



# Guidelines and standards: a methodological perspective

Veerle Foulon  
KU Leuven - Belgium

# Introduction



- Who has used SOPs when doing lab exercises?
- Who has used SOPs when compounding?
- Who has learned to work with pharmacotherapeutic guidelines (asthma, COPD,...)
- Who has learned to work with guidelines for pharmaceutical care processes?
- Who has developed pharmacotherapeutic guidelines with focus on the role of the pharmacist?
- Who has developed guidelines on pharmaceutical care processes?

# Goal of this contribution

- Overview of methods that can be used to develop guidelines
- Where we are in Belgium
- Methodology used for developing guidelines on 'self care' or dispensing of non-prescription drugs
- Methodology for defining interventions in 'new' areas

# Definition of guidelines

“Systematically developed statements to ***assist*** practitioner and patient decisions about appropriate health care for specific clinical circumstances”

# Definition of quality of care

- **Quality of care**

= the degree to which health services for individuals and populations increases the probability of desired health outcomes and is consistent with current professional knowledge<sup>1,2</sup>



# 6 dimensions of quality from IOM <sup>1</sup>

- **Safe** Prevent complications
- **Effective** Provide care based on scientific knowledge that benefit patient.
- **Patient-centered** Focus on specific patient needs
- **Timely** Reducing waits and sometimes harmful delays
- **Efficient** Avoiding waste (including waste of equipment, supplies, ...)
- **Equitable** No distinction in gender, ethnicity, geographic location, ...



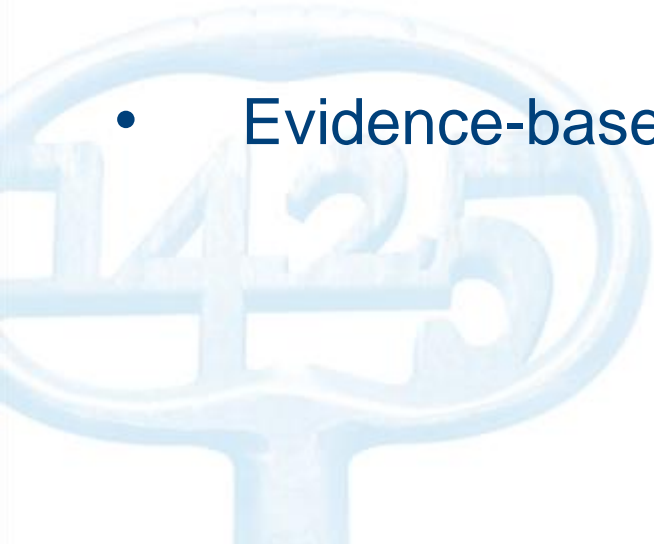
## Methodology for guideline development

# How to develop guidelines?



Three 'classical' methods:

- GOBSAT method
- Consensus-based guidelines
- Evidence-based guidelines





# GOBSAT method

*'Good Old Boys Sat At a Table'*



- Group of experts meeting informally (mostly without systematic review of the literature) to develop guidelines based on own clinical expertise and experience
- Group process is an important element
- Not very transparent:
  - No explicit decision process
  - Difficult for the reader to figure out how the guideline was developed

# Consensus-based guidelines

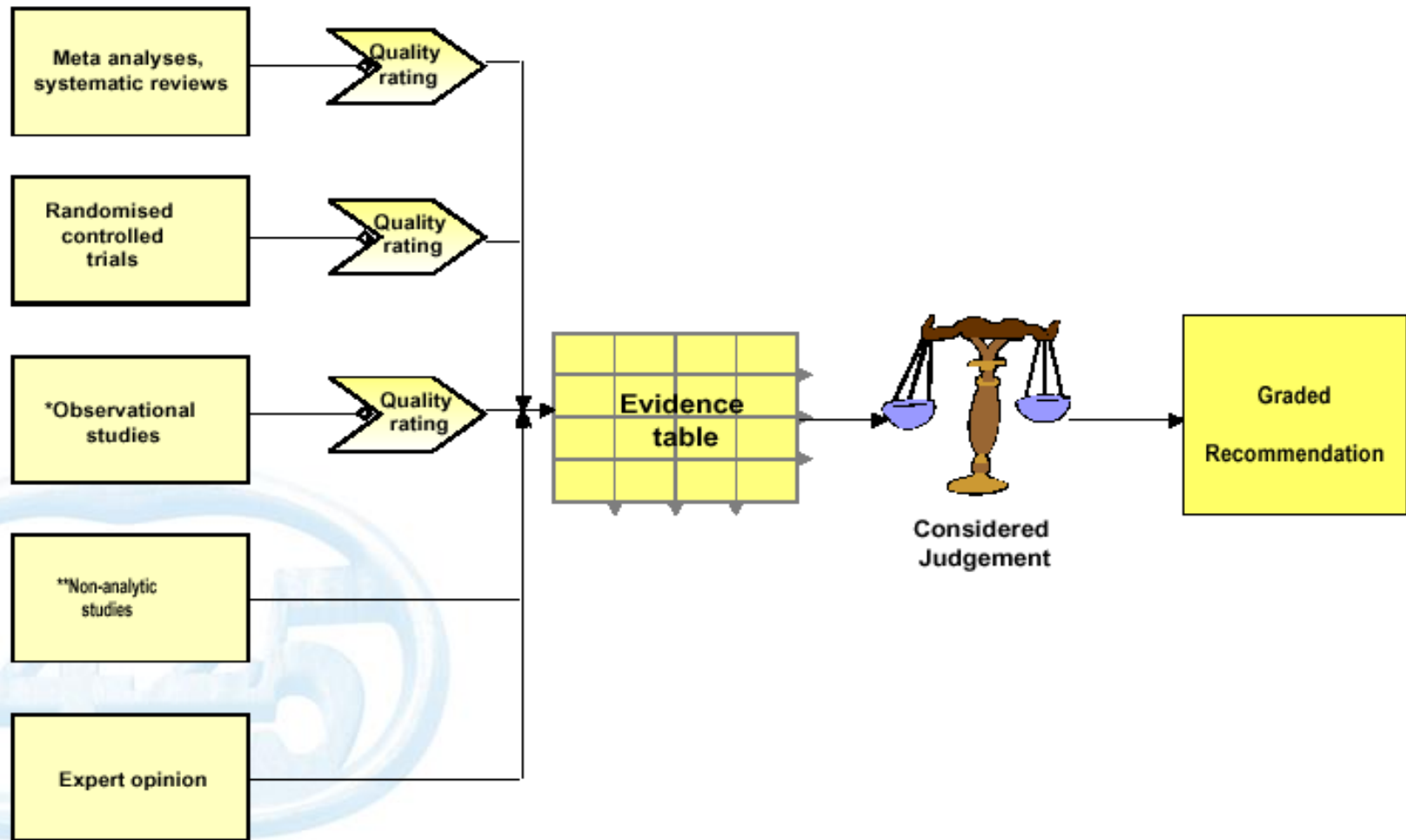


- Group of experts meet formally to develop guidelines, based on expert opinion
- Use of formal consensus techniques (e.g. Delphi technique)
- Cave:
  - No clear distinction between statements supported by evidence and statements not supported by evidence
  - Experts may be wrong

# Evidence-based guidelines

- Basis = (clinical) evidence, obtained through a systematic search of the literature
- Be careful: level of evidence may vary
- HCPs need good reasons not to comply with guidelines based on good RCTs and / or meta-analyses; but they have a large level of freedom not to comply with guidelines based on weak evidence

