



Institut Central des
Hôpitaux Valaisans

Pharmacy
www.ichv.ch

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

Dr J. Beney
ICHV, Sion, Switzerland



European Association
of Hospital Pharmacists

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



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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.

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Presentation outline

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

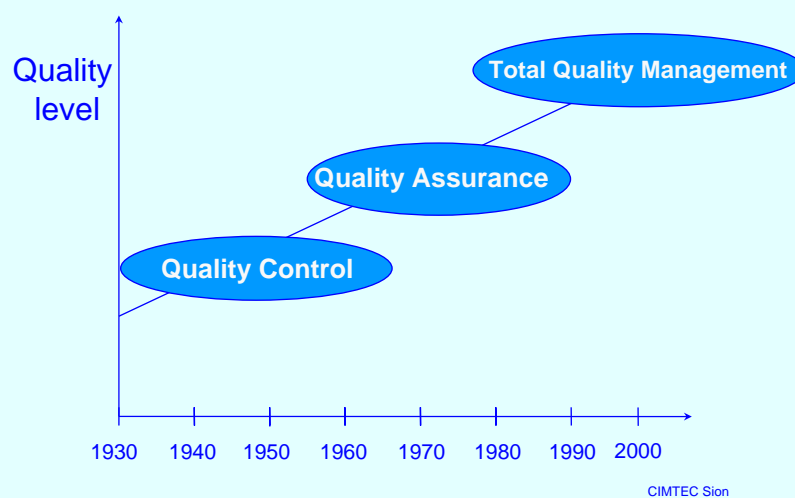
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A brief history of quality



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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

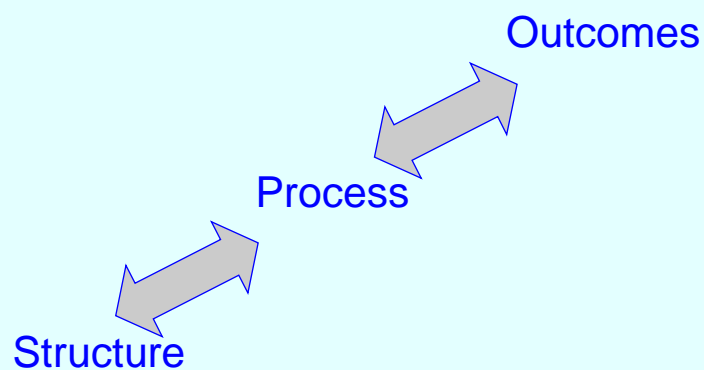
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Avedis Donabedian (1919 - 2000)



« Evaluating the quality of medical care »
(*Milbank Memorial Fund Quarterly* 1966;**44**:166–206)

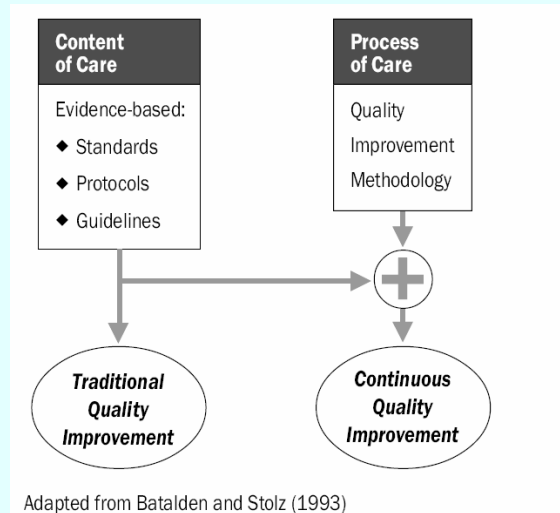
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What has changed these last years ?



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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
468 pages, 1990 (<http://books.nap.edu/catalog/1547.html> accessed February 20th 2006)

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Reference / Evaluation systems

Reference & Evaluation Evaluation only

- | | |
|--|--|
| <ul style="list-style-type: none">• Licensure• Third party assessment
(External Quality Assessment as defined by WHO) | <ul style="list-style-type: none">• Patient surveys• Statistical indicators |
|--|--|

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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.

