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-Quality, Clinical Criteria and Performance Asessment-

Enhancing Medical Professionalism, Interdisciplinarity and Quality of Health Care through Clinical Practice Guideline development

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IMWi - Institut für Medizinisches Wissensmanagement

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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

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Background to Guideline Development: Shared Interests with ERN Network Initiative

- concern about variation, quality, efficiency, and evidence for effectiveness of interventions in health care
- professional interest to define current optimal practice in an era of cost containment
- interest of purchasers (governments, insurers) and patients
- rapid expansion of medical knowledge (more than 1 Million new entries in Medline/PubMed per year)
- understanding of a need for decision aids (not standards) for health care professionals and patients in the individual encounter

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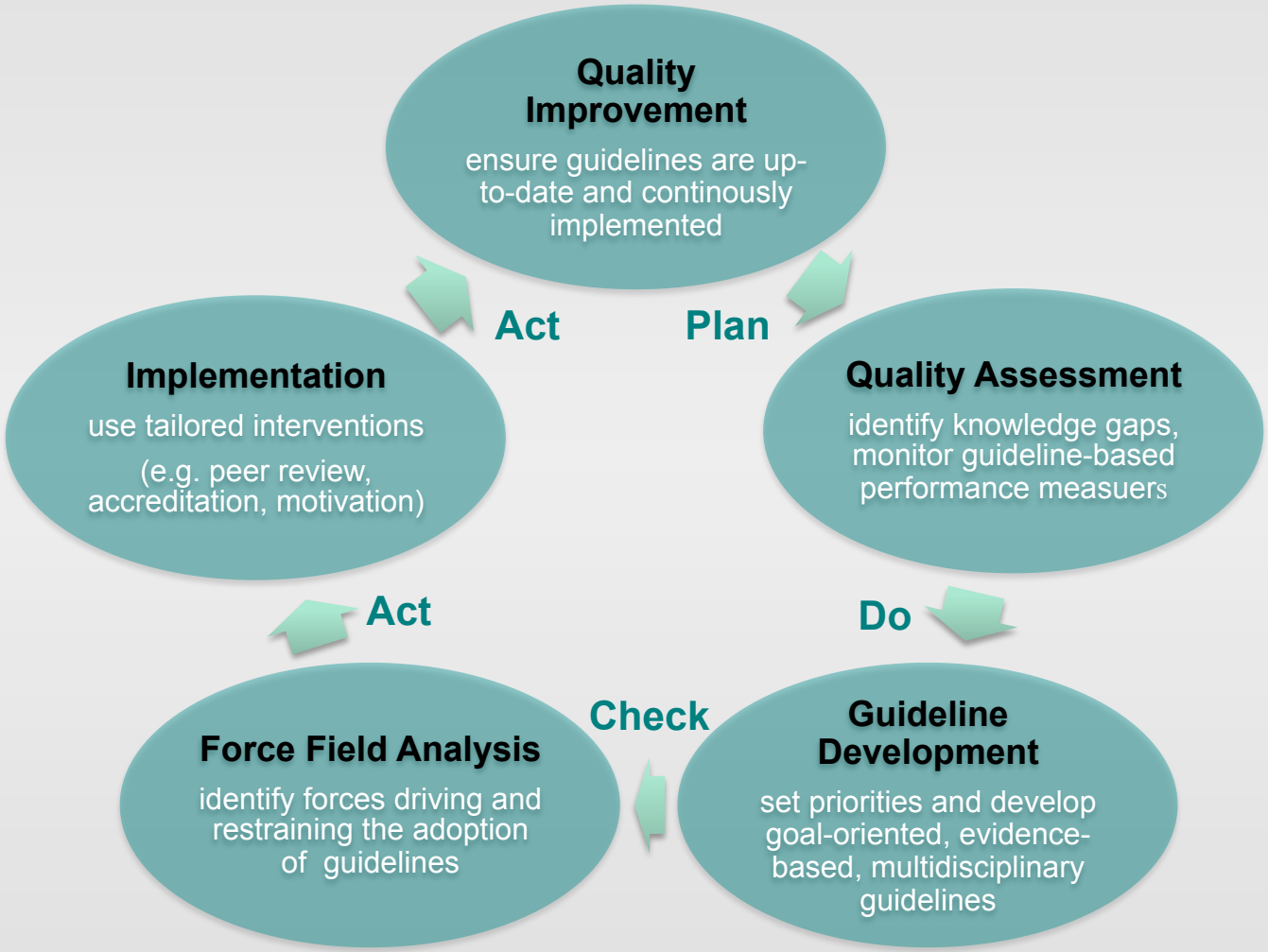
Background to Guideline Development in the German Health Care System