# Development of evidence-based guidelines



# Development of evidence-based guidelines

Grade of Recommendation	Level of Evidence	Therapy/Prevention, Aetiology/Harm
<b>A</b>	<b>1a</b>	<b>Systematic Review</b> of Randomised Controlled Trials (RCT)
	<b>1b</b>	Individual <b>RCT</b> (with narrow confidence interval)
	<b>1c</b>	All or none cohort study
<b>B</b>	<b>2</b>	At least one high quality <b>cohort</b> study
	<b>3</b>	At least one high quality <b>case-control</b> Study
<b>C</b>	<b>4</b>	<b>Case-series</b> (and poor quality cohort and case-control studies)
<b>D</b>	<b>5</b>	<b>Expert opinion</b> without explicit critical appraisal, or based on physiology, bench research or “first principles”

# Development of evidence-based guidelines

Table 11: Modified GRADE quality assessment criteria

Quality of evidence	Study design	Lower if*	Higher if*
High	Randomised trial	<b>Study quality:</b> -1-Serious limitations -2-Very serious limitations -1-Important <b>inconsistency</b> <b>Directness:</b> -1-Some uncertainty -2-Major uncertainty -1- <b>Sparse data</b> -1-High probability of <b>Reporting bias</b>	<b>Strong association:</b> +1-Strong, no plausible confounders, consistent and direct evidence** +2-Very strong, no major threats to validity and direct evidence*** +1-Evidence of a <b>Dose response</b> gradient +1-All <b>plausible confounders</b> would have reduced the effect
Moderate	Quasi-randomised trial		
Low	Observational study		
Very low	Any other evidence		

\* 1 = move up or down one grade (for example from high to moderate)

2 = move up or down two grades (for example from high to low)

The highest possible score is High (4) and the lowest possible score is Very low (1). Thus, for example, randomised trials with a strong association would not move up a grade.

\*\* A relative risk of  $>2$  ( $< 0.5$ ), based on consistent evidence from two or more observational studies, with no plausible confounders

\*\*\* A relative risk of  $> 5$  ( $< 0.2$ ) based on direct evidence with no major threats to validity

# ADAPTE



Step 1

Define the clinical questions

Step 2

Search for source guidelines

Step 3

Screen retrieved guidelines

Step 4

Assess selected source guidelines:  
Quality, consistency, applicability

Step 5

Adapt recommendations to context of use

Step 6

External review

Step 7

Adoption/endorsement and implementation

# AGREE instrument

- 23 items
- 6 domains
  - Scope and purpose
  - Stakeholder involvement
  - Rigour of development
  - Clarity of presentation
  - Applicability
  - Editorial independence



AGREE



## RIGOUR OF DEVELOPMENT

9. The strengths and limitations of the body of evidence are clearly described.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree
------------------------	---	---	---	---	---	---------------------

*Comments*

### User's Manual Description:

Statements highlighting the strengths and limitations of the evidence should be provided. This ought to include explicit descriptions - using informal or formal tools/methods - to assess and describe the risk of bias for individual studies and/or for specific outcomes and/or explicit commentary of the body of evidence aggregated across all studies. This may be presented in different ways, for example: using tables commenting on different quality domains; the application of a formal instrument or strategy (e.g., Jadad scale, GRADE method); or descriptions in the text.

## Where to Look:

---

Examine the paragraphs/chapters describing the guideline development process for information on how the methodological quality of the studies (e.g., risk of bias) were described. Evidence tables are often used to summarize quality features. Some guidelines make a clear distinction between description and interpretation of evidence, for instance, in a results section and a discussion section, respectively.

## How to Rate:

---

### Item content includes the following *CRITERIA*:

- descriptions of how the body of evidence was evaluated for bias and how it was interpreted by members of the guideline development group
- aspects upon which to frame descriptions include:
  - study design(s) included in body of evidence
  - study methodology limitations (sampling, blinding, allocation concealment, analytical methods)
  - appropriateness/relevance of primary and secondary outcomes considered
  - consistency of results across studies
  - direction of results across studies
  - magnitude of benefit versus magnitude of harm
  - applicability to practice context

### Additional *CONSIDERATIONS*:

- Is the item well written? Are the descriptions clear and concise?
- Is the item content easy to find in the guideline?
- Are the descriptions appropriate, neutral, and unbiased? Are the descriptions complete?

# Definition of guidelines

“Clinical practice guidelines are statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options.”

# EB-guidelines: is this always possible?

- Pharmacotherapeutic guidelines: yes
  - Guidelines on 'self care': ?
  - Pharmacotherapeutic guidelines with explicit role of (community) pharmacist: sometimes
  - Guidelines on general pharmaceutical care processes: ?
- Own experience: recommendations on seamless care



## Approaches for improving continuity of care in medication management: a systematic review.

Spinewine A<sup>1</sup>, Claeys C, Foulon V, Chevalier P.

### Author information



### Abstract

**PURPOSE:** Medication-related problems frequently occur during transitions and lead to patient harm, increased use of healthcare resources and increased costs. The objective of this systematic review is to synthesize the impact of approaches to optimize the continuity of care in medication management upon hospital admission and/or discharge.

**DATA SOURCES:** MEDLINE, EMBASE, CINAHL, IPA and the Cochrane Database of Systematic Reviews from 1995 through December 2010.

**STUDY SELECTION:** Controlled, parallel-group trials. Data extraction Data were extracted by one researcher and checked by another. Both reviewers independently assessed the study quality.

**RESULTS:** Thirty studies met the inclusion criteria, but only 14 reached the predefined minimum quality score. Most studies focused on discharge and targeted the patients, sometimes together with primary care providers. The majority of studies found improvements in process measures. Patient education and counseling provided upon discharge and reinforced after discharge, sometimes together with improved communication with healthcare professionals, was shown to reduce the risk of adverse drug events and hospital re-admissions in some studies, but not all. Heterogeneity in study population as well as in intervention and outcome reporting precluded meta-analysis and limited interpretation. Most studies had important methodological limitations and were underpowered to show significant benefits on clinical outcomes.

**CONCLUSIONS:** The evidence for an impact of approaches on optimization of continuity of care in medication management remains limited. Further research should better target high-risk populations, use multicentered designs and have adequate sample size to evaluate the impact on process measures, clinical outcomes and cost-effectiveness.

**KEYWORDS:** continuity of patient care, medication errors, medication therapy management, quality improvement, systematic review

## **Initiatives promoting seamless care in medication management: an international review of the grey literature.**

Claeys C, Foulon V, de Winter S, Spinewine A.

### **Abstract**

**BACKGROUND:** Patients' transition between hospital and community is a high-risk period for the occurrence of medication-related problems.

**AIM OF THE REVIEW:** The objective was to review initiatives, implemented at national and regional levels in seven selected countries, aiming at improving continuity in medication management upon admission and hospital discharge.

**METHOD:** We performed a structured search of grey literature, mainly through relevant websites (scientific, professional and governmental organizations). Regional or national initiatives were selected. For each initiative data on the characteristics, impact, success factors and barriers were extracted. National experts were asked to validate the initiatives identified and the data extracted.

**RESULTS:** Most initiatives have been implemented since the early 2000 and are still ongoing. The principal actions include: development and implementation of guidelines for healthcare professionals, national information campaigns, education of healthcare professionals and development of information technologies to share data across settings of care. Positive results have been partially reported in terms of intake into practice or process measures. Critical success factors identified included: leadership and commitment to convey national and local forces, tailoring to local settings, development of a regulatory framework and information technology support. Barriers identified included: lack of human and financial resources, questions relative to responsibility and accountability, lack of training and lack of agreement on privacy issues.

**CONCLUSION:** Although not all initiatives are applicable as such to a particular healthcare setting, most of them convey very interesting data that should be used when drawing recommendations and implementing approaches to optimize continuity of care.



Belgium: where are we?

