Practice Guidelines: different strategies, same goals

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Practice Guidelines: definition and goals

"*systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances*"

→ to improve the quality of care

→ to improve the appropriateness of care

→ to improve cost-effectiveness

→ to serve as educational tools

Evidence - Based Medicine

- the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients
- the integration of individual clinical expertise with the best available external evidence and patient‘s values and expectations

BMJ 1996; 312: 71-2.

EBM Practice Guidelines

- designed to help practitioners assimilate, evaluate and implement the ever-increasing amount of evidence and opinions on best current practice
- clinical discretion is of the utmost importance in the application of a guideline to an individual patient, because no guideline can ever be specific enough to be applied in all situations

EMB Practice Guidelines

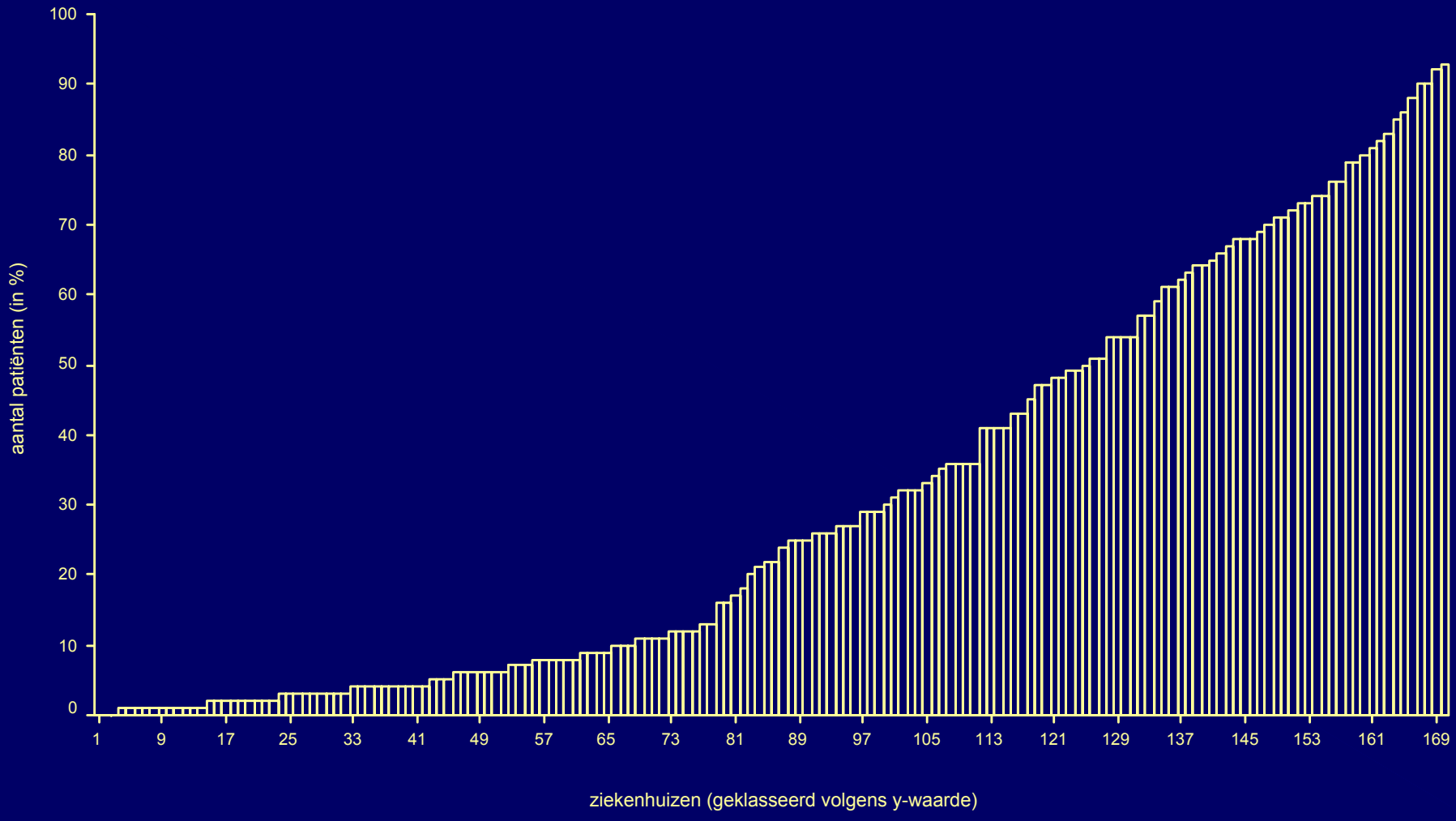
- not a textbook
- not a cookbook
- not a substitute for clinical judgement
- not a standard of care (legal issues)
- not a cost-cutting medicine (ethical issues)

Is there a need for practice guidelines ?