- ownership and responsibility lie with the profession: guidelines are developed by scientific medical societies
- support, coordination and quality assurance are provided by a national umbrella organisation, AWMF (Association of the Scientific Medical Societies in Germany – currently representing 168 member societies)
- AWMF strives for networking with national quality initiatives to promote implementation and evaluation of guidelines
- AWMF is the primary contact to the Guidelines International Network (G-I-N)

Clinical Practice Guidelines at the Core of the PDCA Cycle



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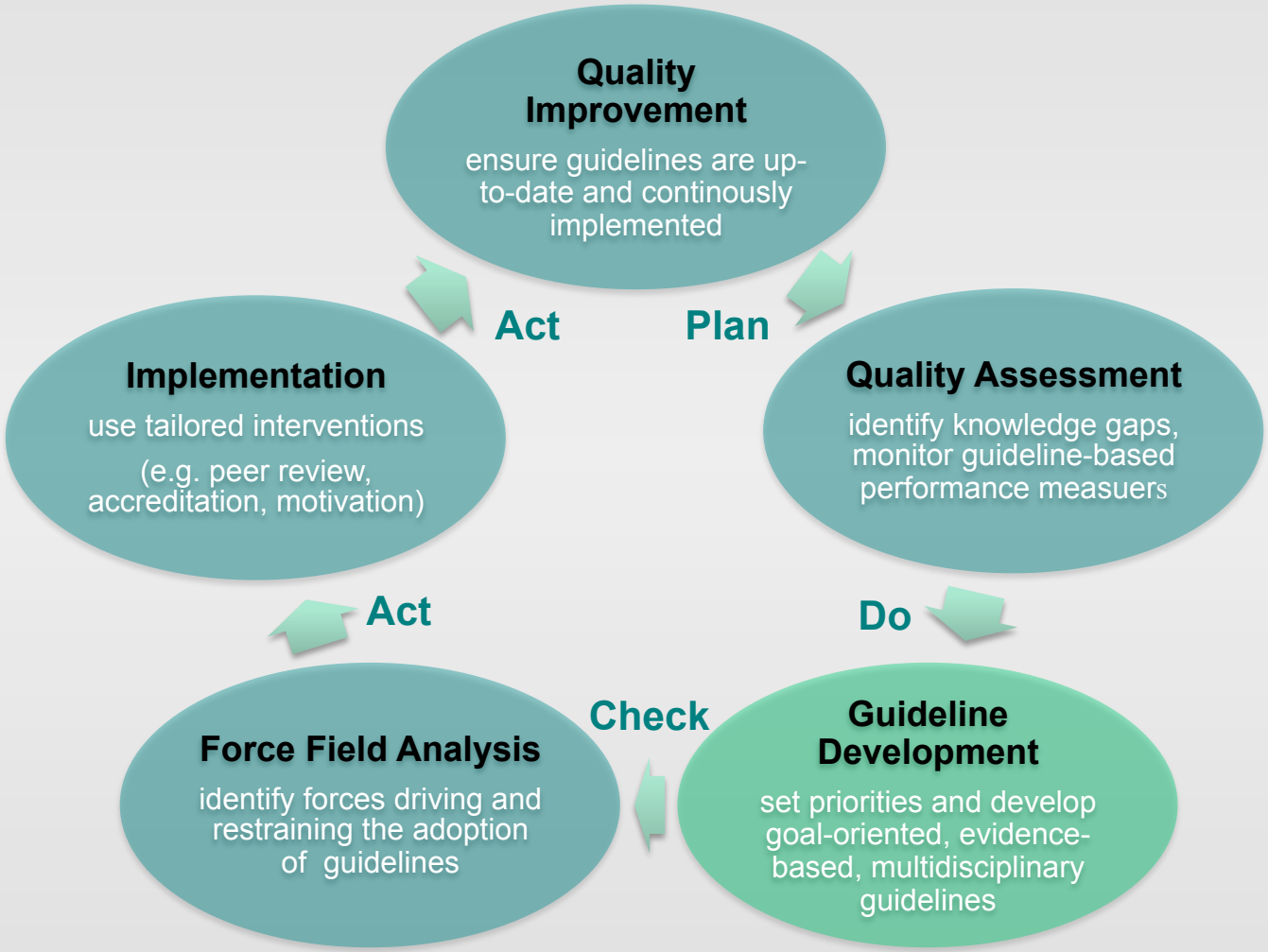