# Belgium: where are we?

- Monodisciplinary guidelines developed by
  - Domus Medica / SSMG (GPs)
  - APB / SSPF-IPSA / VAN (Pharmacists)
  - AXXON (Physiotherapists)
  - CIPIQ'S (Nurses)
  - ...
- Adaptation of Duodecim guidelines
- Platform 'Working group guidelines for primary care'
- First steps towards multidisciplinary guidelines (2 guidelines to be developed by 2015)





## VISIE en DOEL Werkgroep ontwikkeling richtlijnen eerste lijn

Sinds meer dan 15 jaar worden in België richtlijnen ontwikkeld. Er werd een belangrijke expertise opgebouwd binnen de commissie aanbevelingen van Domus Medica vzw en ook binnen andere beroepsgroepen en organisaties. De ontwikkelde richtlijnen krijgen internationaal aandacht via netwerken zoals GIN en door de samenwerking met andere guideline-ontwikkelaars zoals NHG.

### Visie

We hanteren de volgende definitie van richtlijnen: *"Clinical practice guidelines are statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options."* (Institute of Medicine (IOM) 2011)<sup>1</sup>.

Richtlijnen zijn essentieel als referentiepunt om op evidentie gebaseerde kwaliteit van zorg te bereiken. Daartoe moeten deze in voldoende mate ontwikkeld en geupdated worden. Richtlijnen kunnen maar een referentiepunt zijn indien ze ontwikkeld en/of geadapteerd worden aan de lokale context/gezondheidszorg.

Het ontwikkelen en het updaten van richtlijnen is een kernactiviteit van deze werkgroep en de betrokken partners.



# Belgium: where are we?

- Monodisciplinary 'guidelines' developed by APB / SSPF-IPSA / VAN (Pharmacists)
  - disease-specific guidelines: role of the pharmacist
  - new medicines' service: asthma



[Eur Respir J](#). 2008 Apr;31(4):790-9. Epub 2007 Dec 19.

## **Effectiveness of pharmacist intervention for asthma control improvement.**

[Mehuys E<sup>1</sup>](#), [Van Bortel L](#), [De Bolle L](#), [Van Tongelen I](#), [Annemans L](#), [Remon JP](#), [Brusselle G](#).

### **Author information**



### **Abstract**

Education on optimal medication use is an essential strategy to improve asthma control. The current authors investigated whether pharmacist interventions, focused on appropriate use of asthma medication and tailor-made to the patient's current asthma control, would improve asthma control in adult patients. A 6-month randomised, controlled, parallel-group trial was conducted in 66 community pharmacies in Belgium. Patients were randomly assigned to receive usual pharmacist care (n = 94) or a pre-defined pharmacist intervention (n = 107). This intervention mainly focused on improving inhalation technique and medication adherence. Primary outcome was the level of asthma control, as assessed by the Asthma Control Test (ACT). Mean ACT scores did not change from baseline for both study groups. However, a pre-defined subgroup analysis of patients having insufficiently controlled asthma at baseline showed that the intervention had significantly increased the ACT score after 6 months compared with usual care. The intervention also reduced, for the complete study group, reliever medication use and the frequency of night-time awakenings due to asthma. Inhalation technique and adherence to controller medication were significantly better in the intervention group. In conclusion, pragmatic community pharmacy-based programmes can significantly improve therapeutic outcomes in adult asthma patients.

### **Comment in**

Pharmacist interventions in asthma. [[Eur Respir J](#). 2008]

# Belgium: where are we?

- Monodisciplinary 'guidelines' developed by APB / SSPF-IPSA / VAN (Pharmacists)
  - disease-specific guidelines: role of the pharmacist
  - new medicines' service: asthma
  - guidelines for 'self-care'





Methodology used for development of 'self care' guidelines

# Guidelines for 'self care'



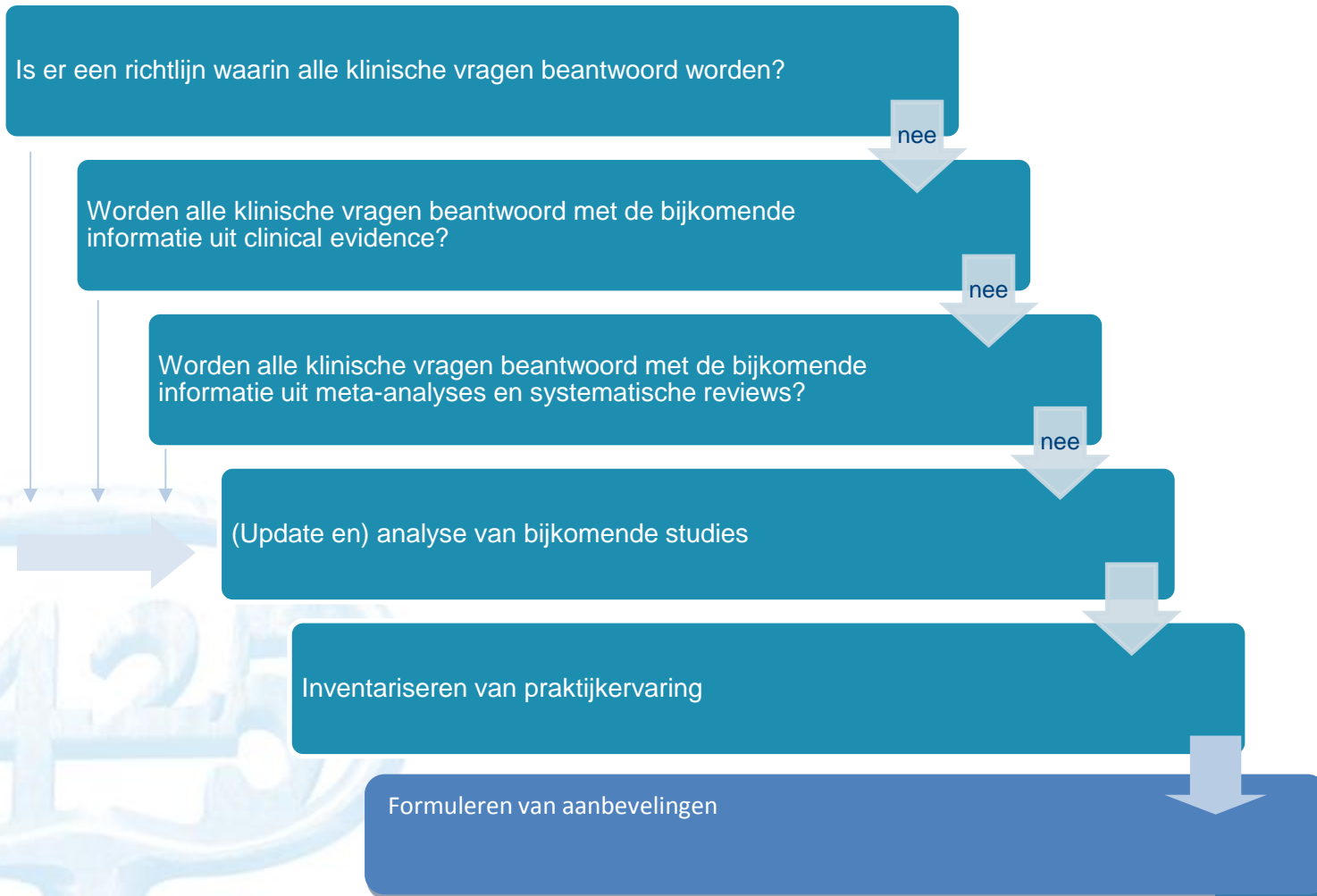
# Guidelines for 'self care'



- Who has guidelines for 'self care' / dispensing of non-prescription drugs in his/her country?



# Methodology





# Why guidelines for 'self care'?

- Aim: to support pharmacists in their role as experts in counseling on non-prescription drugs
- Result:

Pharmacists recognized as experts



added value compared to other distribution channels clear



reliable partner in the first approach of patients with minor complaints

# Methodology

Is there a guideline in which all clinical questions are answered?