- intrinsic desire of health care professionals to offer, and of patients to receive, the best care possible
- large variations in health care delivery:
  over- and under-use, “inappropriateness”
- lag between evidence and practice
- rising health care costs: “cost-effectiveness”

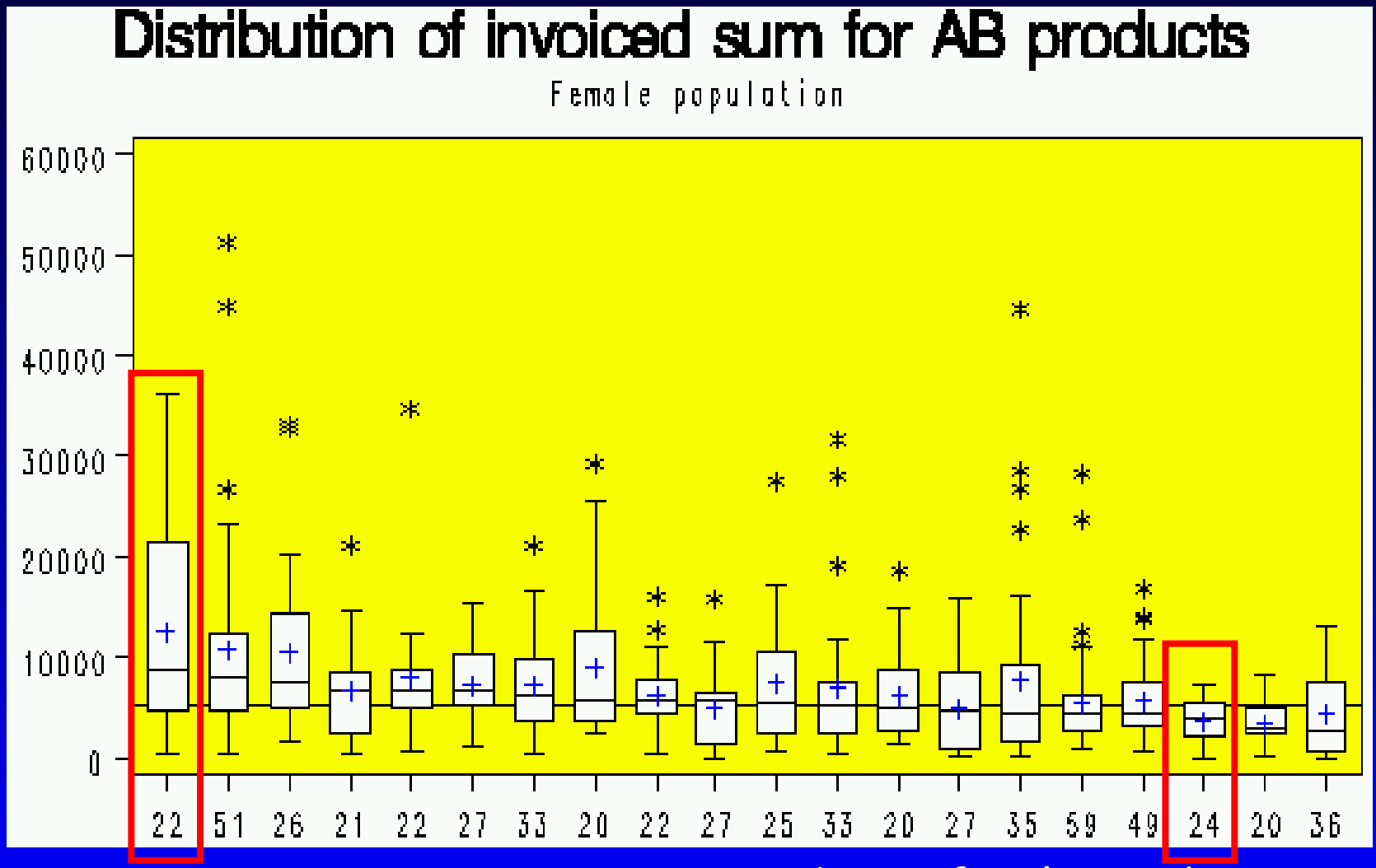
Appendectomy

Fig.8 Per ziekenhuis aantal patiënten met ECG



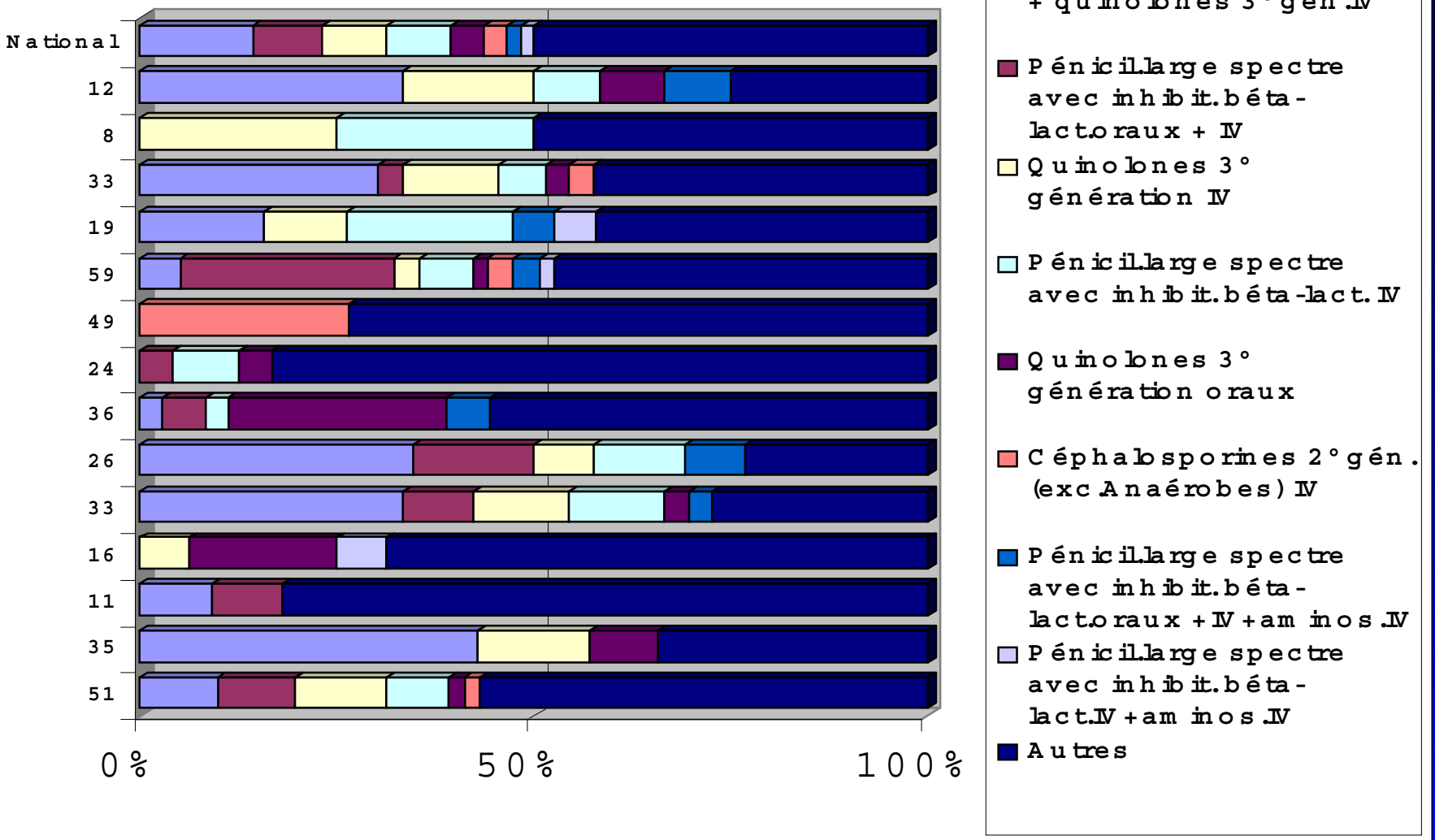
Antibiotics pyelonephritis

BF



number of selected stays

Minimal Data Analysis



EBM - Practice Guidelines: development process

- standards of guideline development must be established
- guideline writers must adhere to these standards so that the scientific validity of the guideline and the clarity of communication is ensured

Clin Infect Dis 2001; 32: 851-4.

Practice Guidelines development process

- GOBSAT method
- consensus conference
- explicit linkage of recommendations and evidence

Practice Guideline Development: GOBSAT

- Group of Experts meet to develop guidelines based on their own clinical judgement and experience

→ sources of bias: selection of group members, same profession, literature, etc

→ small group processes likely to have major influence on decisions

→ difficult for user to assess how recommendations were derived

Practice Guideline Development: Consensus Conferences

- a broad-based panel listens to scientific data presented by experts, weighs the information and then composes a consensus statement that addresses a set of questions previously posed to the panel

→ sources of bias: type of questions, composition of the panel, selection of experts, literature, etc

→ small group processes likely to have major influence on decision

"as much a social as a scientific process"

Practice Guideline Development: AGREE

AGREE = Appraisal of Guidelines
for Research and Evaluation

(E.U., Fifth Framework)

- checklist to allow practitioner or organisation to make an informed judgement about the methods that were used to develop a guideline, and an assessment about the overall quality of the guideline and the recommendations it contains

www.agreecollaboration.org

AGREE Instrument: 6 domains of guideline development

- scope and purpose:

  objectives; specific clinical questions; target patient population
- stakeholder involvement:

  composition of development group, target users
- rigour of development:

  to gather and synthesize the evidence, to formulate, review and update the recommendations

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AGREE Instrument:
6 domains of guideline development

- clarity and presentation:

  formulation and format of the guideline
- applicability:

  organisational, behavioural and cost implications of applying the guideline
- editorial independence:

  conflict of interest from the development group

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Guideline development process

1. Identify and refine the subject area
   - prioritising topics :
     - relevance
     - available evidence
   - refining the subject area:
     - narrowing
     - specific questions
     - purpose

BMJ 1999; 318: 593-6.

