Clinical Practice Guidelines: International Consensus on Methodological Standards

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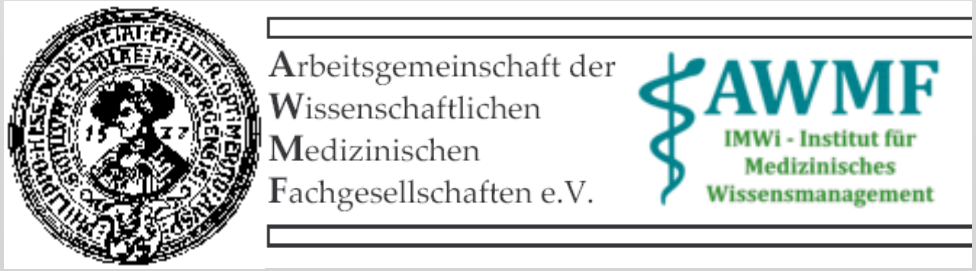
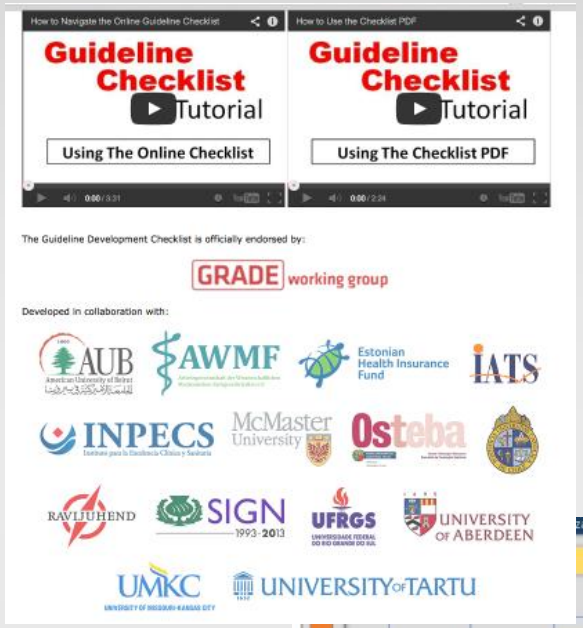
Guidelines International Network



Clinical Practice Guidelines: consensus on methodological principles

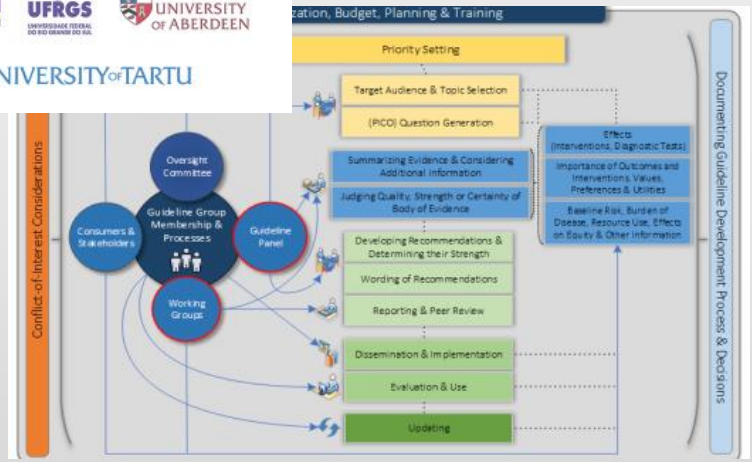
agreetrust.org

iom.edu



G-I-N – McMaster Guideline Development Checklist

g-i-n.net



http://cebgrade.mcmaster.ca/guidecheck.html

Principles of Guideline Development: 1. Transparency

IOM standard 1.1:

The process by which a clinical practice guideline (CPG) is developed and funded should be detailed explicitly and publicly accessible.