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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

Heaton C. External peer review in Europe: an overview from the ExPeRT Project. External Peer Review Techniques. Int J Qual Health Care. 2000 Jun;12(3):177-82.

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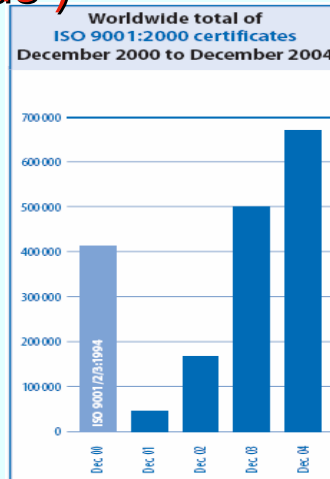


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EQA : ISO 9000 (1 – origin and focus)

- 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 »



<http://www.iso.org/iso/en/prods-services/otherpubs/pdf/survey2004.pdf>
(accessed January 20th 2006)

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EQA : ISO 9000 (2 - standards)

- ISO 9000:2000 standards
 - Quality management system
 - Management responsibility
 - Resource management
 - Product realization
 - Measurement, analysis and improvement

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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

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ISO 9000 : 2000

Weaknesses

- Generic model
- Process (rather than outcomes) oriented

Barriers

- Lack of resources
- Risk of "Over documenting"

Strengths

- Quality Management System
- Well known certificate

Facilitating factors

- Clear commitment of the management
- Shared values across all the organization

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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

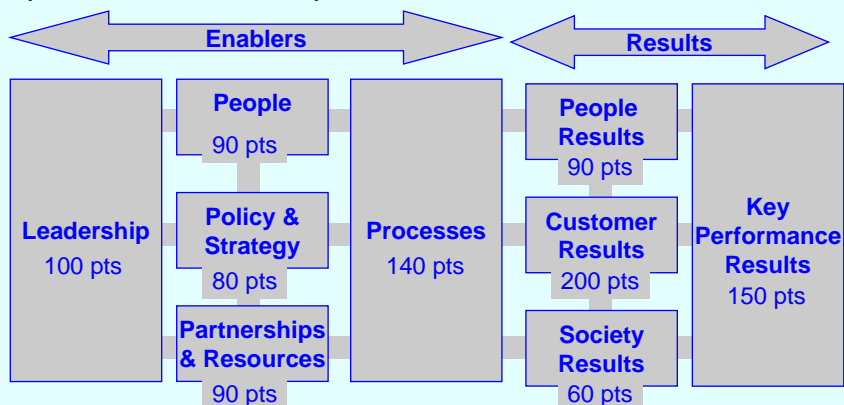
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EQA : EFQM model (2 standards)



Copyright © 1999 - 2003 EFQM www.efqm.org (accessed January 20th 2006)

The EFQM is based on the premise that enablers direct and drive the results.

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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



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EFQM

Weaknesses

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

Barriers

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

Strengths

- Benchmark
- Total quality oriented framework

Facilitating factors

- Sound leadership
- Integration in the managerial process (rather than running parallel to it)

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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

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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

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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

van Weert C. Developments in professional quality assurance towards quality improvement: some examples of peer review in the Netherlands and the United Kingdom. *Int J Qual Health Care.* 2000 Jun;12(3):239-42

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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

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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)

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EQA : Accreditation (2 – standards)

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

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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

Rich DS. New JCAHO medication management standards for 2004. Am J Health Syst Pharm. 2004 Jul 1;61(13): 1349-58.

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JCAHO medication management standards (2004) – example 1

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

Patient-Specific Information Required for Persons Involved in Medication Management

Age
Sex
Current medications
Diagnosis, comorbidities, concurrent conditions
Relevant laboratory test values
Allergies, past sensitivities
Weight and height
Pregnancy and lactation status
Any other information required by the organization for safe medication management



Rich DS. New JCAHO medication management standards for 2004. Am J Health Syst Pharm. 2004 Jul 1;61(13): 1349-58.