Guideline development process

- Guideline development group
  - group members: range of experts
    related disciplines
    professional societies
    multidisciplinary
    at least 6 and no more than 12-15
  - specify roles:
    group leader: process and task
    group members: evidence and expertise
    practicalities

BMJ 1999; 318: 593-6.

Guideline development process

3. Identifying and assessing the evidence
   - systematic review (Cochrane / EB journal / …)
   - literature search (Medline / Embase / …)
   - critical appraisal of the evidence for its relevance, validity and applicability
   - summarising and categorising evidence

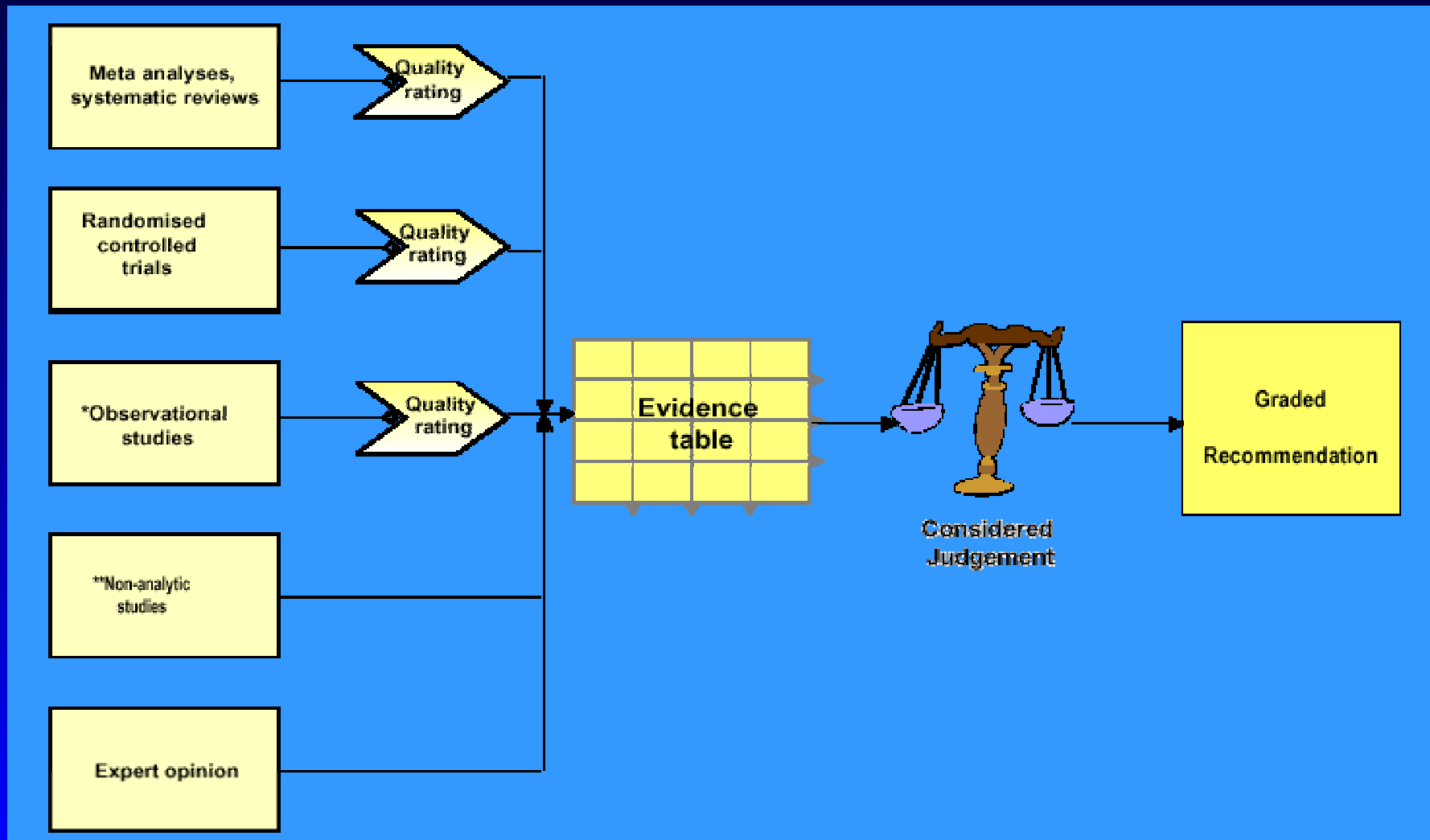
BMJ 1999; 318: 593-6.