Step 1: Search for existing guidelines

Via CEBAM-website: Domus Medica, NHG, EMBPracticeNet, Prodigy, NGC, ...

Are all clinical questions answered with additional evidence from clinical evidence?

Step 2: Search Clinical Evidence.

Via CEBAM-website: BMJ Evidence Centre

# Methodology

Are all clinical questions answered with additional information from meta-analyses and systematic reviews?

Step 3: Recent, relevant meta-analyses and reviews.  
Via Cochrane, Medline, Embase.

(Update and) analysis of additional studies

Step 4: Additional RCT's and observational studies (if needed).  
Via Medline, Embase.

# Methodology

## Inventarisation of practice experience

Step 5: Validation of the guideline by a panel of experts

- ✓ 2 specialized physicians
- ✓ 2 GP's
- ✓ 10 community pharmacists


## Recommendations

Step 6: Evaluation of feedback + adaptations (if needed)

# Methodology

- For some topics: very difficult to find evidence
- Quite often: rather weak evidence



**Display Settings:**  Summary, 20 per page, Sorted by Recently Added**Send to:** **Filter your results:****Results: 1 to 20 of 206**

&lt;&lt; First &lt; Prev Page 1 of 11 Next &gt; Last &gt;&gt;

- [Treatment of diarrhea-predominant irritable bowel syndrome with mesalazine and/or \*\*Saccharomyces boulardii\*\*.](#)

Bafutto M, Almeida JR, Leite NV, Costa MB, Oliveira EC, Resende-Filho J. *Arq Gastroenterol.* 2013 Oct-Dec;50(4):304-9. doi: 10.1590/S0004-28032013000400012. PMID: 24474234 [PubMed - in process] **Free Article**  
[Related citations](#)

- [Prevention and treatment of diarrhoea with \*\*Saccharomyces boulardii\*\* in children with acute lower respiratory tract infections.](#)

Shan LS, Hou P, Wang ZJ, Liu FR, Chen N, Shu LH, Zhang H, Han XH, Han XX, Cai XX, Shang YX, Vandenplas Y. *Benef Microbes.* 2013 Dec 1;4(4):329-34. doi: 10.3920/BM2013.0008. PMID: 24311316 [PubMed - in process]  
[Related citations](#)

- [Management strategies in the treatment of neonatal and pediatric gastroenteritis.](#)

- 3. Ciccarelli S, Stolfi I, Caramia G. *Infect Drug Resist.* 2013 Oct 29;6:133-161. eCollection 2013. Review. PMID: 24194646 [PubMed - as supplied by publisher] **Free PMC Article**  
[Related citations](#)

All (206)

[Clinical Trial \(43\)](#)[English \(179\)](#)[Humans \(159\)](#)[Published in the last 5 years \(60\)](#)[Review \(62\)](#)[Systematic Review \(20\)](#)[Nederlandstalig / Articles in Dutch \(0\)](#)[Belgium as Topic \(MeSH\) \(0\)](#)[Articles from KU Leuven OR UZ Leuven authors \(2\)](#)[Manage Filters](#)**New feature** 

Try the new Display Settings option - Sort by Relevance

PubMed

saccharomyces boulardii and diarrhea

Search

[RSS](#) [Save search](#) [Advanced](#)[Help](#)**Display Settings:**  Summary, 20 per page, Sorted by Recently Added**Send to:** **Filter your results:****Results: 20**

- [Effectiveness and safety of \*Saccharomyces boulardii\* for acute infectious diarrhea.](#)
  1. Dinleyici EC, Eren M, Ozen M, Yargic ZA, Vandenplas Y. Expert Opin Biol Ther. 2012 Apr;12(4):395-410. doi: 10.1517/14712598.2012.664129. Epub 2012 Feb 16. Review. PMID: 22335323 [PubMed - indexed for MEDLINE] [Related citations](#)
  
- [Probiotics for the prevention of pediatric antibiotic-associated diarrhea.](#)
  2. Johnston BC, Goldenberg JZ, Vandvik PO, Sun X, Guyatt GH. Cochrane Database Syst Rev. 2011 Nov 9;(11):CD004827. doi: 10.1002/14651858.CD004827.pub3. Review. PMID: 22071814 [PubMed - indexed for MEDLINE] [Related citations](#)
  
- [Meta-analysis: the effects of \*Saccharomyces boulardii\* supplementation on \*Helicobacter pylori\* eradication rates and side effects during treatment.](#)
  3. Szajewska H, Horvath A, Piwowarczyk A. Aliment Pharmacol Ther. 2010 Nov;32(9):1069-79. doi: 10.1111/j.1365-2036.2010.04457.x. Epub 2010 Sep 16. Erratum in: Aliment Pharmacol Ther. 2010 Dec;32(11-12):1408. PMID: 21039671 [PubMed - indexed for MEDLINE] [Related citations](#)

[All \(206\)](#)[Clinical Trial \(43\)](#)[English \(179\)](#)[Humans \(159\)](#)[Published in the last 5 years \(60\)](#)[Review \(62\)](#)[Systematic Review \(20\)](#)[Nederlandstalig / Articles in Dutch \(0\)](#)[Belgium as Topic \(MeSH\) \(0\)](#)[Articles from KU Leuven OR UZ Leuven authors \(2\)](#)[Manage Filters](#)**New feature**

Try the new Display Settings option - Sort by Relevance

**KU LEUVEN**

**AUTHORS' CONCLUSIONS:** Despite heterogeneity in probiotic strain, dose, and duration, as well as in study quality, the overall evidence suggests a protective effect of probiotics in preventing AAD. Using 11 criteria to evaluate the credibility of the subgroup analysis on probiotic dose, the results indicate that the subgroup effect based on dose ( $\geq 5$  billion CFU/day) was credible. Based on high-dose probiotics, the number needed to treat (NNT) to prevent one case of diarrhea is seven (NNT 7; 95% CI 6 to 10). However, a GRADE analysis indicated that the overall quality of the evidence for the primary endpoint (incidence of diarrhea) was low due to issues with risk of bias (due to high loss to follow-up) and imprecision (sparse data, 225 events). The benefit for high dose probiotics (*Lactobacillus rhamnosus* or *Saccharomyces boulardii*) needs to be confirmed by a large well-designed randomized trial. More refined trials are also needed that test strain specific probiotics and evaluate the efficacy (e.g. incidence and duration of diarrhea) and safety of probiotics with limited losses to follow-up. It is premature to draw conclusions about the efficacy and safety of other probiotic agents for pediatric AAD. Future trials would benefit from a standard and valid outcomes to measure AAD.