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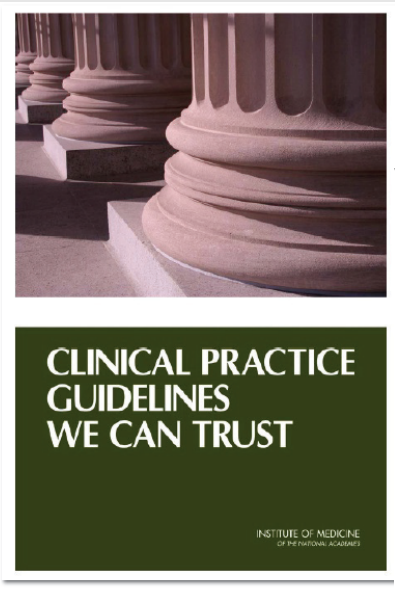
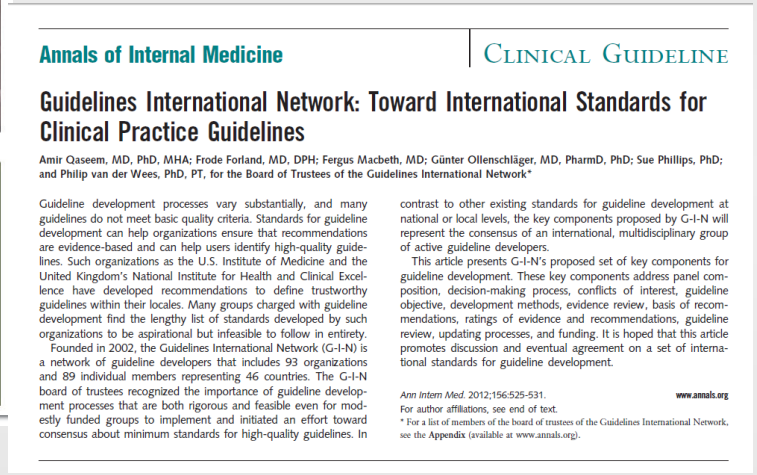
Guideline Development: International Consensus on Methodological Principles

agreetrust.org



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



Annals of Internal Medicine | CLINICAL GUIDELINE

Guidelines International Network: Toward International Standards for Clinical Practice Guidelines

Amir Qaseem, MD, PhD, MHA; Frode Forland, MD, DPH; Fergus Macbeth, MD; Günter Ollenschläger, MD, PharmD, PhD; Sue Phillips, PhD; and Philip van der Wees, PhD, PT, for the Board of Trustees of the Guidelines International Network*

Guideline development processes vary substantially, and many guidelines do not meet basic quality criteria. Standards for guideline development can help organizations ensure that recommendations are evidence-based and can help users identify high-quality guidelines. Such organizations as the U.S. Institute of Medicine and the United Kingdom's National Institute for Health and Clinical Excellence have developed recommendations to define trustworthy guidelines within their locales. Many groups charged with guideline development find the lengthy list of standards developed by such organizations to be aspirational but infeasible to follow in entirety.