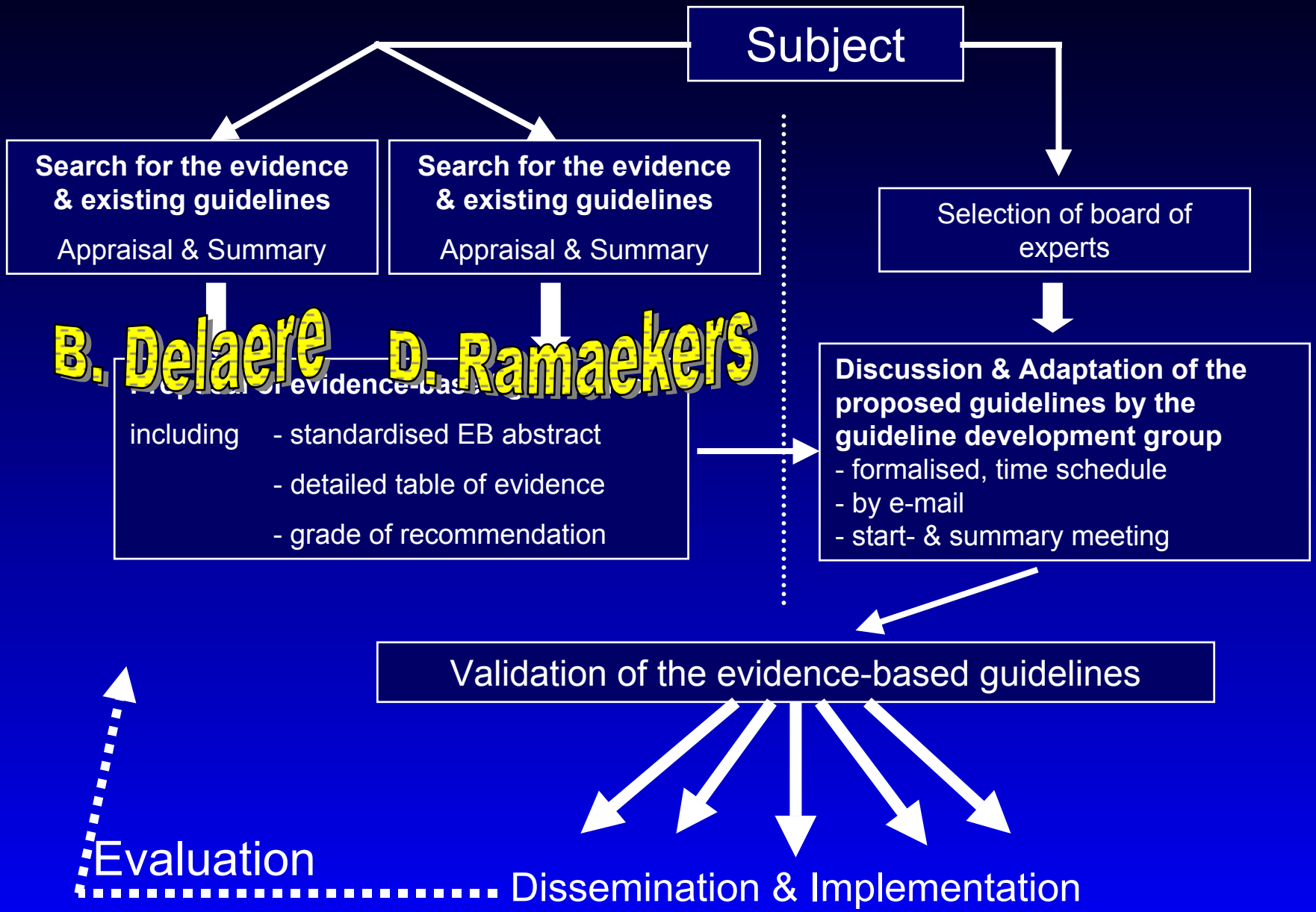
Guideline development process

4. Translating evidence into a clinical practice guideline
   - integration of critical appraisal with clinical expertise and experience and with feasibility issues
   - interpretation of “environmental” context: public health, policy, payment, but also local susceptibility data for infectious diseases guideline
   - interpretation when strong evidence is lacking (generalisation / extrapolation / expert opinion)
   - grading of the strength of recommendation

BMJ 1999; 318: 593-6.

Development of E-B guidelines




Subject
Search for the evidence & existing guidelines
Appraisal & Summary
Search for the evidence & existing guidelines
Appraisal & Summary
Selection of board of experts
B. Delaere
D. Ramaekers
including - standardised EB abstract
- detailed table of evidence
- grade of recommendation
Discussion & Adaptation of the proposed guidelines by the guideline development group
- formalised, time schedule
- by e-mail
- start- & summary meeting
Validation of the evidence-based guidelines
Evaluation
Dissemination & Implementation

Levels of evidence (revised SIGN)

1++	meta analysis, systematic reviews of RCT, RCT with very low risk of bias
1+	idem with low risk of bias
2++	case-control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal
2+	idem with low risk of confounding or bias and a moderate probability that the relationship is causal
3	non-analytic studies, e.g. case reports, case series
4	expert opinion

www.sign.ac.uk

Grades of recommendations
(revised SIGN)