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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

Rich DS. New JCAHO medication management standards for 2004. Am J Health Syst Pharm. 2004 Jul 1;61(13): 1349-58.

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JCAHO medication management standards (2004) – example 3

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

Elements of the JCAHO Medication-Order Review Process^a

Appropriateness of the drug, dose, frequency, and route of administration
Therapeutic duplication
Real or potential allergies or sensitivities
Real or potential interactions between the ordered medication and other medications, food, and laboratory test values
Other contraindications
Variation from organizational criteria for use
Other relevant medication-related issues or concerns

^aJCAHO = Joint Commission on Accreditation of Healthcare Organizations.

Rich DS. New JCAHO medication management standards for 2004. Am J Health Syst Pharm. 2004 Jul 1;61(13): 1349-58.

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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)

Rich DS. New JCAHO medication management standards for 2004. Am J Health Syst Pharm. 2004 Jul 1;61(13): 1349-58.

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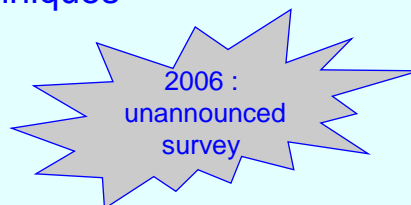


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EQA : Accreditation (3 - evaluation)

- 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



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Accreditation

Weaknesses

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

Barriers

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

Strengths

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

Facilitating factors

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

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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.

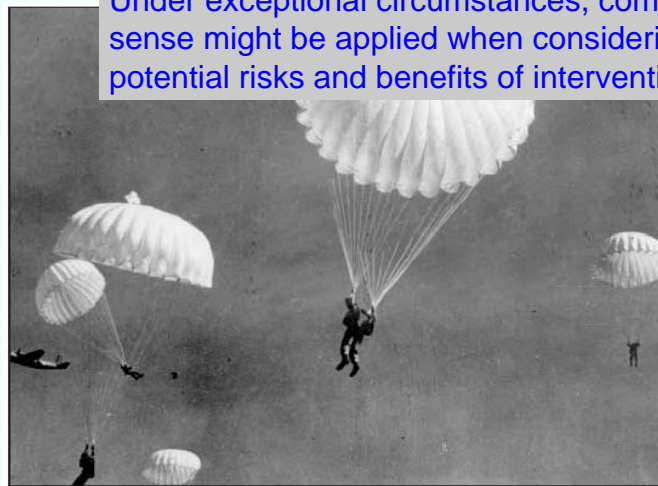
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Under exceptional circumstances, common sense might be applied when considering the potential risks and benefits of interventions.



Parachutes reduce the risk of injury after gravitational challenge, but their effectiveness has not been proved with randomised controlled trials

Smith GC, Pell JP. Parachute use to prevent death and major trauma related to gravitational challenge: systematic review of randomised controlled trials. *BMJ*. 2003 Dec 20;327(7429):1459-61.

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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.

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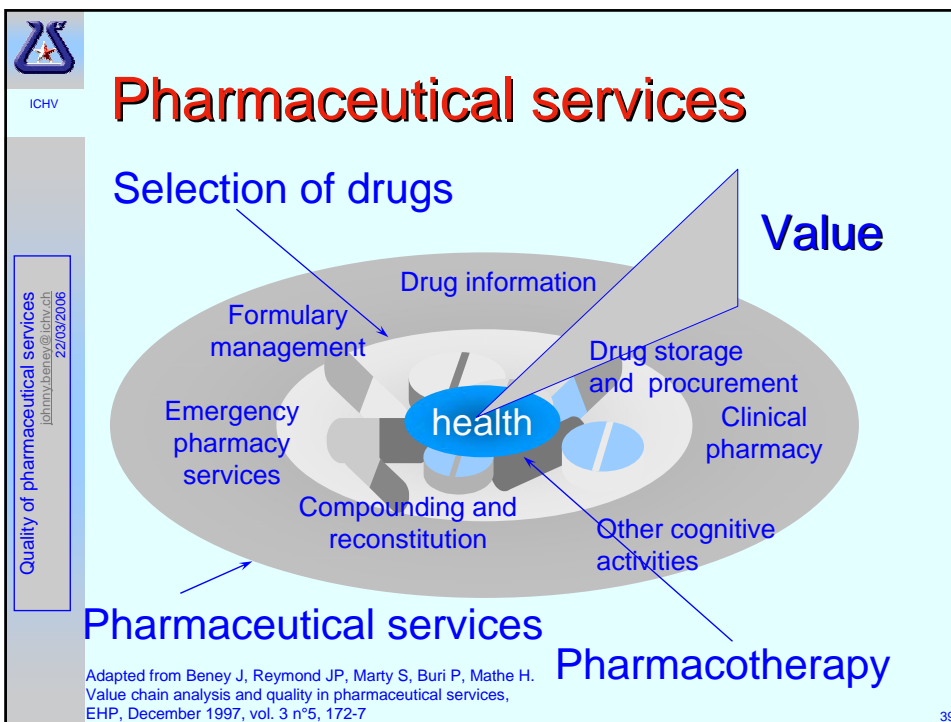
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Quality issues