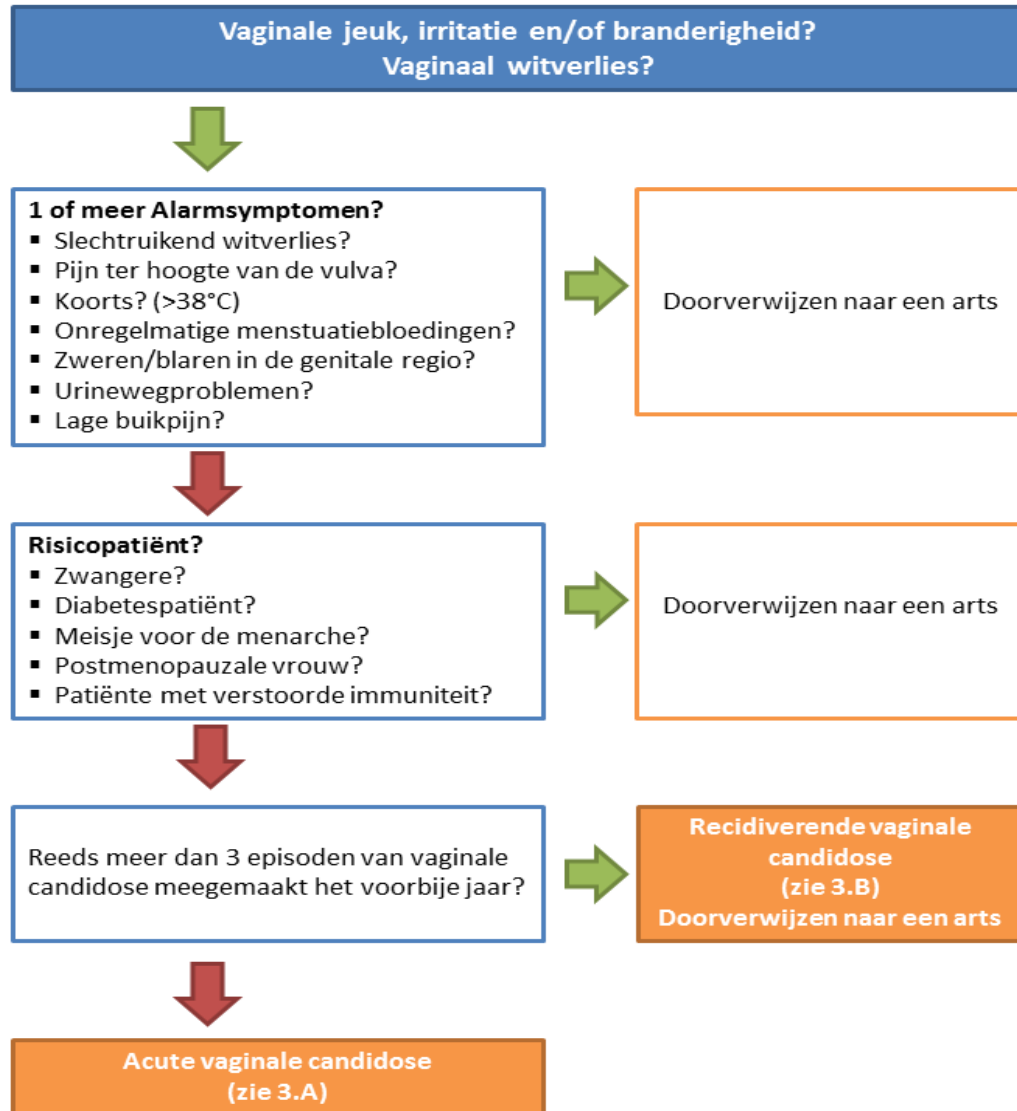
### **Update of**

[Cochrane Database Syst Rev. 2007;\(2\):CD004827.](#)

PMID: 22071814 [PubMed - indexed for MEDLINE]



# Flow charts



# Flow charts

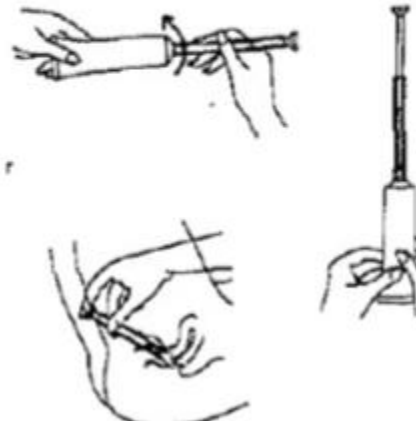
	Niet-Medicamenteus	Medicamenteus
<b>Acute Vaginale Candidose</b>	<ul style="list-style-type: none"><li>▪ Houd de vaginale flora zo goed mogelijk in stand. (4.A)<ul style="list-style-type: none"><li>✓ Vermijd het gebruik van zeep.</li><li>✓ De vagina hoeft niet vaker dan nodig gereinigd te worden.</li></ul></li><li>▪ Creëer een ongunstig milieu voor schimmels en gisten. (4.B)<ul style="list-style-type: none"><li>✓ Vermijd strakke, synthetische (onder)broeken.</li><li>✓ Beperk het gebruik van inlegkruisjes.</li></ul></li></ul>	<ul style="list-style-type: none"><li>▪ Lokale behandeling met antimycotica. (5.A) Deze preparaten dienen steeds voldoende lang gebruikt te worden. Vette excipiënten, aanwezig in vaginale crèmes en ovules, kunnen de kwaliteit van condooms en pessaria aantasten.</li><li>▪ Voorschriftplichtige, orale behandeling met antimycotica.</li></ul>
<b>Recidiverende Vaginale Candidose</b> <b>Preventie</b>	<ul style="list-style-type: none"><li>▪ Houd de vaginale wand zo goed mogelijk in tact. (4.C)<ul style="list-style-type: none"><li>✓ Cave tampons en vaginale droogte tijdens de geslachtsgemeenschap.</li></ul></li></ul>	
<b>Recidiverende Vaginale Candidose</b> <b>Behandeling</b>	<ul style="list-style-type: none"><li>▪ Vermijd overdracht van intestinale bacteriën naar de vagina. (4.D)<ul style="list-style-type: none"><li>✓ Vermijd het dragen van strings.</li><li>✓ Veeg na ontlasting steeds van de vagina richting de anus.</li></ul></li></ul>	<ul style="list-style-type: none"><li>▪ Doorverwijzen naar een arts. De behandeling bestaat meestal uit een inductiefase en een onderhoudsfase. Hierbij is therapietrouw erg belangrijk.</li></ul>

# Patient information

## PATIËNTENINFORMATIE

### 7.A. APPLICATIE VAN EEN VAGINALE CRÈME

- Was de handen voor gebruik.
- Breng de crème 's avonds aan voor het slapengaan. Neerliggen voorkomt lekkage van de crème.
- Open de verzegeling van de tube en draai de applicator op de tube.
- Vul de applicator met crème door onderaan op de tube te duwen. Het binnenste deel van de huls schuift nu naar buiten. Verwijder de applicator van de tube wanneer de eindmarkering bereikt is.
- Lig op je rug met opgetrokken en gespreide knieën. Breng een beetje crème aan vooraan op de applicatorhuls, dit bevordert het inbrengen.
- Spreid de schaamlippen met de ene hand en breng met de andere hand het uiteinde van de buitenste huls zo diep mogelijk in de vagina.
- Duw langzaam op het binnenste deel van de applicator en tracht de crème zo volledig mogelijk in te brengen.
- Verwijder de applicator uit de vagina.
- Indien nodig kan een maandverband of inlegkruisje gebruikt worden om lekkage op te vangen.
- De bijgevoegde applicatoren zijn steeds wegwerp-applicatoren en worden niet opnieuw gebruikt. Dit om herbesmetting te voorkomen.
- Houd de therapie voldoende lang vol zoals aangeraden door je arts of apotheker.
- Hou er rekening mee dat crèmes en ovules de werking van condooms en pessaria verminderen en dit tot 3 dagen na stopzetting van de behandeling.



# What has been developed?

- Problems of eye and eyelid
- Vaginal candidiasis
- Diarrhea
- Constipation
- Gastric distress (reflux, dyspepsia, nausea, vomiting)
- Anorectal complaints





## Adaptation of Duodecim-guidelines

# Adaptation of Duodecim guidelines

- Finnish guidelines for GPs
- Translated to French and Dutch
- Adaptation needed
  
- Rigorous process
- Follows Adapte procedure



# Example Duodecim guideline

## Hordeolum and chalazion

EBM Guidelines

2.12.2013 • Latest change 2.12.2013

Tero Kivela

- [Essentials](#)
- [Epidemiology](#)
- [Symptoms and findings](#)
- [Differential diagnosis](#)
- [Treatment](#)
- [Criteria for referral](#)

### Essentials

- A hordeolum develops when a sebaceous gland in the lid margin (gland of Zeis, leading to external hordeolum or stye) or in the tarsus (meibomian gland, leading to internal hordeolum) becomes acutely infected.
- The most common causative agent is *Staphylococcus aureus*.
- When the glandular duct, either due to a hordeolum or otherwise, becomes obstructed and the glandular secretions are released into the adjacent tissues forming a lipogranuloma, a chalazion is developed.
- The granulation tissue may form a wattle-like pyogenic granuloma on the conjunctival side at the site of the chalazion.