→ a transparent development process makes clear how authors weighed evidence, pathophysiologic reasoning, expert experience, values of patients and the society and
allows users to judge reasonableness of recommendations

www.iom.edu/Reports/2011/Clinical-Practice-Guidelines-We-Can-Trust.aspx

Principles of Guideline Development: 2. Stakeholder Involvement

The Guideline Development Group should be multidisciplinary and balanced including representatives of

professional groups

- medical speciality societies
- professional associations
- methodological experts

German Breast Cancer Guideline:
n= 30 societies/organisations

target population and patients

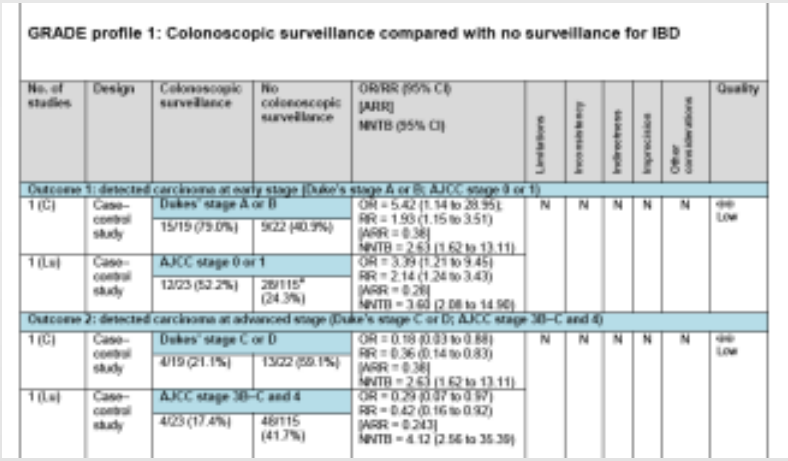
→ those, who are addressed/affected by the recommendations

NOT: industry (however: may be consulted)

Example: http://www.awmf.org/leitlinien/detail/ll/032-045OL.html

Principles of Guideline Development: 3. Systematic Review of the Evidence

- Establish cooperation of clinicians and methodologists
- Document strategy used to search and select evidence in a way it can be reproduced by others
- Identify risks of bias- critically appraise the evidence
- Document results: evidence tables / profiles



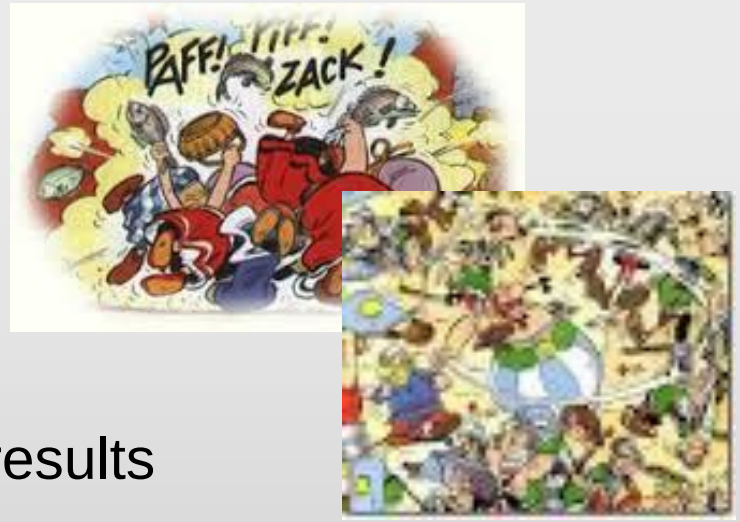
GRADE profile 1: Colonoscopic surveillance compared with no surveillance for IBD

No. of studies	Design	Colonoscopic surveillance	No colonoscopic surveillance	OR/RR (95% CI) [ARR] NNTB (95% CI)	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations	Quality
Outcome 1: detected carcinoma at early stage (Duke's stage A or B; AJCC stage 0 or 1)										
1 (C)	Case–control study	Dukes' stage A or B: 15/19 (79.0%)	Dukes' stage A or B: 9/22 (40.9%)	OR = 5.42 (1.14 to 26.95); RR = 1.93 (1.15 to 3.51) [ARR = 0.38] NNTB = 2.63 (1.62 to 13.11)	N	N	N	N	N	⊕⊕ Low
1 (Lo)	Case–control study	AJCC stage 0 or 1: 13/23 (52.2%)	28/115[a] (24.3%)	OR = 3.39 (1.21 to 9.45); RR = 2.14 (1.24 to 3.43) [ARR = 0.28] NNTB = 3.60 (2.88 to 14.96)						
Outcome 2: detected carcinoma at advanced stage (Duke's stage C or D; AJCC stage 3B–C and 4)										
1 (C)	Case–control study	Dukes' stage C or D: 4/19 (21.1%)	Dukes' stage C or D: 13/22 (59.1%)	OR = 0.18 (0.03 to 0.88); RR = 0.36 (0.14 to 0.83) [ARR = 0.38] NNTB = 2.63 (1.62 to 13.11)	N	N	N	N	N	⊕⊕ Low
1 (Lo)	Case–control study	AJCC stage 3B–C and 4: 4/23 (17.4%)	48/115 (41.7%)	OR = 0.29 (0.07 to 0.97); RR = 0.42 (0.16 to 0.92) [ARR = 0.243] NNTB = 4.12 (2.56 to 35.39)						