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

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

Chassin MR, Galvin RW. The urgent need to improve health care quality. Institute of Medicine National Roundtable on Health Care Quality. JAMA. 1998 Sep 16;280(11):1000-5.

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Cohen MM, Kimmel NL, Benage MK, Cox MJ, Sanders N, Spence D, Chen J. **Medication safety program reduces adverse drug events in a community hospital.** Qual Saf Health Care. 2005 Jun;14(3):169-74

↓ 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

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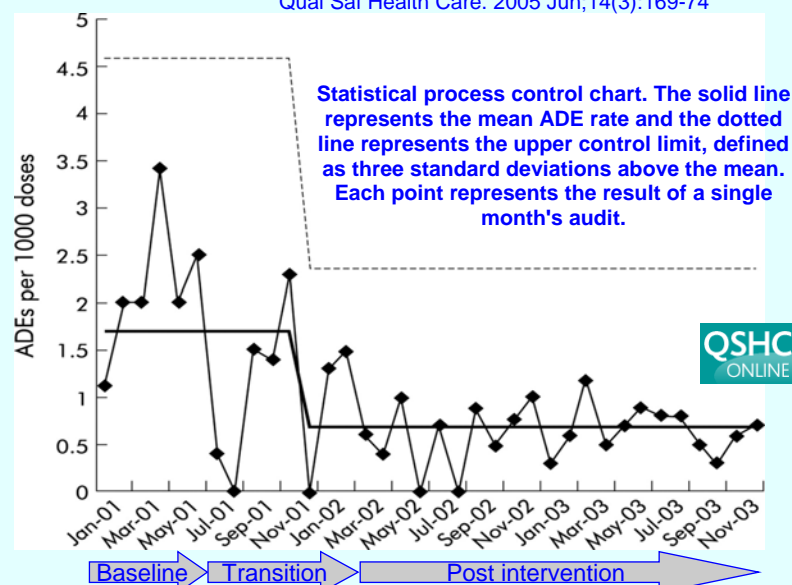


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Cohen MM, Kimmel NL, Benage MK, Cox MJ, Sanders N, Spence D, Chen J. **Medication safety program reduces adverse drug events in a community hospital.** Qual Saf Health Care. 2005 Jun;14(3):169-74

↓ Misuse :



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Fertleman M, Barnett N, Patel T. **Improving medication management for patients: the effect of a pharmacist on post-admission ward rounds.** Qual Saf Health Care. 2005 Jun;14(3):207-11.

↓ 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

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Fertleman M, Barnett N, Patel T. **Improving medication management for patients: the effect of a pharmacist on post-admission ward rounds.** Qual Saf Health Care. 2005 Jun;14(3):207-11.

↓ Overuse :

Table 2 Total cost of drugs on admission and discharge

	Annual cost of preadmission drugs	Predicted annual cost of discharge drugs	Difference between admission/discharge costs	Mean increase in annual medication cost post discharge per patient	% increase in drug costs between admission and discharge
Pre-intervention	£22625*	£32238	+£9613	£181	42.3%
Intervention	£30753	£36855	+£6102	£122	19.8%

*Value may not reflect patients full medication list due to poor drug history taking in this group.