# Adapte: example

STAP 5 Selectie van aanbevelingen voor verdere adaptatie				
Titel Duodecim richtlijn: Hordeolum and chalazion				
Internationale richtlijnen en Belgische informatie waarmee werd vergeleken: 1. CKS Hordeolum; 2. CKS Chalazion				
Algemene opmerkingen Duodecim-richtlijn die van belang zijn bij eventuele adaptatie: In de Duodecim worden geen graden van aanbeveling / evidentie vermeld. Er worden bovendien geen referenties gegeven.				
BESLUIT				
	Aanbeveling uit de Duodecim guideline	Aanbeveling adapteren? Ja/nee	Richtlijn/EBM-informatie geselecteerd voor adaptatieproces [Vermeld hier de bronnen/referenties waarmee je rekening hebt gehouden bij je besluit om al dan niet te adapteren.]	Commentaar - toelichting bij gemaakte keuzes
Klinische vraag 1: Wat zijn de symptomen van een hordeolum?	Lokale zwelling van de oogleden, roodheid en gevoeligheid (intern en extern hordeolum). Een extern hordeolum bevat geelgekleurd pus.	Ja	CKSHordeolum	
Klinische vraag 2: Wat zijn de	Vast onderhuids knobbeltje onder het bovenste ooglid. Ontstaat meestal vanuit een	Ja	CKSChalazion	Omachrijving / ophijting van symptomen zou gestructureerder kunnen. Best ook effect op visus vermelden.

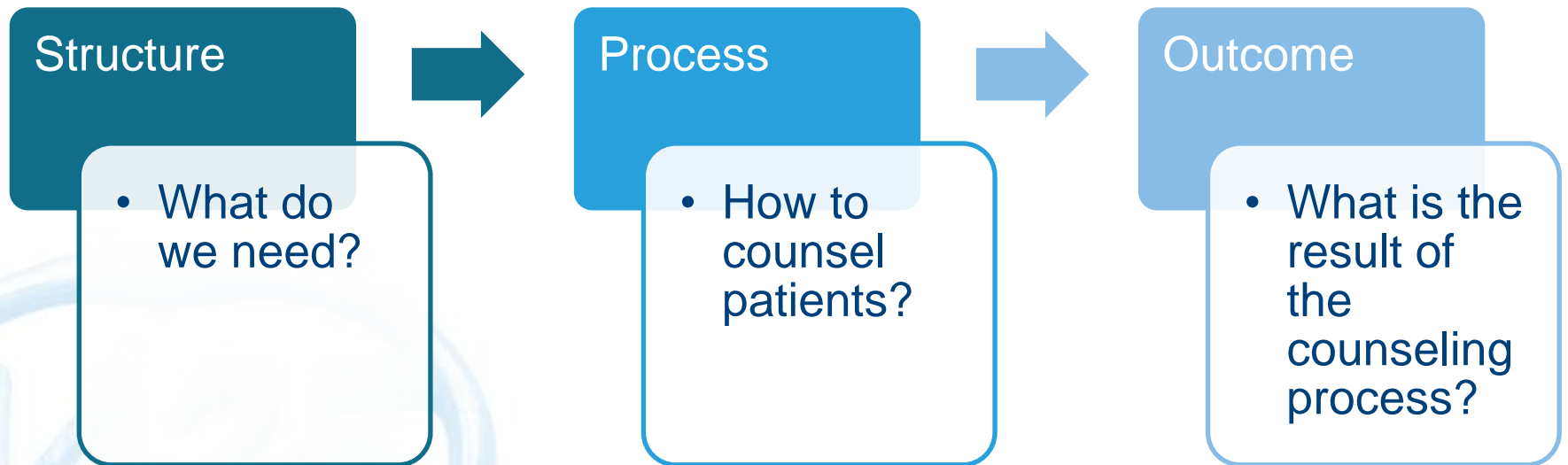




Methodology used for development of guidelines in new area's

# Development of interventions / process indicators in new area's

- Counseling patients on oral anti-cancer drugs



# Methodology

- Based on research projects + literature
  - Proposal of recommendations / process indicators
  - Validation by experts (Delphi-technique)

‘To which extent does this indicator say something about the quality of care’?

2-round Delphi-approach; indicators were considered ‘valid’ if > 80 % of respondents answered ‘to a very large extent’ or ‘to a large extent’
  - Validation by a patient panel: ongoing

# Methodology

- Validation by experts:

Profession	Number
Hospital pharmacist	6
Nurse	6
Oncologist	4
Onco-coach	2
Psychologist	1
PhD Student	1

Tabel: Overzicht

# Procesindicatoren: overview

Theme	Start number of QI's	Added in D1	Final set of QI	
			ORIGINAL	NEW
Coordination of care	10	14	6	7
Communication with the patient: style, structure and content	16	4	12	3
Education: structure and content	13	7	7	5
Start-up of medication: use of the medication, adherence and side-effects	21	1	15	4
Follow-up of medication use	15	7	15	3
Psychosocial support	14	2	9	1
Involvement of family and friends	6	4	5	0
<b>Total number of QI's</b>	<b>95</b>	<b>39</b>	<b>69</b>	<b>23</b>

# Questions? Comments?



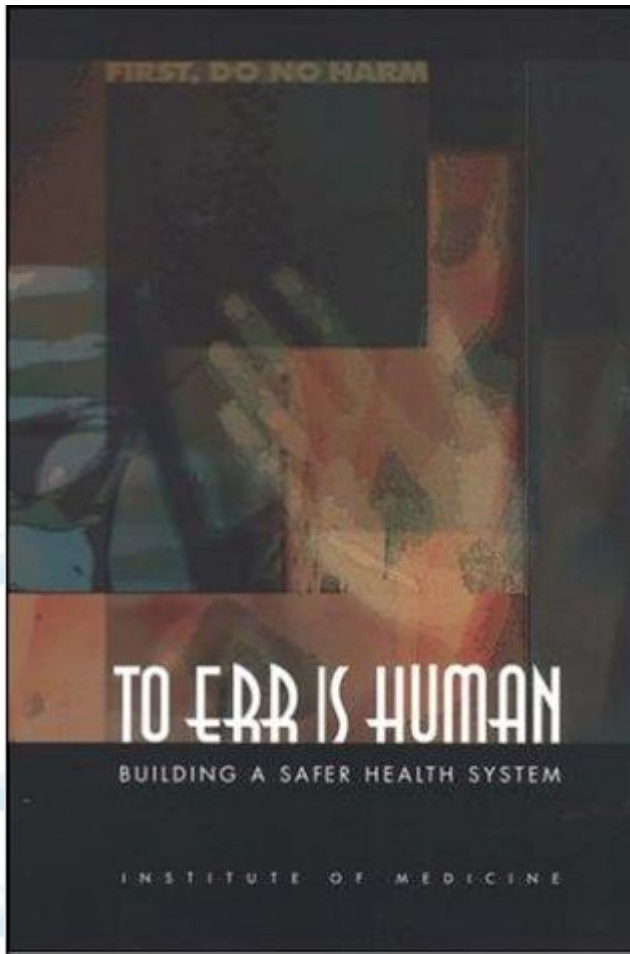
# Introduction

- 6 important dimensions in quality of care
- How to measure quality of care?
- Validation of quality indicators
- Literature on quality indicators
- What is a “care pathway”?
- Practical tips to develop quality indicators

# 6 Important dimensions to measure quality of care

**November 1999**

## **Safety in healthcare**



- 44,000 to 98,000 deaths annually in hospitals due to medical errors.
- The Institute of Medicine report made it painfully clear, the health care system itself was between the fifth and ninth leading cause of death in the United States.