Founded in 2002, the Guidelines International Network (G-I-N) is a network of guideline developers that includes 93 organizations and 89 individual members representing 46 countries. The G-I-N board of trustees recognized the importance of guideline development processes that are both rigorous and feasible even for modestly funded groups to implement and initiated an effort toward consensus about minimum standards for high-quality guidelines. In contrast to other existing standards for guideline development at national or local levels, the key components proposed by G-I-N will represent the consensus of an international, multidisciplinary group of active guideline developers.

This article presents G-I-N's proposed set of key components for guideline development. These key components address panel composition, decision-making process, conflicts of interest, guideline objective, development methods, evidence review, basis of recommendations, ratings of evidence and recommendations, guideline review, updating processes, and funding. It is hoped that this article promotes discussion and eventual agreement on a set of international standards for guideline development.

Ann Intern Med. 2012;156:525-531. www.annals.org

For author affiliations, see end of text.

* For a list of members of the board of trustees of the Guidelines International Network, see the **Appendix** (available at www.annals.org).

http://www.g-i-n.net/activities

IOM standard 1.1:

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

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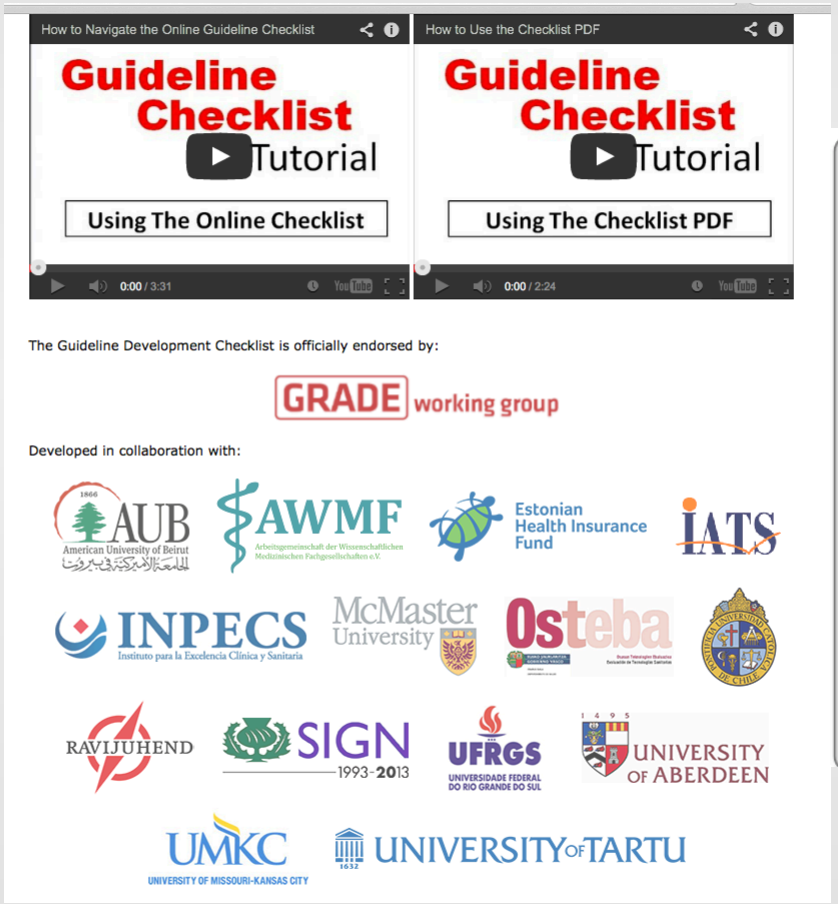
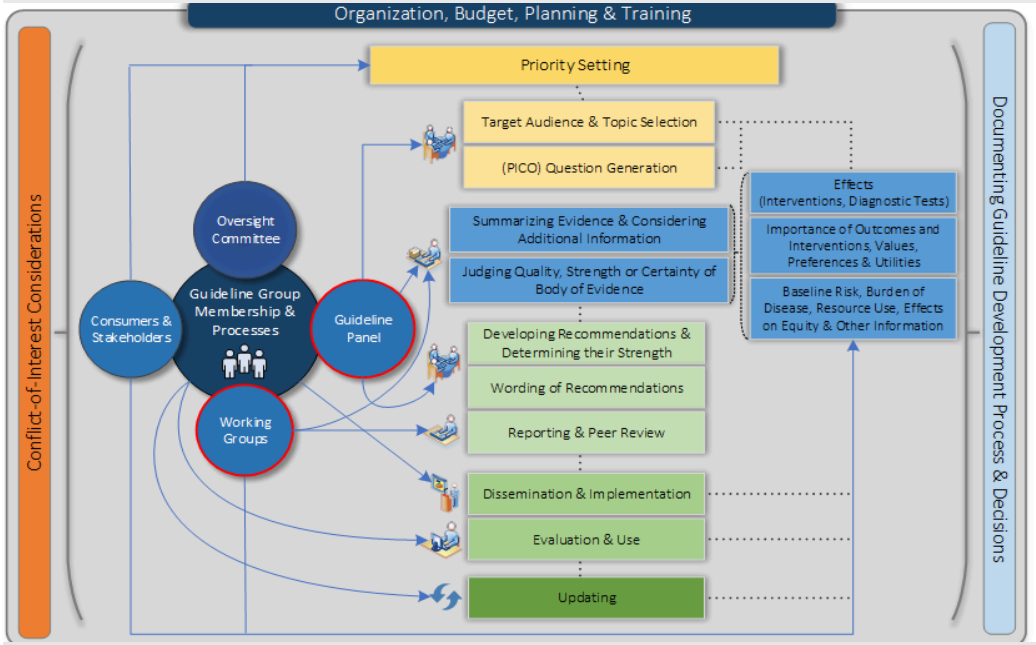
Open access to methodological support: The Guideline Development Checklist





