Quality of pharmaceutical services: a tool to help improve the safety of the medication process?

Dr J. Beney
ICHV, Sion, Switzerland

11th Congress of the EAHP
Quality and Medication Safety Hand in Hand
22nd - 24th March 2006, Palexpo Congress Centre, Geneva, Switzerland

---

EAHP policy on potential conflicts of interest

J. Beney is a member of the GSASA “Quality & security committee” which developed the RQPH/RQS (Quality Referential for Hospital Pharmacy)

J. Beney is a quality auditor for RQPH, wage for this activity is paid to his employer.
Presentation outline

• **Brief history**
  • Various references / evaluation systems
  • What are the evidences ?
  • Application to pharmaceutical services
  • Conclusion

A brief history of quality

![Graph showing the evolution of quality levels from 1930 to 2000.]

- Quality Control
- Quality Assurance
- Total Quality Management

Quality level:

- 1930
- 1940
- 1950
- 1960
- 1970
- 1980
- 1990
- 2000
What about health care?

• To err is human (1999)
• Crossing the quality chasm (2001)
• Is the focus on quality in health care really so new?
  • Precursors:
    • Florence Nightingale (1820-1910)
      Use of statistics
    • Ernest Avery Codman (1869-1940)
      Outcomes
    • Archie Cochrane (1909-1988)
      Evidence Based Medicine
    • Avedis Donabedian (1919-2000)
      Structure, process, outcome

Avedis Donabedian (1919 - 2000)

« Evaluating the quality of medical care »
(Milbank Memorial Fund Quarterly 1966;44:166–206)
What has changed these last years?

Institute of Medicine’s definition

« Quality of care is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge. »

Medicare: A Strategy for Quality Assurance, Volume I
Kathleen N. Lohr, Editor; Committee to Design a Strategy for Quality Review and Assurance in Medicare, Institute of Medicine
Presentation outline

• Brief history
• References / evaluation systems
  • What are the evidences?
  • Application to pharmaceutical services
  • Conclusion

Reference / Evaluation systems

Reference & Evaluation
• Licensure
• Third party assessment (External Quality Assessment as defined by WHO)

Evaluation only
• Patient surveys
• Statistical indicators
**Licensure**

- A process by which a governmental authority grants permission to an individual or an organization to operate. A process that
  - Ensures that legal requirements are met (public health protection and safety)
  - Focuses on structure and does not usually address clinical process or performance
  - Is done before opening, in return of payment of a fee with minimal or no inspection
- Licensure is based on minimum standards and therefore does not foster innovation for consumer or provider.

**External Quality Assessment (EQA)**

All kinds of organizational review which use written standards.

- Industry based / generics models
  - ISO 9000
  - EFQM Excellence model
- Health care based
  - Peer Review
  - Accreditation

EQA : ISO 9000
(1 – origin and focus )

• Originally designed for manufacturing industry (ISO 9001/2/3/4)
• Certification widely available from independent auditors (regulated by a national accreditation agency)
• Adapted in 2000 to be more « services oriented »

(accessed January 20th 2006)

EQA : ISO 9000
(2 - standards)

• ISO 9000:2000 standards
  • Quality management system
  • Management responsibility
  • Resource management
  • Product realization
  • Measurement, analysis and improvement
EQA : ISO 9000 (3 - evaluation)

- Evaluation: External audit by a certification entity
  - Within 1994 version: are you doing what the manual says you should be doing?
  - Within the 2000 version: will this process help you achieve your stated objectives? is it a good process or is there a better one or a better way to do it?
- Product: Certification, a proof that
  - A quality management system is established
    - It ensures constant results
    - It promotes continuous quality improvement
  - Management is actively involved

ISO 9000 : 2000

Weaknesses
- Generic model
- Process (rather than outcomes) oriented

Strengths
- Quality Management System
- Well known certificate

Barriers
- Lack of resources
- Risk of “Over documenting”

Facilitating factors
- Clear commitment of the management
- Shared values across all the organization
EQA : EFQM model
(1 – origin and focus)

- European Foundation for Quality Management (1988)
- European’s answer to US Malcolm Baldrige National Quality Award (MBNQA)
  - MBNQA : Award introduced as a response to Japanese quality success
- A model that can be used as
  - A frame of reference for quality management
  - A tool for self assessment
  - A national or international quality award

EQA : EFQM model
(2 standards)