# 6 dimensions of quality from IOM <sup>1</sup>

- **Safe** Prevent complications
- **Effective** Provide care based on scientific knowledge that benefit patient.
- **Patient-centered** Focus on specific patient needs
- **Timely** Reducing waits and sometimes harmful delays
- **Efficient** Avoiding waste (including waste of equipment, supplies, ...)
- **Equitable** No distinction in gender, ethnicity, geographic location, ...

# Definition of quality of care

- **Quality of care**

= the degree to which health services for individuals and populations increases the probability of desired health outcomes and is consistent with current professional knowledge<sup>1,2</sup>



# Introduction

- 6 important dimensions in quality of care
- How to measure quality of care?
- Validation of quality indicators
- Literature on quality indicators
- What is a “care pathway”?
- Practical tips to develop quality indicators

# How to measure quality of care?

- **Indicators** to measure/evaluate quality of care = a **measurable** element of practice performance for which there is **evidence or consensus** that it can be used **to assess the quality of care**, and hence change the quality of care provided.<sup>1</sup>

- **A measurable element**

*It has to be feasible to measure in practice. Example: impossible to do indirect calorimetric if you don't have access to such a device.*

- **Evidence or consensus**

*The indicators you measure have to be evidence-based (literature, guidelines) or there has to be a consensus (with physicians on the ward) that it is important for quality of care*

# How to measure quality of care?

- Different indicators based on Donabedian's classic division<sup>1,2,3</sup>: SPO structure



**“Having the right things”**

**“Doing things right”**

**“Having the right things happen”**

# Example: Hand hygiene

## Example: SPO indicators for Hand hygiene

**Structure** Availability of disinfectant in each room in the hospital

**Process** Proportion of healthcare professionals who follow hand hygiene guidelines

**Outcome** Number of infections according to improper hand hygiene (effect: a decrease in infections)



# How to measure quality of care?

- Examples of indicators for the pharmacy



- Availability of hospital pharmacists to number of patients in hospital
- Access to specific technologies (specific equipment for preparation)
- Proportion of correctly delivered medication to the patient
- Proportion of number of good extemporaneous mixtures to all extemporaneous mixtures
- Medical error
- Quality of life of patient

# Examples for Parenteral Nutrition

Examples of process measures	Examples of outcome measures
Ensuring the training program of HPN patients includes pump use and care, catheter care and recognizing common problems. <sup>2</sup>	Absence of septic complications <sup>1,2</sup>
Monitor periodically liver function tests <sup>2</sup>	Absence of hepatic complications <sup>1</sup>
Perform bone densitometry upon initiation of Home parenteral nutrition and periodically thereafter. <sup>2</sup>	Absence of metabolic complications <sup>1</sup>
Monitor patients' quality of life <sup>2</sup>	Quality of life of patient <sup>2</sup>
Composing the diet (carbohydrates, lipids, proteins) <sup>1</sup>	Weight gain or loss <sup>2</sup>

<sup>1</sup> Ramos et al. Quality Evaluation of total parenteral nutrition in acute care setting. Journal of Evaluation in Clinical practice; 2006.

<sup>2</sup> Dreesen et al. Development of quality of care interventions for adult patients on home parenteral nutrition (HPN) with a benign underlying disease using a two-round Delphi approach. Clinical Nutrition; 2012.



# Defining an indicator: example for PN

## For example: Number of catheter-related infections

<b>Relationship to quality</b>	Better processes of care (handhygiene, care of catheter) reduce number of catheter related sepsis, which represents better quality/less mortality.
<b>Definition</b>	Number of catheter-related infections in patients receiving parenteral nutrition with central venous catheter in hospital (during certain study period). <i>Definition of catheter-related infections to be defined.</i>
<b>Numerator</b>	Number of patients with central venous catheter receiving parenteral nutrition in hospital and experiencing catheter-related infection
<b>Denominator</b>	Number of all patients with central venous catheter receiving parenteral nutrition in hospital
<b>Type of indicator</b>	Outcome indicator

# State-of-the-art description

<b>Indicator Number</b>	<i>Number assigned to each indicator</i>
<b>Indicator name</b>	<i>A brief title that uniquely identifies the measure</i>
<b>Description</b>	<i>A brief explanation of the measure's focus, such as the activity or the area on which the measure centers attention.</i>
<b>Rationale/ relation to quality</b>	<p><i>Rationale for measuring the process or outcome indicator:</i></p> <ul style="list-style-type: none"> <li>- <i>Variability in outcomes- performance or key indicators as indicated by literature</i></li> <li>- <i>Relation between indicator and quality of care</i></li> </ul> <p><i>Rationale for measuring baseline variable: risk analysis concerning baseline variables.</i></p>
<b>Type of indicator/variable</b>	<ul style="list-style-type: none"> <li>- <i>Process indicator: a measure that indicates the performance of (compliance with) a key intervention</i></li> <li>- <i>Outcome indicator: a measure that indicates the result of a performance (or non-performance) of a key-intervention</i></li> <li>- <i>Baseline variable /covariable used for risk analysis</i></li> </ul>
<b>Numerator</b>	<i>Represents the portion for the denominator that satisfies the condition of the indicator</i>
<b>Denominator</b>	<p><i>Represents the population evaluated by the indicator:</i></p> <ul style="list-style-type: none"> <li>- <i>Inclusion criteria: specific information describing the population</i></li> <li>- <i>Exclusion criteria: specific information describing the population that</i></li> </ul>

# State-of-the-art description

<b>Data Collection method</b>	<ul style="list-style-type: none"> <li>- <i>In which way are the data collected?</i></li> <li>- <i>At what time point are the data collected?</i></li> <li>- <i>Which data have to be collected?</i></li> </ul>
<b>Data elements for indicator</b>	<p><i>Indicates wich data are necessary to measure indicator</i>  <i>Italic: data necessary to built up other data (ie 6 items for Katz-score)</i></p>
<b>Data reported as</b>	<ul style="list-style-type: none"> <li>- <i>Aggregate rate generated fro mcount data reported as a proportion</i></li> <li>- <i>Aggregate rate generated from count data reported as a ratio</i></li> <li>- <i>Aggregate measures of central tendency (ie lenght of stay)</i></li> </ul>
<b>Expected outcome</b>	<ul style="list-style-type: none"> <li>- <i>Reference values in literature</i></li> </ul>
<b>Improvement expected as (outcome)</b>	<ul style="list-style-type: none"> <li>- <i>Indicates which improvement is expected</i></li> </ul>
<b>Criteria to meet (process)</b>	<ul style="list-style-type: none"> <li>- <i>Indicates the optimal goal that is targeted</i></li> </ul>
<b>References</b>	<ul style="list-style-type: none"> <li>- <i>Specific literature references that are used to support the importance of the indicator measure</i></li> <li>- <i>References concerning measuring tools</i></li> </ul>

1. From European Pathways Society

Accessible at <http://www.e-p-a.org/index2.html> (Last accessed August 20 2012)

2. Examples for parenteral nutrition in Spanish available. Book on indicadores de calidad de los servicios de una unidad de soporte natricional especializado, 2008. Madrid Hospital Universitario La Paz at ICU. Coordinator Abelardo Garcia de Lorenzo.