A	at least one meta analysis, systematic review or RCT rated as 1++, directly applicable to the target population body of evidence consisting of studies rated as 1+, directly applicable to target population and demonstrating overall consistency of results
B	body of evidence including studies rated as 2++ , directly applicable to target population and demonstrating consistency of results extrapolated evidence from studies rated on 1++ or 1+
C	body of evidence including studies rated as 2+, directly applicable to target population and demonstrating consistency of results extrapolated evidence from studies rated as 2++
D	evidence levels 3 or 4 extrapolated evidence from studies rated as 2+

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IDSA clinical practice guidelines

Quality of evidence	
I	evidence from at least one RCT
II	evidence from at least one well-designed CT without randomisation; from cohort or case-controlled analytic studies; from multiple time-series studies; from dramatic results in uncontrolled experiments
III	evidence from opinions of respected authorities, based on clinical experience, descriptive studies or reports of expert committees

Clin Infect Dis 1994; 18: 421.

IDSA clinical practice guidelines

Strength of recommendation	
A	strong evidence of efficacy and substantial clinical benefit support recommendation for use
B	moderate evidence of efficacy or strong evidence of efficacy but limited clinical benefit supports recommendation for use
C	insufficient evidence to support a recommendation for or against use, or evidence of efficacy might not outweigh adverse consequences or alternative approaches
D	moderate evidence of lack of efficacy or of adverse outcome supports a recommendations against use
E	good evidence of lack of efficacy or of adverse outcome supports a recommendation against use

Clin Infect Dis 1994; 18: 421.

Guideline development process

5. Reviewing and updating guidelines
   - external review to ensure validity, clarity and applicability
     - expert in clinical content
     - expert in systemic review or guideline development
     - potential users of the guideline
   - scheduled process of updating

BMJ 1999; 318: 593-6.

Guideline development process: further issues

- dissemination of the guideline
- implementation strategies and barriers
- evaluation of the use and impact of the guideline and its recommendations

Are guidelines following guidelines ?

- adherence to methodological standards
  (n=279 guidelines; 1985-1997)
  - development and format 51 %
  - identification and summary of evidence 34 %
  - formulation of recommendations 46 %
- overall improvement from 36.9 % (1985) to 50.4 % (1997), but identification and summary of evidence remained weak (36 %)

JAMA 1999; 281: 1900-5.

Practice guidelines developed by speciality societies (1988-1998)

- inclusion of professional with different speciality: 28 % (mostly epidemiologist: 26 %)
- information on systematic literature search: 13 %
- criteria to grade the strength of evidence: 18 %
- overall 54 % of guidelines did not meet any criterion

Lancet 2000; 355: 103-6.

Clinical practice guidelines: COPD

	CTS	ATS	ERS	BTS	FRE	SWI
stop smoking	+	+	+	+	+	+
vaccine						
influenza	+	+	+	+	+	+
pneumococcus	+/-	+	+/-	-	+	+
bronchodilator						
beta 2 agonist	2	1	½	1	½	2
ipratropium	1	2	½	2	½	1
inhaled steroids	+/-	+/-	+/-	+	+/-	+/-
mucolytics	+/-	-	-	-	+/-	+

Arch Intern Med 2001; 161: 69-74.

Clinical practice guidelines:
candidemia, unstable patient, no prior fluco

consensus conference						
	fluco	ampho B	ampho B + 5 FC	ampho B lipid	ampho B + fluco	fluco + 5 FC
neutropenia	2/20	1/20	10/20	2/20	4/20	1/20
solid organ TX	7/18	4/18	4/18	2/18	1/18	0/18
non-neutropenic	5/20	4/20	4/20	2/20	5/20	0/20

Clin Infect Dis 1997; 25: 43-59.

Clinical practice guideline: candidemia

consensus conference				
dose of fluco (mg)	< 400	400	800	>800
stable	1/20	18/20	1/20	0/20
deteriorating	0/20	1/20	18/20	1/20
dose of ampho B (mg/kg)	< 0.5	0.5-0.7	0.8-1.0	>1.0
stable	1/20	14/20	5/20	0/20
deteriorating	0/20	2/20	14/20	4/20

Clin Infect Dis 1997; 29: 43-59.

Clinical practice guideline: candidemia (IDSA)

- C. albicans, C. tropicalis, C. parapsilosis:
  - ampho B 0.6 mg/kg/d (AI)
  - fluconazole 6 mg/kg/d (AI)
- C. glabrata:
  - ampho B ≥ 0.7 mg/kg/d (B III)
  - fluconazole 12 mg/kg/d in less-critically ill patients (BIII)
- C. krusei:
  - ampho B 1.0 mg/kg/d (BIII)
- for 2 weeks after the last positive blood culture and resolution of signs and symptoms (A III)

Clin Infect Dis 2000; 30: 662-78.