Table 4 Cost of drugs stopped from admission to discharge

	No of patients	No of patients in whom drugs were stopped	No of drugs stopped	Predicted cost saving from drugs stopped per annum	Mean saving per patient per annum
Pre-intervention	50	3	5	£276	£5.52
Intervention	53	19	42	£4699	£88.60

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

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McConnell KJ, Humphries TL, Raebel MA, Merenich JA. **Clinical pharmacy specialist implementation of lisinopril therapy in patients with coronary artery disease and diabetes mellitus.** Pharmacotherapy. 2003 Dec;23(12):1564-72.

↓ 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 CPCR pharmacist
- **Outcome :** nb. of patients achieving optimal dosage of ACE inhibitor

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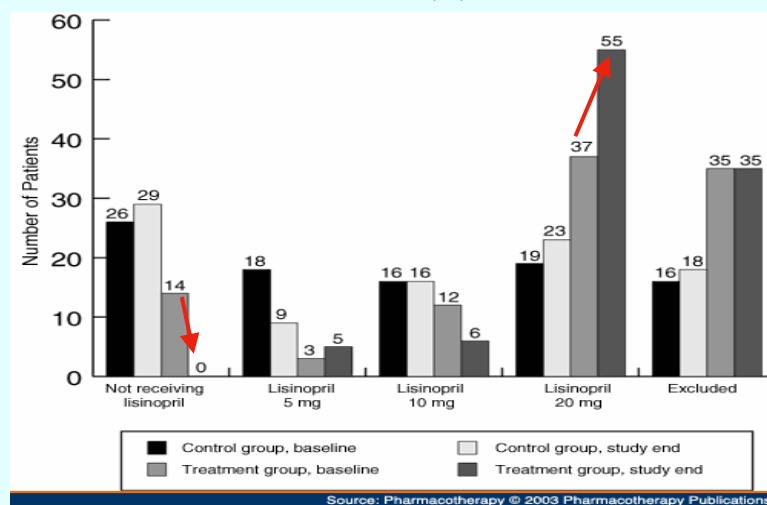


