators for implementation



- Relationship with doctors
- Remuneration
- Pharmacy layout
- Patient expectation or need
- Communication and teamwork
- Manpower/staff
- External support or assistance

Implications



- Sustainability beyond pilot project period is an issue
- Programs must offer benefits from both professional and business (profitability) perspective
- All services must have an implementation strategy
- Remuneration needed not only for service, but also for implementation
- Flexibility required for different types of pharmacies
- New approach to education/training required (not just clinical aspects):
 - → Facilitators
 - Preparation for change
 - Implementation process

Is medication review by pharmacists of any use?



- ➤ The HOMER trial (RCT)
 - Home-based medication review after discharge (twice)
 - → Patients aged ≥ 80 years, admitted as an emergency
 - → Taking two or more drugs daily after discharge
 - → Four components of intervention
 - Education about their drugs
 - Removal of out-of-date drugs
 - Information of the GP about ADR or interactions
 - Provision of adherence aids if necessary

Holland R, Lenaghan E, Harvey I et al. Does home based medication review keep older people out of hospital? The HOMER randomised controlled trial. *BMJ.* 2005;330:293.

Outcome measures



- > Primary outcome measure:
 - Total number of emergency hospital admissions over 6 month
- Secondary outcome measures
 - Mortality
 - → Quality of life (QOL), EQ-5D
 - → Cost-effectiveness
 - Focus on those costs considered to be of most significance:
 Intervention costs, costs due to hospital admission, primary care costs

Outcomes



- Significantly higher rate of hospital admissions in the intervention group
- Non significant gain in quality of life
- Small but not statistically significant reduction in mortality

Possible limitations of the study

- Review with access only to the patient, their medication and discharge advice note, not to full medical record
- Not a holistic medication review
- Treatment optimized during hospital stay
- > The groups were not well matched for diseases

Cost-effectiveness



Low probability of cost effectiveness

Possible reasons:

- Two visits to do four tasks
- Failure to measure drug costs before and after
- Treatment optimized during hospital stay

Pacini M, Smith RD, Wilson EC, Holland R. Home-Based Medication Review in Older People: Is it Cost Effective? *Pharmacoeconomics*. 2007;25:171-180.

Zermansky AG, Freemantle N. Is medication review by pharmacists of any use? *Pharmacoeconomics*. 2007;25:91-92.

Conflicting answers



- Different outcomes due to differences in used methods
 - what is done, who does it, on whom is it done
- RCT of clinical medication reviews (same level)
 - Reduced drug costs
 - Reduced number of drugs prescribed
 - Reduced inappropriate prescribing
 - Reduced or increase hospital admission
 - → Reduced falls

Summary SMR



- Medication review research mostly descriptive
- Few studies involved randomised controlled design
- Main impact measures in RCTs
 - Mean number of medications per patient
 - Medication costs per patient
- Lack of CLEAR clinical evidence supporting the effectiveness of the SMR model in the ambulatory setting
- Research should be part of any ongoing implementation of the HMR

Discussion



Participants' experiences ...???



Types of review



Туре	Pills	Medical history	Medical record	Patient
Druglist review		?		
Brown bag review		?		
Record review				
Clinical medication review				

Zermansky A., ESCP Spring Conference 2006

Define Core Elements of PCNE-SMR



- Medication therapy review
 - Type: ambulatory clinical medication review
- → A written report
- A personal medication record
- A medication action plan
- Intervention and referral
- Documentation and follow-up

Patient inclusion criteria (1)



- → Patients older than 60-65 years and/or
- → Taking 5 or more regular medications¹ or
- → Taking more than 12 doses of medication per day¹ or
- → Medication regimen changed four or more times in the last 12 months¹ or
- → More than three different (chronic) illnesses¹ or
- → History of noncompliance¹ or
- → Use of drugs that require therapeutic drug monitoring¹ or

¹Koecheler JA, et al. Indicators for the selection of ambulatory patients who warrant pharmacist monitoring. *Am J Hosp Pharm.* 1989;46:729-732.

Patient inclusion criteria (2)



or

- Symptoms suggestive of an adverse drug reaction or
- Sub-therapeutic response to treatment with medicines or
- Medication from more than one prescriber or
- At least one chronic disease or one specific chronic disease or
- Total monthly cost of medication exceeds? or
- Patients classified in need of care who live in a home setting (AUS)

Possible Objectives of the workshop



- Defining objectives of systematic medication reviews
- Developing a PCNE framework for planning, conducting, and evaluating systematic medication reviews which is adaptable to different healthcare settings
- Developing PCNE recommendations for a study protocol

Criteria for effective pharmacist medication review (1)



- Use a systematic approach to medication review
- Ensure adequate training, accreditation and ongoing educational training
- Establish appropriate links to ensure pharmacist is working as a part of the primary health care team
- Maintain effective working relationship with GPs

Criteria for effective pharmacist medication review (2)



- Always involve the patient
- Decide on the most important and realistic intervention
- Ensure follow up to check that recommendations are acted upon
- Identify an experienced mentor to discuss ongoing problems and options

Medication appropriateness (1)



- Explicit criteria
 - Standardized guidelines
 - → Focus on a single drug or drug class
 - → Designed to be applicable to medication orders/prescriptions with minimal clinical data
 - Can be incorporated into computerised systems
- Implicit criteria
 - → Use clinical knowledge and judgment to assess prescribing appropriateness