The EFQM is based on the premise that enablers direct and drive the results.
**EQA : EFQM model**

(3 - evaluation)

- Self assessment
- Organizations with a mature form of quality management are challenged by the EFQM to apply for national or international quality award.
  - Report by experienced assessors (0-1’000 pts)
  - > 500 pts -> site visit
  - > 550 pts -> Finalist
  - > 620 pts -> Prize Winner
  - Award Winner

---

**EFQM**

**Weaknesses**
- Generic model
- No document of goal attainment (certificate or accreditation, etc.)

**Strengths**
- Benchmark
- Total quality oriented framework

**Barriers**
- Terminology
- Lack of trained staff to run self-assessment

**Facilitating factors**
- Sound leadership
- Integration in the managerial process (rather than running parallel to it)
EQA: Peer Review
(1 – origin and focus)

• Originated and developed in the Netherlands (Visitatie: re-registration of medical associations members) and in UK
• Grounded in the medical profession
• Aims to improve the quality of the care process
• by focusing on the quality of individuals or clinical teams’ performance (not on the whole organization)
• Initiated and co-ordinated by the relevant professional entities and scientific associations

EQA: Peer Review
(2 – standards)

• Health care oriented
• Speciality based
  • Standards of good quality care or best practices are used when available
  • Ongoing development of guidelines when standards are not available
• Limited access
### EQA: Peer Review (3 - evaluation)

#### Netherlands
- Elaborated criteria for reviewers (up-to-date knowledge, open-minded, constructive attitude)
- Review process formally structured, information gathered through:
  - Questionnaires
  - Structured interviews
- Results are confidential to the departments visited

#### United Kingdom
- Written instructions for volunteers, no training
- Review process follows the workflow of the department, information gathered through:
  - Observation
  - Ad hoc interviews
- Results are confidential to the departments visited

---

### Peer Review

#### Weaknesses
- Focus on the quality of individuals as opposed to whole hospital
- Isolated from other quality activities

#### Strengths
- Focus on the quality of care
- Endorsed by clinical professions

#### Barriers
- Lack of resources
- Lack of expertise
- Lack of an overall plan

#### Facilitating factors
- Medical record systems
- Protected time to act on review findings

---

EQA: Accreditation
(1 – origin and focus)

- Originated in US health care (1917 - Minimum Standards for Hospitals. ACS)
- Reviews are conducted by professional peers
- Aim at encouraging organizational development and performance through multidisciplinary assessment of healthcare functions
- Originally designed as an independent (non governmental) voluntary programme
- Subsequently adopted in different countries as a mandatory programme (France, Italy, Scotland)

EQA: Accreditation
(2 – standards)

- Health care oriented
- Ideal achievable standards (versus minimum standards for licensure)
- Emphasis on safety
  - Examples of JCAHO medication management standards
**Joint Commission medication management standards**

**Old standards**
- Four steps
  - Ordering and prescribing
  - Preparing and dispensing
  - Administration
  - Monitoring

**2004 standards**
- Emphasis on medication safety
- Two more steps
  - Medication selection and procurement
  - Storage


---

**JCAHO medication management standards (2004) – example 1**

- **MM.1.10**: Patient-specific information is readily accessible to those involved in the medication management system

<table>
<thead>
<tr>
<th>Patient-Specific Information Required for Persons Involved in Medication Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
</tr>
<tr>
<td>Sex</td>
</tr>
<tr>
<td>Current medications</td>
</tr>
<tr>
<td>Diagnosis, comorbidities, concurrent conditions</td>
</tr>
<tr>
<td>Relevant laboratory test values</td>
</tr>
<tr>
<td>Allergies, past sensitivities</td>
</tr>
<tr>
<td>Weight and height</td>
</tr>
<tr>
<td>Pregnancy and lactation status</td>
</tr>
<tr>
<td>Any other information required by the organization for safe medication management</td>
</tr>
</tbody>
</table>

**JCAHO medication management standards (2004) – example 2**

- MM.2.10. Medication available for dispensing or administration are selected, listed, and procured on criteria
  - Formulary committee (not a unilateral effort by the pharmacy department)
  - Information on new drugs added to the formulary


---

**JCAHO medication management standards (2004) – example 3**

- MM.4.10 All prescriptions or medication orders are reviewed for appropriateness