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

Stakeholder Involvement: Composition of the Guideline Development Group

The GDG should be multidisciplinary and balanced including representatives of

Professional groups

- medical speciality societies
- professional associations
- methodological experts

Target population and patients

Arbeitsgemeinschaft Radiologische Onkologie (ARO)
Arbeitsgemeinschaft für Psychoonkologie (PSO)
Arbeitsgemeinschaft für Rehabilitation, Nachsorge und Sozialmedizin (ARNS)
Arbeitsgemeinschaft Gynäkologische Onkologie (AGO)
Arbeitsgruppe Supportivmaßnahmen in der Onkologie (ASO)
Berufsverband der Frauenärzte
Berufsverband Dt. Pathologen
Bundesgeschäftsstelle Qualitätssicherung (BQS)
Bundesverband Frauenselbsthilfe nach Krebs
Chirurgische Arbeitsgemeinschaft für Onkologie (CAO)
Deutsche Gesellschaft der Plastischen, Rekonstruktiven und Ästhetischen Chirurgen
Deutsche Gesellschaft für Allgemein- und Familienmedizin (DEGAM)
Deutsche Gesellschaft für Gynäkologie und Geburtshilfe (DGGG)
Deutsche Gesellschaft für Medizinische Informatik, Biometrie und Epidemiologie (GMDS)
Deutsche Gesellschaft für Pathologie
Deutsche Gesellschaft für Senologie (DGS)
Deutsche Gesellschaft für Ultraschall i.d. Medizin (DEGUM)
Deutsche Röntgengesellschaft
Klinische Epidemiologie, Tumorregister München (TRM)
Konferenz Onkologischer Kranken- und Kinderkrankenpflege (KOK)
Koordinatorin der Zentren für erbl. Brust- u. Eierstockkrebs
Women's Health Coalition e.V (WHC)
Zentralverband der Physiotherapeuten/ Krankengymnasten (ZVK)