Medication appropriateness (2)



> Explicit

- Inappropriate for the elderly (Beers, McLeod)
- → Inappropriate drug-disease combination (Beers, McLeod)
- Inappropriate drug-drug combination (McLeod)
- > Implicit
 - Drug therapy problems (Strand)
- Combination
 - Medication appropriateness index (MAI)

Beers criteria



- ➤ Criteria for potentially inappropriate medication use in older adults (≥ 65 years)
 - Independent of diagnoses or condition
 - e.g. short acting nifedipin, concern: potential for hypotension and obstipation/constipation
 - → Considering diagnoses or condition e.g. propranolol with COPD/asthma
- Based on expert consensus developed through
 - Extensive literature review
 - Questionnaire evaluation using Delphi technique

Fick DM, et al. Updating the Beers criteria for potentially inappropriate medication use in older adults: results of a US consensus panel of experts. *Arch Intern Med.* 2003;163:2716-2724.

McLeod (1)



- List of inappropriate prescribing for elderly people
- Based on expert consensus developed through
 - → Extensive literature review
 - Questionnaire evaluation using Delphi technique
- Ranking of clinical importance of risks and suggestion of alternative therapies

McLeod PJ, Huang AR, Tamblyn RM, Gayton DC. Defining inappropriate practices in prescribing for elderly people: a national consensus panel. *CMAJ.* 1997;156:385-391.

McLeod (2)



- Prescription of drugs generally contraindicated for elderly people, example:
 - → Long-term prescription of long-half-life benzodiazepine to treat insomnia
 - Alternative therapy: Nondrug therapy or short-half-life benzodiazepine
- Prescription of drugs that can cause drug-druginteractions
- Prescription of drugs that can cause drug-diseaseinteractions

MAI – Medication appropriateness index (1)



- Designed to measure ten components of prescribing
- Support from explicit definitions and instructions for use
 - Combination of explicit criteria with implicit judgment
- Designed to be applied to the medical record by a clinician, usually a pharmacist
- Not designed to include the needs of the individual patients

Samsa GP, et al. A summated score for the medication appropriateness index: development and assessment of clinimetric properties including content validity. J Clin Epidemiol. 1994;47:891-896.

MAI – Medication appropriateness index (2)



- > 10 item scale
 - → Indication
 - → Effectiveness
 - Dosage
 - Direction
 - Drug-drug interactions
 - Drug-disease interactions
 - Direction practicality
 - Duplication
 - → Duration
 - Medical expense

For each criterion:

- Operational definitions
- Explicit instructions
- Examples

MAI – Medication appropriateness index (3)



- 3-point scale to rank as "appropriate", "marginally appropriate" or "inappropriate"
- Weighting scheme permits a score for each drug and also an overall patient score
- Developed for use in outpatient elderly clinics
 - Medical data easily accessible
- Modifications exist for different settings, e.g.
 - Ambulatory older persons
 - Community pharmacy

Fitzgerald LS, et al. Reliability of a modified medication appropriateness index in ambulatory older persons. *Ann Pharmacother.* 1997;31:543-548.

Kassam R, Martin LG, Farris KB. Reliability of a modified medication appropriateness index in community pharmacies. *Ann Pharmacother.* 2003;37:40-46.

MAI – Medication appropriateness index (4)



Specific instructions for index criterion direction

Question: Are the directions correct?

1	2	3	9
Correct		Incorrect	do not know

Definition

Directions are defined as the instructions in the use of a medication by a patient. The question assesses the route of administration, relationship to food and liquid, the schedule and time of the day

Instructions

The directions are incorrect when they specify the wrong route of administration, give wrong or no instructions regarding food and liquid (when they exist),.....

Examples

Simvastatine 40 mg/day: Incorrect (must specify in the evenings)

Clinical indicators



- Indicators of preventable drug-related morbidity (PDRM)
 - Strategy to reduce drug related morbidity and drug related admission
 - → To identify patients at risk
- Development of 52 indicators for PDRM in the US¹
 - Developed from a literature review
 - Validated using the Delphi technique
- Assessment of transferability to UK and generation of new indicators²

¹MacKinnon NJ, Hepler CD. Preventable drug-related morbidity in older adults 1. Indicator development. J Manag Care Pharm. 2002;8:365-371.

²Morris CJ, Cantrill JA, Hepler CD, Noyce PR. Preventing drug-related morbidity--determining valid indicators. *Int J Qual Health Care.* 2002;14:183-198.

Examples for clinical indicators¹



Pattern of care:

Use of an ACE inhibitor without baseline monitoring of electrolytes, subsequent monitoring at 10-14 days and then every six month thereafter

Outcome: Hyperkalaemia

Pattern of care:

In the absence of any contraindication, failing to prescribe aspirin in a patient with a history of myocardial infarction

Outcome: A second myocardial infarction

¹Morris CJ, Cantrill JA, Hepler CD, Noyce PR. Preventing drug-related morbidity--determining valid indicators. *Int J Qual Health Care*. 2002;14:183-198

Drug-related problems – Strand, L.M.



- Categories and common causes
 - Unnecessary drug
 - Needs additional drug therapy
 - Ineffective drug
 - Dosage too low
 - Adverse drug reaction
 - Dosage too high
 - → Noncompliance
 - Drug interactions

Strand LM. et al., Drug-related problems: their structure and function. *DICP*. 1990;24:1093-1097.