<table>
<thead>
<tr>
<th>Elements of the JCAHO Medication-Order Review Process</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appropriateness of the drug, dose, frequency, and route of administration</td>
</tr>
<tr>
<td>Therapeutic duplication</td>
</tr>
<tr>
<td>Real or potential allergies or sensitivities</td>
</tr>
<tr>
<td>Real or potential interactions between the ordered medication and other medications, food, and laboratory test values</td>
</tr>
<tr>
<td>Other contraindications</td>
</tr>
<tr>
<td>Variation from organizational criteria for use</td>
</tr>
<tr>
<td>Other relevant medication-related issues or concerns</td>
</tr>
</tbody>
</table>

*JCAHO = Joint Commission on Accreditation of Healthcare Organizations.

JCAHO medication management standards (2004) – example 4

- MM.4.20 Medications are prepared safely
  - When an onsite licensed pharmacy is available, sterile medication, i.v. admixtures, and other drugs are compounded or admixed only in the pharmacy, except in emergencies or when this practice is not feasible (e.g. when the duration of product stability is short)


EQA : Accreditation (3 - evaluation)

- Focus on improvement rather than just quality attainment
- Evaluation of structures, process and outcomes
- Includes risk management
- Use of different techniques
  - E.g. JCAHO
    - Self evaluation
    - Survey (audit)
    - Patients surveys
    - Statistical indicators
    - Sentinel events

2006 : unannounced survey
Accreditation

**Weaknesses**
- Onerous for small facilities
- Risk of lowering standards to be more attractive to potential participants

**Strengths**
- Can promote public accountability
- Encompasses different approaches (audit, survey, statistical indicators, risk management)

**Barriers**
- Increased workload
- When mandatory, accreditation becomes another form of licensure

**Facilitating factors**
- Strong government support
  (funding, subsidy of assessment, financial incentives)

Presentation outline

- Brief history
- References / evaluation systems
- **What are the evidences?**
- Application to pharmaceutical services
- Conclusion
Are quality improvement programmes effective?

- There is little research evidence as to their effectiveness.
- This lack of evidence does not mean that quality programmes are not effective, but is rather due to
- the failure to publish quality improvement work
- and the methodological challenges of
  - measuring outcomes,
  - attributing a causality to these complex interventions to organizations or health care systems.

Under exceptional circumstances, common sense might be applied when considering the potential risks and benefits of interventions.

Are Randomized Controlled Trials (RCT) the gold standard for QI?

- Different goals:
  - The primary goals of original research are to discover and publish generalizable results.
  - The goal of quality improvement (QI) is to enhance performance. Publication about QI is more about sharing experience and learning rather than sharing results.
- RCT were developed to meet the needs of original research, not the ones of QI or risk management.
- Other tools (e.g. statistical process control, interrupted time series, before-after studies, etc.) can/must be used to evaluate QI.

Presentation outline

- Brief history
- References / evaluation systems
- What are the evidences?
- Application to pharmaceutical services
- Conclusion
Quality of pharmaceutical services

Pharmaceutical services

Selection of drugs

Drug information

Formulary management

Emergency pharmacy services

Compounding and reconstitution

Drug storage and procurement

Clinical pharmacy

Other cognitive activities

Pharmaceutical services

Pharmacotherapy

Value

Selection of drugs

Formulary management

Emergency pharmacy services

Compounding and reconstitution

Drug information

Drug storage and procurement

Clinical pharmacy

Other cognitive activities

Pharmaceutical services

Pharmacotherapy

Value

Selection of drugs

Formulary management

Emergency pharmacy services

Compounding and reconstitution

Drug information

Drug storage and procurement

Clinical pharmacy

Other cognitive activities

Pharmaceutical services

Pharmacotherapy

Quality issues

<table>
<thead>
<tr>
<th>Type</th>
<th>Definition</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Misuse</td>
<td>Appropriate choice, error in use</td>
<td>Error in dose calculation of digoxin</td>
</tr>
<tr>
<td>Overuse</td>
<td>No indication but used</td>
<td>Antibiotic for a viral upper respiratory tract infection</td>
</tr>
<tr>
<td>Underuse</td>
<td>Failure to use when indicated</td>
<td>No beta-blocker after AMI (when no contraindication exist)</td>
</tr>
</tbody>
</table>

Pharmaceutical services can help reduce Misuse, Overuse and/or Underuse.