→ those, who are adressed/affected by the recommedations

Example: German Breast Cancer Guideline. www.awmf.org

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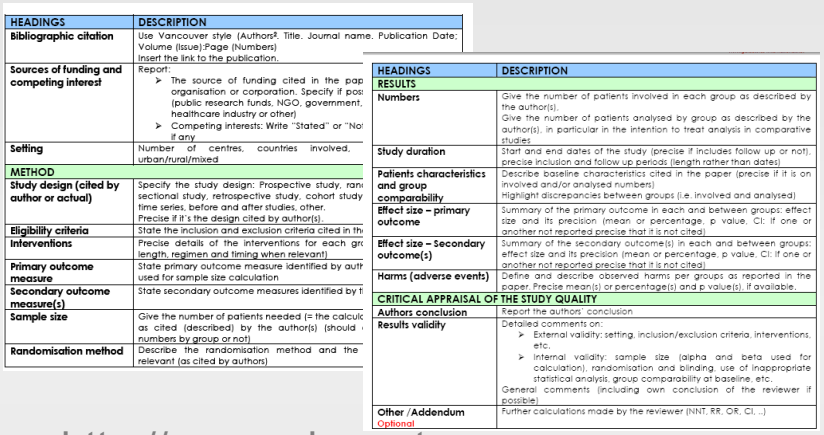
Rigor of Development: Systematic Review of the Evidence

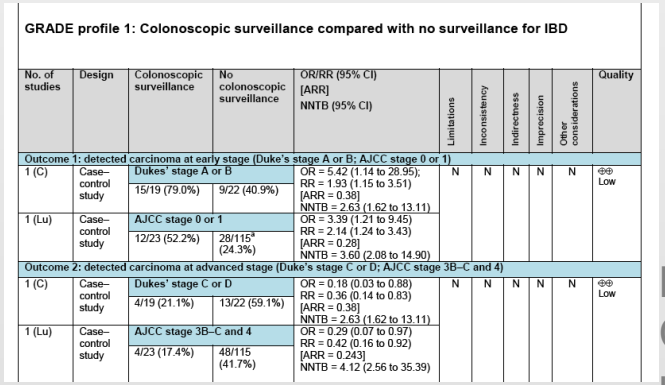
- Document strategy used to search and select evidence in a way it can be reproduced by others
- Identify risks of bias- critically appraise evidence
- Document results: evidence tables / profiles



HEADINGS	DESCRIPTION
Bibliographic citation	Use Vancouver style (Authors[3]. Title. Journal name. Publication Date; Volume (Issue):Page (Numbers) Insert the link to the publication.
Sources of funding and competing interest	Report: ➢ The source of funding cited in the pap organisation or corporation. Specify if pos (public research funds, NGO, government, healthcare industry or other) ➢ Competing interests: Write "Stated" or "No if any
Setting	Number of centres, countries involved, urban/rural/mixed
METHOD	
Study design (cited by author or actual)	Specify the study design: Prospective study, ran sectional study, retrospective study, cohort study time series, before and after studies, other. Precise if it's the design cited by author(s).
Eligibility criteria	State the inclusion and exclusion criteria cited in th
Interventions	Precise details of the interventions for each gr length, regimen and timing when relevant)
Primary outcome measure	State primary outcome measure identified by auth used for sample size calculation
Secondary outcome measure(s)	State secondary outcome measures identified by t
Sample size	Give the number of patients needed (= the calcul as cited (described) by the author(s) (should numbers by group or not)
Randomisation method	Describe the randomisation method and the relevant (as cited by authors)

HEADINGS	DESCRIPTION
RESULTS	
Numbers	Give the number of patients involved in each group as described by the author(s). Give the number of patients analysed by group as described by the author(s), in particular in the intention to treat analysis in comparative studies
Study duration	Start and end dates of the study (precise if includes follow up or not), precise inclusion and follow up periods (length rather than dates)
Patients characteristics and group comparability	Describe baseline characteristics cited in the paper (precise if it is on involved and/or analysed numbers) Highlight discrepancies between groups (i.e. involved and analysed)
Effect size – primary outcome	Summary of the primary outcome in each and between groups: effect size and its precision (mean or percentage, p value, CI: if one or another not reported precise that it is not cited).
Effect size – Secondary outcome(s)	Summary of the secondary outcome(s) in each and between groups: effect size and its precision (mean or percentage, p value, CI: if one or another not reported precise that it is not cited).
Harms (adverse events)	Define and describe observed harms per groups as reported in the paper. Precise mean(s) or percentage(s) and p value(s), if available.
CRITICAL APPRAISAL OF THE STUDY QUALITY	
Authors conclusion	Report the authors' conclusion
Results validity	Detailed comments on: ➢ External validity: setting, inclusion/exclusion criteria, interventions, etc. ➢ Internal validity: sample size (alpha and beta used for calculation), randomisation and blinding, use of inappropriate statistical analysis, group comparability at baseline, etc. General comments (including own conclusion of the reviewer if possible)
Other /Addendum Optional	Further calculations made by the reviewer (NNT, RR, OR, CI, ...)