NICE Clinical Guideline 118, 2011: Evidence profile (GRADE) Colonoscopic surveillance for prevention of CRC in patients with ulcerative colitis, Crohn's disease or adenomas

Principles of Guideline Development: 4. Structured Consensus Process

- formal, evidence based techniques to avoid bias (preferrably Nominal Group and Delphi)
- guided by an independent, experienced moderator
- ensuring effective group interaction
- avoiding bias, such as :
  - selection of participants
  - majority / minority influence
  - social loafing
  - groupthink
  - brainstorming



- documentation of processes and results
- allowing for scientifically justified dissent

Principles of Guideline Development: 5. Manangement of Conflicts of Interest

1. Guideline developers should make all possible efforts to not include members with direct financial or relevant indirect COIs
2. The definition of COI and its management applies to all members of a Guideline Development Group…and this should be determined before a panel is constituted
3. A GDG should use standardized forms for disclosure of interests
4. A GDG should disclose interests publicly, including all direct financial and indirect COI
5. All members of a GDG should declare and update any changes in interests at each meeting of the group and at regular intervals
6. Chairs of GDGs should have no direct financial or relevant indirect COI.
   When COIs of a chair are avoidable, a co-chair with no COIs should be appointed
7. Experts with relevant COI and specific knowledge or expertise may be permitted to participate in discussion of individual topics, but there should be an appropriate balance of opinion
8. No member of the GDG deciding about the direction or strength of a recommendation should have a direct financial COI
9. An oversight committee should be responsible for developing and implementing rules related to COI.

Ann Intern Med. 2015;163:548-553, available open access:
http://annals.org/article.aspx?articleid=2450219

Reporting Standards for Guideline-based Performance Measures

1. Quality of the Guideline according to G-I-N Standards and AGREE II and of additional [evidence] sources, if used
2. Quality of evidence and/or the strength of recommendation qualifying the guideline recommendations to be used for PM development
3. Consensus methods used to select the PM from guideline recommendations
4. Consideration of core PM attributes:
   - Relevance (as a minimum: potential for improvement/clinical relevance)
   - Scientific Soundness (as a minimum: the evidence supporting the measure)
   - Feasibility (as a minimum: clarity of definition and measurability)
5. Unambiguous Specification of Numerator and Denominator
6. Intended use of the PM (e.g. quality improvement, quality assurance with or without accountability purposes as p4p, public reporting) and level in the health system (local, regional, national)
7. Practice test of PM prior to their broader implementation and routine use
8. Review and reevaluation: criteria for deciding to change or stop using PM
9. Composition of the panel deciding on PM

Nothacker M. et al, G-I-N Performance Measures Working Group in press

Clinical Practice Guidelines: Definitions

Systematically developed statements

to assist physicians and, if necessary, other healthcare professionals and patients

with decisions about appropriate health care in specific clinical circumstances

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 1990, 2011: http://www.iom.edu

Standards: ISO Definitions

A normative document,

developed according to consensus procedures,
which has been approved by the ISO membership and P-members of the responsible committee

in accordance with Part 1 of the ISO/IEC Directives as a draft International Standard and/or as a final draft International Standard and which has been published by the ISO Central Secretariat.

…a document that provides requirements, specifications, guidelines or characteristics

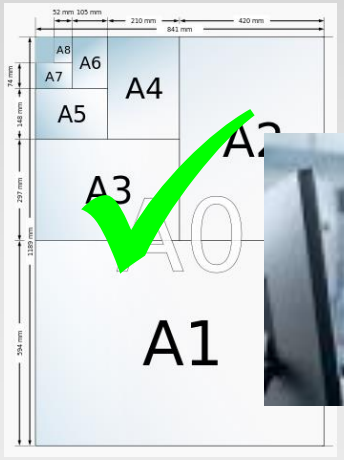
that can be used consistently to ensure that materials, products, processes and services are fit for their purpose.