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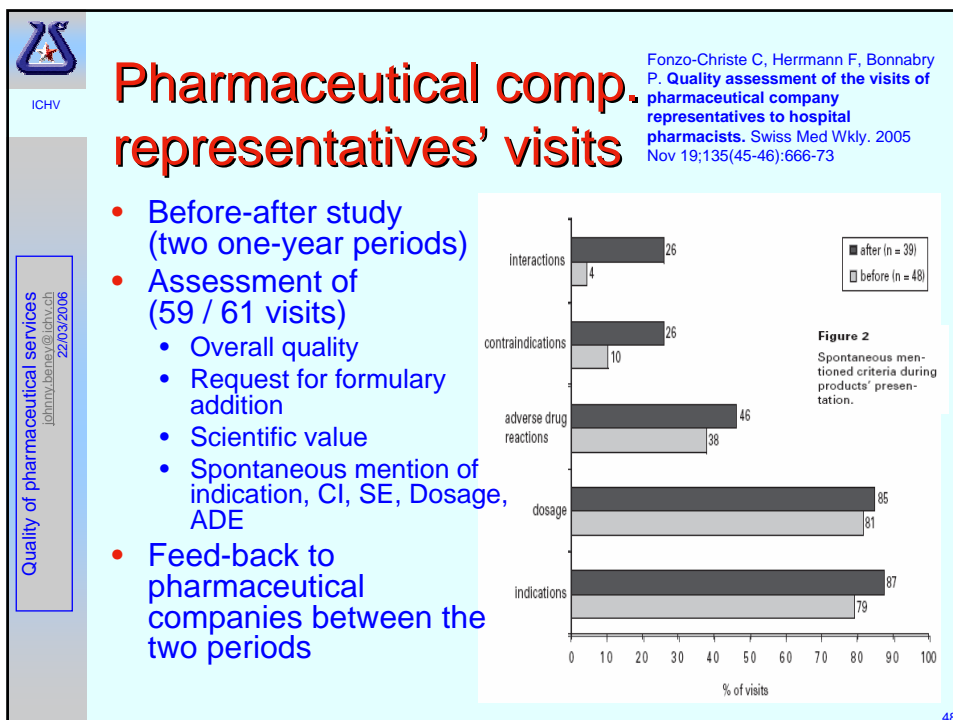
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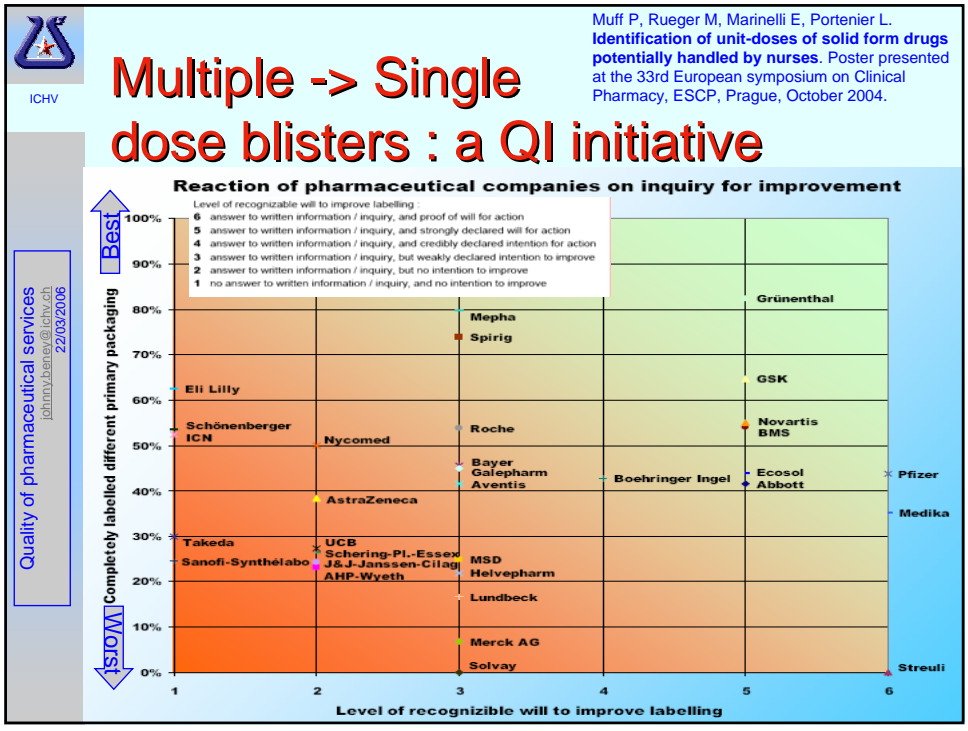
McConnell KJ, Humphries TL, Raebel MA, Merenich JA. **Clinical pharmacy specialist implementation of lisinopril therapy in patients with coronary artery disease and diabetes mellitus.** Pharmacotherapy. 2003 Dec;23(12):1564-72.

↓ Underuse :



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Single dose blister

Gamme

- 50 ou 100 gélules de 100 mg, 300 mg ou 400 mg

Nom commercial

- Similarité avec le nom DCI (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:

100 mg:

Gélules blanches taille 3

300 mg :

Gélules jaunes taille 1

400 mg:

Gélules oranges taille 0

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Look-alike : use of the GSASA forum

- Nalbuphine - Naloxone - Viviane Amos - ICHV 8/02/06
- Nalbuphine - Naloxone - Patrik Muff - HSF 8/02/06
- Nalbuphine - Naloxone - Patrik Muff - HSF 8/02/06
- Nalbuphine - Naloxone - Michela Pironi - Ospedale San Giovanni 8/02/06
- Nalbuphine - Naloxone - Fonzo-Christe Caroline - HUG 8/02/06
- Nalbuphine - Naloxone - Leu Marschler Ruth - Spital-Pharmazie 8/02/06
- Nalbuphine - Naloxone - Martinelli Enea - SpIt 8/02/06