Recommendations non-pregnant women

MILD PYELONEPHRITIS - empirical therapy

- **The efficacy of fluoroquinolones for empiric therapy has been established (1++, A).**
- **Oral therapy is proposed for patients without clinical signs of severe sepsis (1++, A). Outpatient treatment with oral fluoroquinolones is safe in absence of severe sepsis and renal insufficiency, and with the ability to take oral medication (1+, B).**
- **First generation fluoroquinolones (FQ_1), such as norfloxacine, are not recommended because of their low serum concentration (4, D).**
- **Association of an aminoglycoside is not recommended in absence of severe sepsis (1+, B).**
- **Co-trimoxazole, ampicillin and first generation cephalosporins cannot be recommended as empiric therapy due to the high level of resistance in many regions of Belgium.**

Implementation of clinical practice guidelines

- passive methods of disseminating and implementing guidelines (publication; mailing) rarely lead to changes in professional behaviour
- multifaceted interventions may be required
- choice of strategies depends upon
  - available resources
  - perceived barriers
  - research evidence about effectiveness and efficiency of different strategies

BMJ 1999; 318: 728-30.
Med Care 2001; 39 (II): 55-69.

Implementations strategies

→ professional interventions:

educational outreach, audit and feedback, reminders, etc

→ organisational interventions:

clinical pharmacist, ID specialist, etc

→ financial interventions:

reimbursement, professional incentives, etc

→ regulatory interventions

→ social interventions

BMJ 1999; 318: 728-30.

“ *Evidence-based medicine guideline development should be completed by evidence-based guideline implementation”*

Barriers to physician adherence to clinical practice guidelines

knowledge

- lack of awareness
- lack of familiarity

attitudes

- lack of agreement with guidelines in general or with a specific guideline
- lack of outcome expectancy
- lack of self-efficacy
- inertia of previous practice

behaviour/external barriers

- patient factors
- guideline factors
- environmental factors

JAMA 1999; 282: 1458-65.

Knowledge of guidelines for the prevention of Infective Endocarditis

speciality (n)		success rate (%)
ID physician	(20)	100
cardiologist	(10)	100
otolaryngologist	(9)	78
internist	(40)	70
gynecologist	(17)	53
pediatrician	(26)	50
general surgeon	(13)	46
orthopedic surgeon	(11)	36

J Hosp Infect 2000; 45: 311-17.

Practice guideline to reduce hospital admission for CAP

- overall non-adherence 43.6 %
- physicians with more pneumonia experience more likely not to follow the guideline ($p < 0.01$)
- reasons for non-adherence
  - active co-morbidities (55 %)
  - primary care physician's wish (41 %)
  - worse pneumonia than guideline indicated (36 %)
  - patient's preference (17 %)
  - inadequate home support (16 %)

Arch Intern Med 2000; 160: 98-104.

Physicians' perception of practice guidelines

- personal experience and opinions of colleagues more useful
- other sources of information more useful
- not transferable to patient or local situation
- threaten physician's autonomy
- developed for cost-containment reasons
- externally imposed
- administrative > informative or educational
- no enthusiasm for multi-disciplinary involvement

Arch Intern med 2001; 161: 2037-42.

Implementation of perioperative antibiotic prophylaxis in Belgium

- limited reimbursement of antibiotics during day –1/0/+1
- fixed sum for antibiotics (“forfait”) attributed to each surgical intervention
- exception for antibiotics prescribed for treatment of intercurrent infections (to be declared)
- imposed by Royal Decree May 1997/Dec 1998