International Organization for Standardization:
http://www.iso.org/iso/home/standards.htm

Definition and Methodological Principles: Differences between Standards and Guidelines

	Standards	Guidelines
trigger for development	market requirement, need for standardisation	improvement potential, public health need, need for information about new technologies
stakeholder involvement	interested parties, including experts from the industrial, technical and business sectors “entrance fee”	healthcare professionals, patient representatives, methodologists-industry not allowed, applicants with conflicts of interests restricted
methodology of development	informal consensus, informed by evidence, dissent not reported	systematic review of the evidence, structured consensus (formal techniques)
key aspects covered	technical specifications, systems, persons	clinical health care services, interventions
goal for assessment of implementation	conformity (normative requirements)	appropriateness (reference ranges)
availability	for a fee	for free
responsiveness to new evidence	relatively low	relatively high

Standards: need for a discussion about indications and contraindications

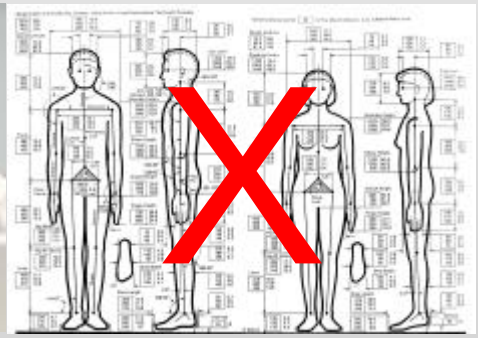


ISO 216 paper sizes

DIN EN ISO 15189:2014, 17025:2005
medical laboratories

DIN EN ISO/IEC 17021:2011
certification bodies for management systems
DIN EN ISO 9001:2008
quality management
DIN EN ISO/IEC 17024:2012
certification bodies for persons

shared decisions



patients

Patient's right
to appropriate health care on an individualised basis

Physician

objective experience
competence
intuition, ethos

consciousness of individual and societal perspective

individual decision- making situation

Patient

subjective experience
expectations
values, preferences
coping, self-efficacy
cultural aspects