Forum GSASA

Author: Viviane Amos
Institution: ICHV

Subject: Nalbuphine - Naloxone
Date: 2006-02-08 11:09:40

Bonjour à tous,

Suite au retrait du commerce de Narcan, nous avons pris en liste Naloxon Orpha. Actuellement, le retrait du commerce de Nubain nous oblige à prendre en liste le seul autre produit sur le commerce : Nalbuphin Orpha. Or, les emballages de Naloxon Orpha et Nalbuphine Orpha se ressemblent « comme deux gouttes d'eau » : même taille, même design, même couleur, induisant ainsi un risque de confusion. De plus, ces deux produits commencent par les trois lettres « Nal ».

Avez-vous pris en stock ces deux produits ? Comment avez-vous géré ce risque de confusion ?

Forum GSASA

Author: Leu Marschler Ruth
Institution: Spital-Pharmazie

Subject: Nalbuphine - Naloxone
Date: 2006-02-08 11:18:07

Wir haben beide Produkte an Lager und auch bereits bei der Firma interveniert.

Gemäss Antwort der Firma vom 25.01.06 ist sich die Firma des Problems in der Zwischenzeit bewusst geworden. Geänderte Packungen mit farblichen Unterscheidungen sind bereits von Swissmedic genehmigt worden und werden bei der nächsten Produktion verwendet werden.

Gesehen habe ich keine Verpackung hoffe aber, dass sich das Problem dadurch entschärfen wird.

Forum GSASA

Author: Fonzo-Christe Caroline
Institution: HUG


Subject: Nalbuphine - Naloxone
Date: 2006-02-08 11:49:06

Salut Viviane!

Nous avons comme tous vu le risque de confusion. Nous avons aussi fait un courrier au fabricant avec copie à Swissmedic. Pour l'instant, en attendant de voir les nouveaux emballages, nous avons reconditionné les emballages de Nalbuphine Orpha en emballages HUG et réétiqueté les ampoules. Nous avons également envoyé un avis avec photos couleur aux unités. Je te transmets volontiers une copie de ce document si tu le souhaites.

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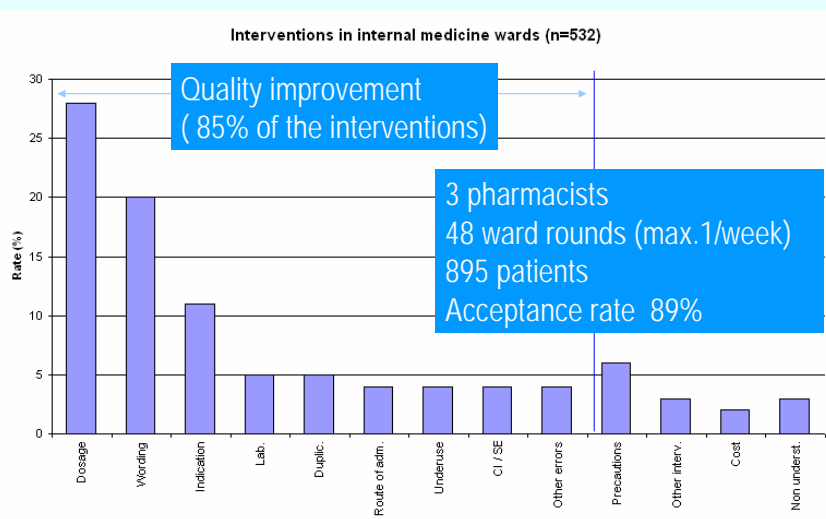
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Clinical pharmacy at ICHV

Ansermot N, Beney J, Marty S, Reymond J.Ph. Impact de la revue des Kardex et de l'intégration du pharmacien dans la visite médicale des départements de médecine. présenté au congrès GSASA, St-Gall, novembre 2003

Interventions in internal medicine wards (n=532)



Quality of pharmaceutical services
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Presentation outline

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

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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.

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Conclusion

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

Yes..., but...

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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.

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Thanks for your attention !