Misuse:

- Setting: a US not-for-profit 489-bed non-teaching hospital
- Aim: to reduce ADE
- Intervention:
  - Work on culture change
  - Identification of high risk drugs (based on internal error reporting)
  - Multiple interventions (protocols e.g. warfarin, Heparin, sedation, potassium, insulin, PCA orders, switch, etc.)
  - FMEA conducted on the pharmacy dispensing system
- Outcome: ADE, identified with help of a trigger tool (rash, use of vitamin K, use of naloxone, etc.) from a random sample of patient charts

Statistical process control chart. The solid line represents the mean ADE rate and the dotted line represents the upper control limit, defined as three standard deviations above the mean. Each point represents the result of a single month's audit.
Overuse:

- Setting: a UK district hospital, which provides acute medical services to a population of 300'000
- Aim: To improve medication management
- Intervention:
  - A senior pharmacist became a member of the post-admission ward round
- Outcomes:
  - Impact on drug expenditure
  - Impact on medication associated risks

Overuse:


Funding for a post-admission ward round pharmacist has been granted as a result of this study.
Underuse:

- Setting: Kaiser (US) Clinical Pharmacy Cardiac Risk Service
  Region wide consultants providing patient counselling on a variety of coronary artery disease (CAD)-related drug management issues
- Aim: To improve the use of ACE inhibitors in patients with both CAD and Diabetes (-> lisinopril 20 mg/day)
- Intervention:
  - Inpatient: staff education (one-to-one, voice and mail communication)
  - Outpatient management by a CPCRS pharmacist
- Outcome: nb. of patients achieving optimal dosage of ACE inhibitor

Quality Referential for Hospital Pharmacy: a Swiss initiative

ISO 9001:2000

ISO 9001:2000 requirements
- Quality management system
- Management responsibility
- Resource management
- Product realization
- Measurement, analysis and improvement

ISO 9001:2000 auditor

Audit

Hospital pharmacy specific requirements
- Formulary
- Drug Information
- Drug Manufacturing
- Medication Process
- Risk management

Hospital pharmacist auditor

Peer Review

QRHP certificate

Pharmaceutical comp. representatives’ visits

- Before-after study (two one-year periods)
- Assessment of (59/61 visits)
  - Overall quality
  - Request for formulary addition
  - Scientific value
  - Spontaneous mention of indication, CI, SE, Dosage, ADE
- Feed-back to pharmaceutical companies between the two periods

Reference:
Multiple -> Single dose blisters: a QI initiative

Muff P, Rueger M, Marielli E, Portenier L.

Single dose blister

- 50 ou 100 gélules de 100 mg, 300 mg ou 400 mg
- **Nom commercial**
  - Similitude avec le nom DGI (gabapentine) pour éviter toute confusion
- **Emballage**
  - Les gélules sont séparables individuellement grâce au blister perforé
  - Chaque blister porte les informations suivantes: nom du produit, principe actif, dosage, nom du fabricant, numéro de lot et date de péremption
  - Emballage secondaire avec 1, 2 ou 3 bandes selon la dose
- **Gélules**
  - Gélules de différentes tailles et couleurs selon la dose pour éviter toute confusion:
    - 300 mg : Gélules jaunes taille 1
    - 400 mg : Gélules oranges taille 0
Look-alike:
use of the GSASA forum

Clinical pharmacy
at ICHV

Interventions in internal medicine wards (n=532)

Quality improvement
(85% of the interventions)

3 pharmacists
48 ward rounds (max.1/week)
895 patients
Acceptance rate 89%
Presentation outline

- Brief history
- References / evaluation systems
- What are the evidences?
- Application to pharmaceutical services
- Conclusion

Conclusion: quality programmes

- No quality programme has proven to be superior to others.
- Quality improvement probably requires implementation of aspects of various approaches.
- Performance measurement systems should aim to manage and improve hospital performance, rather than generate unreliable ranking and comparisons.
- Incentives rather than constraint should be used.
Conclusion

Is quality of pharmaceutical services a tool to help improve the safety of the medication process?

Yes…, but…

Conclusion: pharm. services

• Medication safety requires hospital-wide efforts and leadership commitment.
• Quality implies a careful evaluation of customers' needs.
• Such evaluation allows pharmaceutical services to be embedded in the hospital quality improvement process.
• When these conditions are fulfilled, pharmaceutical services can help reduce drug overuse, underuse and misuse.
Thanks for your attention!