External Knowledge: decision support

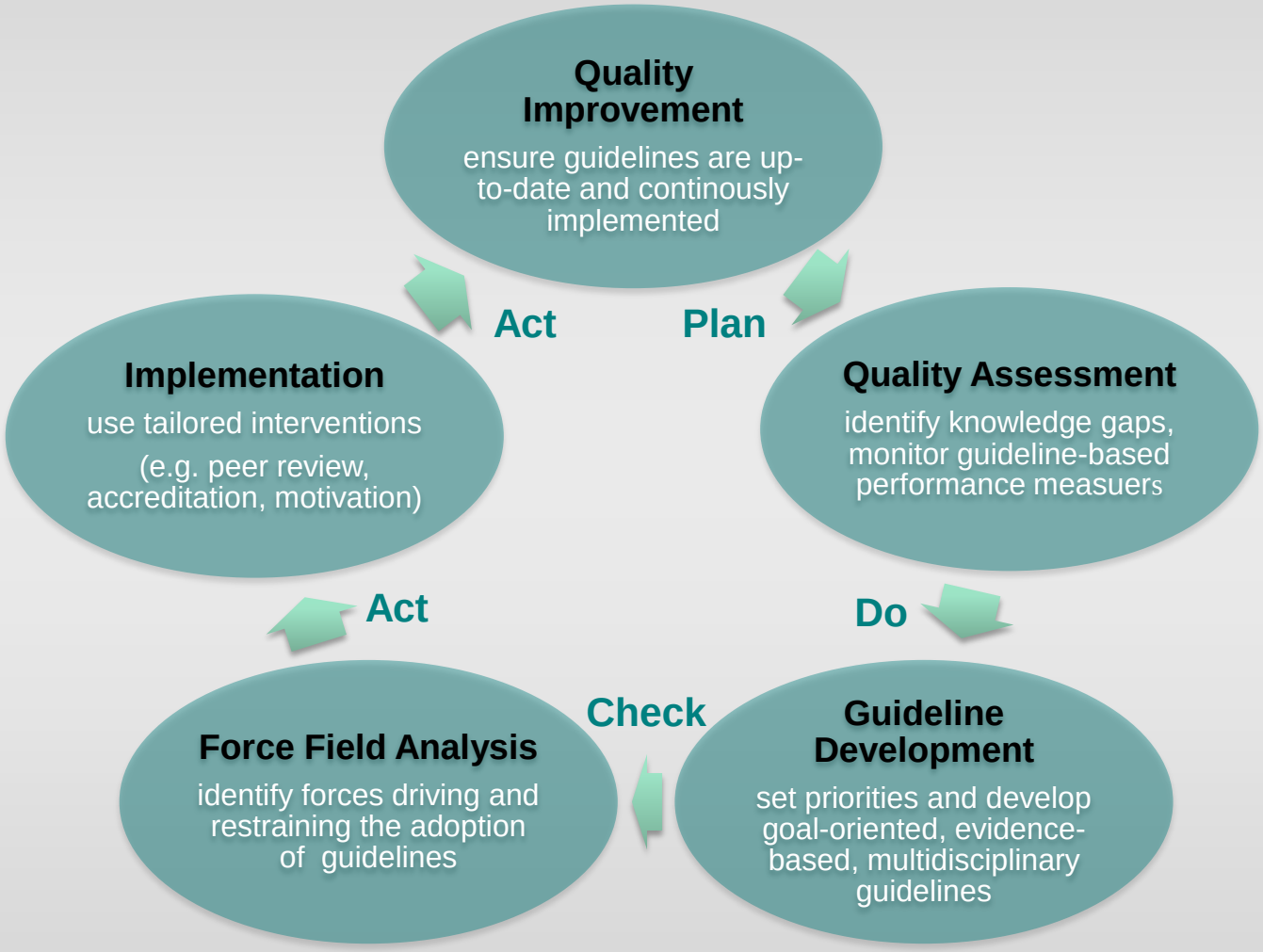
Clinical Practice Guidelines

Systematic Reviews
Knowledge Banks

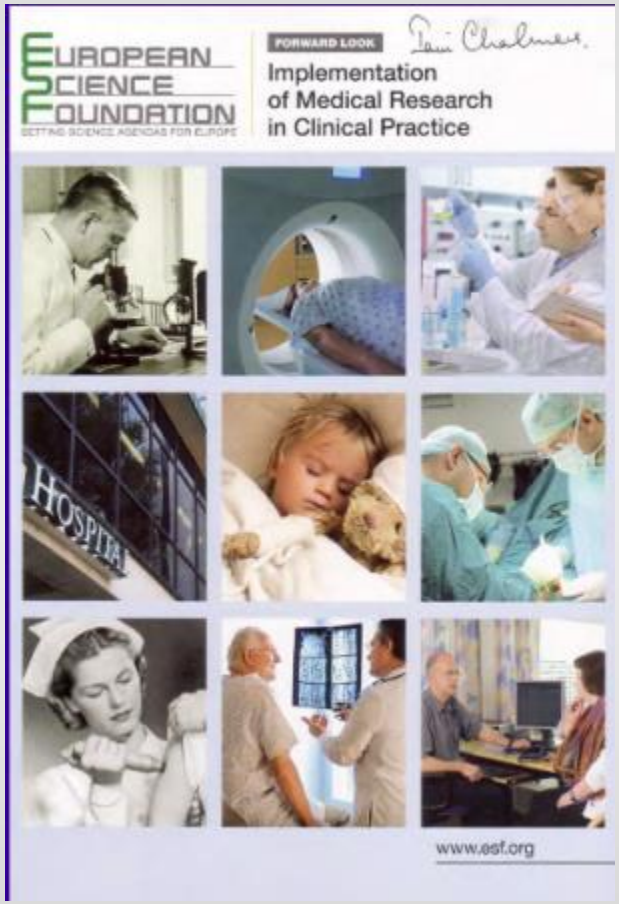
legal, ethical, social, economic framework of the system

AWMF

Outlook: Clinical Practice Guidelines at the Core of the PDCA Cycle



Outlook: Guidelines may be the way forward to improve quality at the european level



Conclusions

- The development process of a guideline and accompanying performance measures must be outlined in detail in a a method-report
- The method report should be outlined at the beginning of a guideline project – agenda for all, who are involved
- Clinical Practice Guidelines are the instruments to optimise health care delivery by assisting professionals and patients to make informed decisions, taking into account the needs of individuals
- We need to differentiate between Standards and guideline-based performance measures