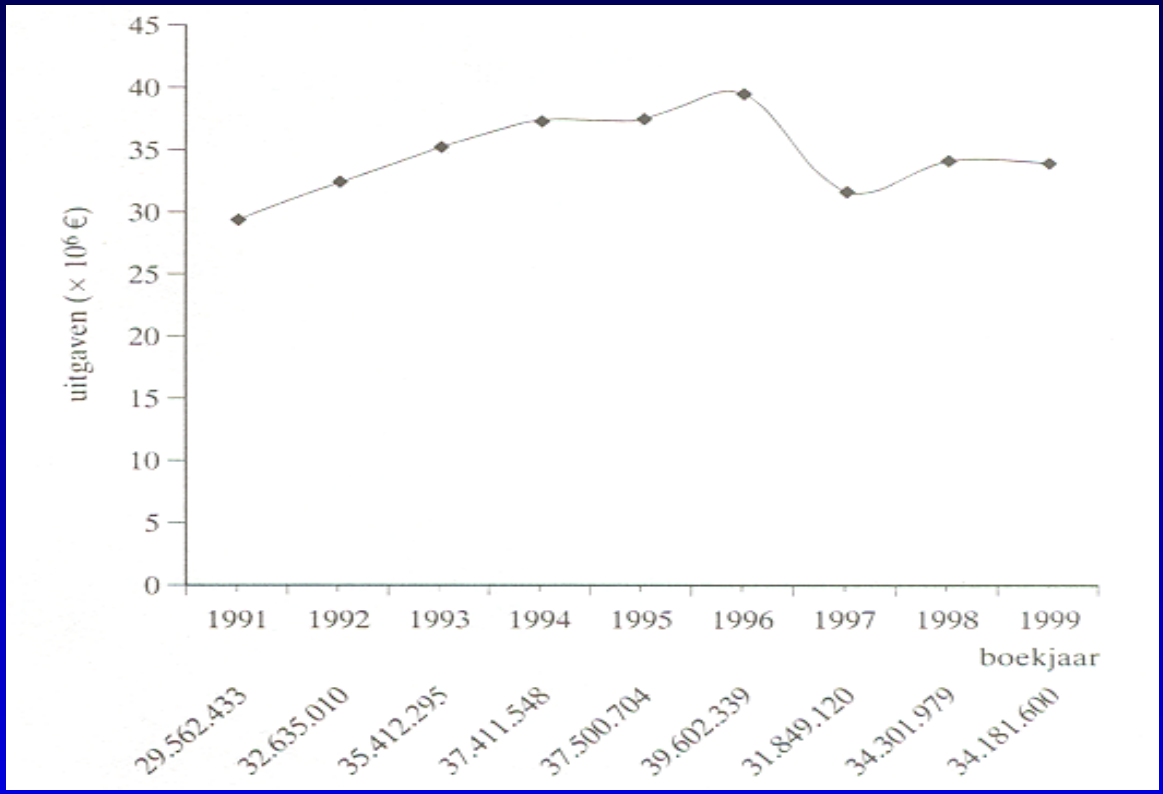
Ned Tijdschr Geneeskd 2001; 145: 1773-7.

Implementation of perioperative antibiotic prophylaxis in Belgium

	1986 (%)	1992-93 (%)	1998-99 (%)
correct timing	53	71	70.4
correct indication	92	86	96.5
duration ≥ 2 days	50	21	8.5
choice of AB			
1st gen cephalo	28	52	66.1
2nd gen cephalo	17	24	28.7

WIV-ISP. Scientific Institute for Public Health.

Implementation of perioperative antibiotic prophylaxis in Belgium



Ned Tijdschr Geneeskd 2001; 145:1773-7.

Infectious Diseases Clinical Practice Guidelines

- clinical practice guidelines can improve the quality and cost-effectiveness of I.D. hospital care

Clin Infect Dis 2001; 32: 728-41.
Clin Infect Dis 2001; 33: 289-95.

- infectious diseases consultation can improve the appropriateness of clinical management and antimicrobial therapy

Q J Med 1996; 89: 789-97.
Clin Infect Dis 1998; 27: 478-86.

Appropriateness of the empirical treatment for bacteremia (%)

department (no of episodes)	ID specialist	other physician	p-value
intensive care (68)	74	39	0.021
internal medicine (63)	87	46	0.013
gastroenterology (73)	76	42	0.007
other unit (131)	69	49	0.064
emergency (84)	80	77	1.000

Clin Infect Dis 1999; 29: 60-6.

Academic detailing to improve the use of broadspectrum antibiotics: a randomized controlled trial

- days of unnecessary use of target antibiotics was 37 % lower for intervention services than for controls ($p < 0.001$)
- risk of receiving a day of unnecessary target antibiotics was reduced by 41 % ($p < 0.001$): fewer starts, more discontinuations
- risk of prescribing unnecessary target antibiotics continued to decline throughout the entire study period
- no measurable negative clinical effects (length of stay, transfer to ICU, readmission rate, death rate)

Arch Intern Med 2001; 161: 1897-1902.

European Study Group on Antibiotic Policy: Recommendations

- establishment of a rational antibiotic policy is a key issue for both better care of patients and combating antimicrobial resistance
- a national expert committee on antibiotic policy should be established in each country and should develop guidelines for creating and auditing rational antibiotic policies
- each health care institution should have a therapeutics committee to develop a local antibiotic policy based on national recommendations

Clin Microbiol Infect 2001; 7 (suppl 6): 16-21.

E.U. Conferences Recommendations

A multidisciplinary Antimicrobial Management Team (AMT) is considered to be the most appropriate structure to adapt, implement and evaluate ID guidelines and interventions in hospitals according to local epidemiology, antibiotic consumption patterns and antibiotic resistance data.

Copenhagen Conference 1998.
Brussels Conference 2001.

Clinical Practice Guidelines: conclusions

- high quality practice guidelines rely upon high quality guideline development methods using an explicit linkage of the level of evidence and the strength of recommendations
- implementation of practice guidelines requires tuned and multifaceted interventions
- good practice guidelines can serve as a tool for education and evaluation

Clinical Practice Guidelines: conclusions

- infectious diseases practice guidelines must be developed according to international standards
- infectious diseases practice guidelines must take into account the “microbial party”, i.e. local epidemiology and antibiotic resistance patterns
- a local Antimicrobial Management Team is essential for the interpretation, translation, implementation and evaluation of infectious diseases practice guidelines in the hospital