# Introduction

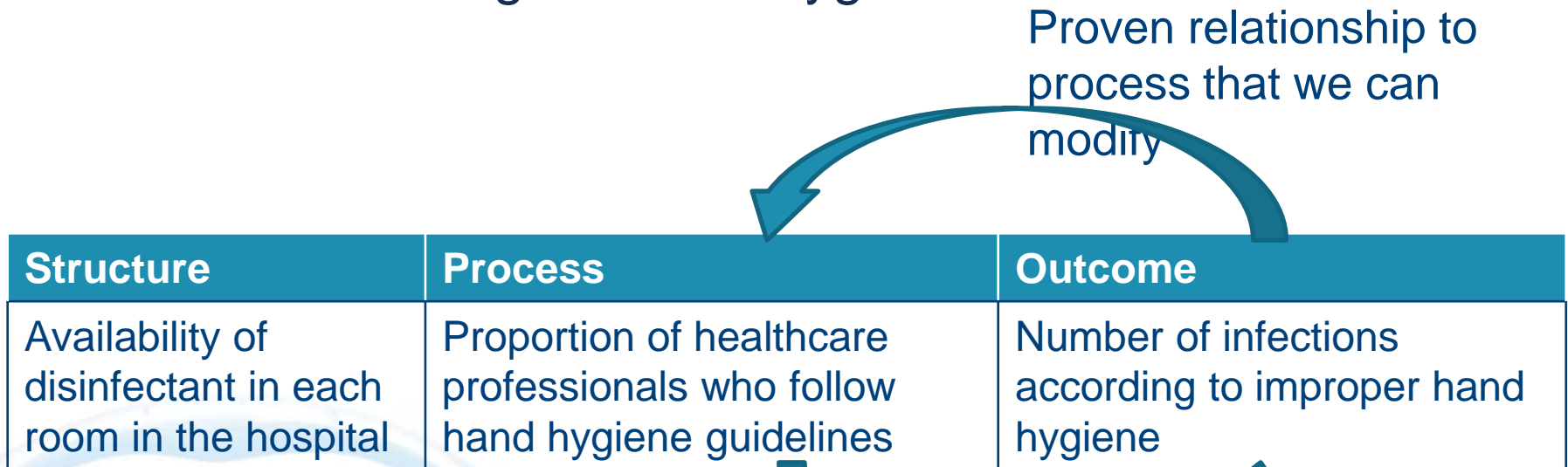
- 6 important dimensions in quality of care
- How to measure quality of care?

• Validation of quality indicators

- Literature on quality indicators
- What is a “care pathway”?
- Practical tips to develop quality indicators

# Validation of indicators

- Incidence of good hand hygiene



- Tempting to measure
- Far removed from outcome

# Validation of indicators

- When is an indicator valid?
  - Process (or structure): proven relationship to an outcome we care about
  - Outcome: proven relationship to processes we can modify to change the outcome
- Structure:
  - Can pass the validity test but are far removed from outcomes
  - Tempting to use because of availability (volume of services, board certification, accreditation status, staffing measures)

# Introduction

- 6 important dimensions in quality of care
- How to measure quality of care?
- Validation of quality indicators
- Literature on quality indicators
- What is a “care pathway”?
- Practical tips to develop quality indicators

# Use of the AIRE instrument

- AIRE = Appraisal of Indicators through Research and Evaluation
- AIRE is a questionnaire with 20 statements
- Rating statements with 4-point Likert scale using 4 quality domains:
  - Purpose, relevance, organizational context
  - Stakeholder involvement
  - Scientific evidence
  - Additional evidence/formulation/usage



# Use of the AIRE instrument: example

- Indicator:

*“ Proportion of HPN patients who receive HPN in a cyclic period (at night), not continuously.”*

- First statement of the AIRE instrument

1) **The purpose of the indicator is described clearly**

Purpose: why is the indicator developed (quality improvement or external accountability?) → methods of manuscript

4	3	2	1
---	---	---	---

Strongly agree

Strongly disagree

# Review: Indicators in hospital care

## Using quality indicators to improve hospital care: a review of the literature.

Maartje de Vos, Wilco Graafmans, Mieneke Kooistra, Bert Meijboom, Peter Van der voort, Gert Westert P. International journal for quality in healthcare 2009; 21 (2); 119-129; Netherlands.

- Review of literature (Medline, Cochrane library) concerning strategies for implementing quality indicators in hospital care.
- 21 studies included with focus on care processes (20/21), not on outcomes.
- Concluded that effective strategies to implement quality indicators do exist but that there is a considerable variation in methods used and level of change achieved.

# Cochrane: audit and feedback

## **Audit and feedback: effects on professional practice and health care outcomes. (Review)**

Ivers N, Jamtvedt G, Flottorp S, Young JM, Odgaard-Jensen J, French SD, O'Brien MA, Johansen M, Grimshaw J, Oxam AD. Cochrane Database Syst Rev 2012 Jun 13;6;CD000259

- Review of Cochrane collaboration

7 databases with inclusion of 140 studies

- Aim

What are effects of implementation strategy “*audit and feedback*” in practice? Why can effects vary?

- Conclusion

Audit and feedback can be effective and effects vary widely across the included studies.

# Introduction

- 9 important dimensions in quality of care
- How to measure quality of care?
- Validation of quality indicators
- Literature on quality indicators
- What is a “care pathway”?
- Practical tips to develop quality indicators

# What is a care pathway?

- A care pathway is a **complex intervention** for the **mutual decision making and organisation of care processes** for a **well-defined** group of patients during a well-defined period.
- Characteristics of a care pathway:
  - An explicit statement of the **goals and key elements of care** based on evidence, best practice, patients' explanations and their characteristics.
  - The **facilitation of the communication** among the team members and with patients and families.
  - The **coordination of the care process** by coordinating the roles and sequencing the activities of the multidisciplinary care team, patients and their relatives.
  - The documentation, monitoring and evaluation of variances and **outcomes**
  - The identification of the **appropriate resources**.

# Introduction

- 6 important dimensions in quality of care
- How to measure quality of care?
- Validation of quality indicators
- Literature on quality indicators
- What is a “care pathway”?
- Practical tips to develop quality indicators

# In practice

- Own research on Home Parenteral Nutrition:
  - **Quality indicator development**
    - (1) **Literature review** on HPN guidelines to identify important interventions in process of care<sup>1</sup>
    - (2) **Expert opinion** on guidelines found in literature in collaboration with ESPEN-HAN and CIF working group.<sup>2</sup>



CAPANAH Trial

**Field test:** are the developed interventions followed up in practice? (multicenter study with 13 hospitals in Belgium)

<sup>1</sup> Dreesen et al. Guidelines recommendations on care of adult patients receiving home parenteral nutrition: a systematic review of global practices. Clinical Nutrition. 2012.

<sup>2</sup> Dreesen et al. Development of quality of care interventions for adult patients on home parenteral nutrition (HPN) with an underlying disease using a two-round Delphi approach. Clinical Nutrition; 2012.

# Practical tips to start

- Identifying process indicators in practice with experts over different European countries for EDUCATION

Examples of own research<sup>1</sup>:

- Ensuring the training program includes pump use and care, catheter care and recognizing common problems
- Making a checklist available of criteria for which competence of the patient is achieved
- Making written information with clear messages available for all patients to take home after education



# Practical tips to start

- Identifying **outcome indicators** in practice with experts over different European countries<sup>1</sup>

Indicator	Average <sup>a</sup>
Incidence of CRI	8.45
Incidence of rehospitalization of HPN patients	6.45
QoL during HPN treatment	
Incidence of dehydration	4.86
Weight gain or loss	4.17
Sense of security of the patient at home	3.93
Incidence of an infection at the insertion site of the catheter	2.55
Incidence of catheter obstruction	2.48
Incidence of central venous thrombosis	2.31
Prevalence of intrahepatic cholestasis	2.06
Prevalence of osteoporosis	1.55

# Practical tips to start

- Take into account:
  - 6 dimensions of health care: Safe, effective, patient-centered, timely, efficient, equitable
- Use quality indicators with SPO structure
- Ensure the quality indicator is valid
- Do not re-create quality indicators. If they are available, use them.