http://www.g-i-n.net - GIN Evidence Tables Working Group: Template for summarising studies addressing Intervention questions



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

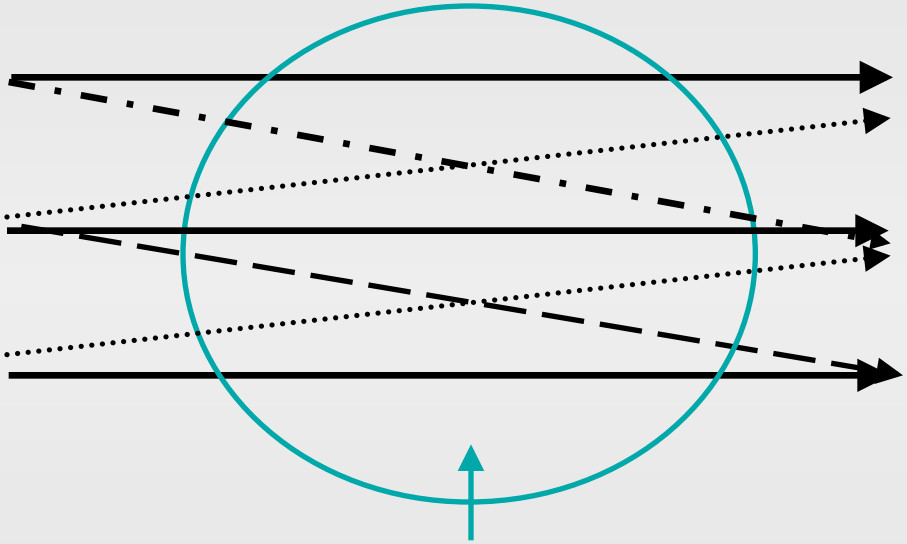
No. of studies	Design	Colonoscopic surveillance	No colonoscopic surveillance	OR/RR (95% CI) [ARR] NNTB (95% CI)	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations	Quality
Outcome 1: detected carcinoma at early stage (Duke's stage A or B; AJCC stage 0 or 1)										
1 (C)	Case–control study	Dukes' stage A or B		OR = 5.42 (1.14 to 28.95); 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
		15/19 (79.0%)	9/22 (40.9%)							
1 (Lu)	Case–control study	AJCC stage 0 or 1		OR = 3.39 (1.21 to 9.45) RR = 2.14 (1.24 to 3.43) [ARR = 0.28] NNTB = 3.60 (2.08 to 14.90)						
		12/23 (52.2%)	28/115[a] (24.3%)							
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		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
		4/19 (21.1%)	13/22 (59.1%)							
1 (Lu)	Case–control study	AJCC stage 3B–C and 4		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)						
		4/23 (17.4%)	48/115 (41.7%)							

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

Rigor of Development: from Evidence to Recommendations

Quality of evidence

Strength of recommendation



1 – high

2 - moderate

3 - low
4 - very low

do / don´t do
„we recommend“

probably do/don´t do
„we suggest“

uncertain
„can be considered“
„we do not know“

considered judgment
a criteria-guided group decision using formal consensus methods (e.g. Nominal Group Technique)

DM-CPG programme – method report (www.versorgungsleitlinien.de/english/methods)
European Council, Recommendation (2001) 13
GRADE 2004 (www.gradeworkinggroup.org)

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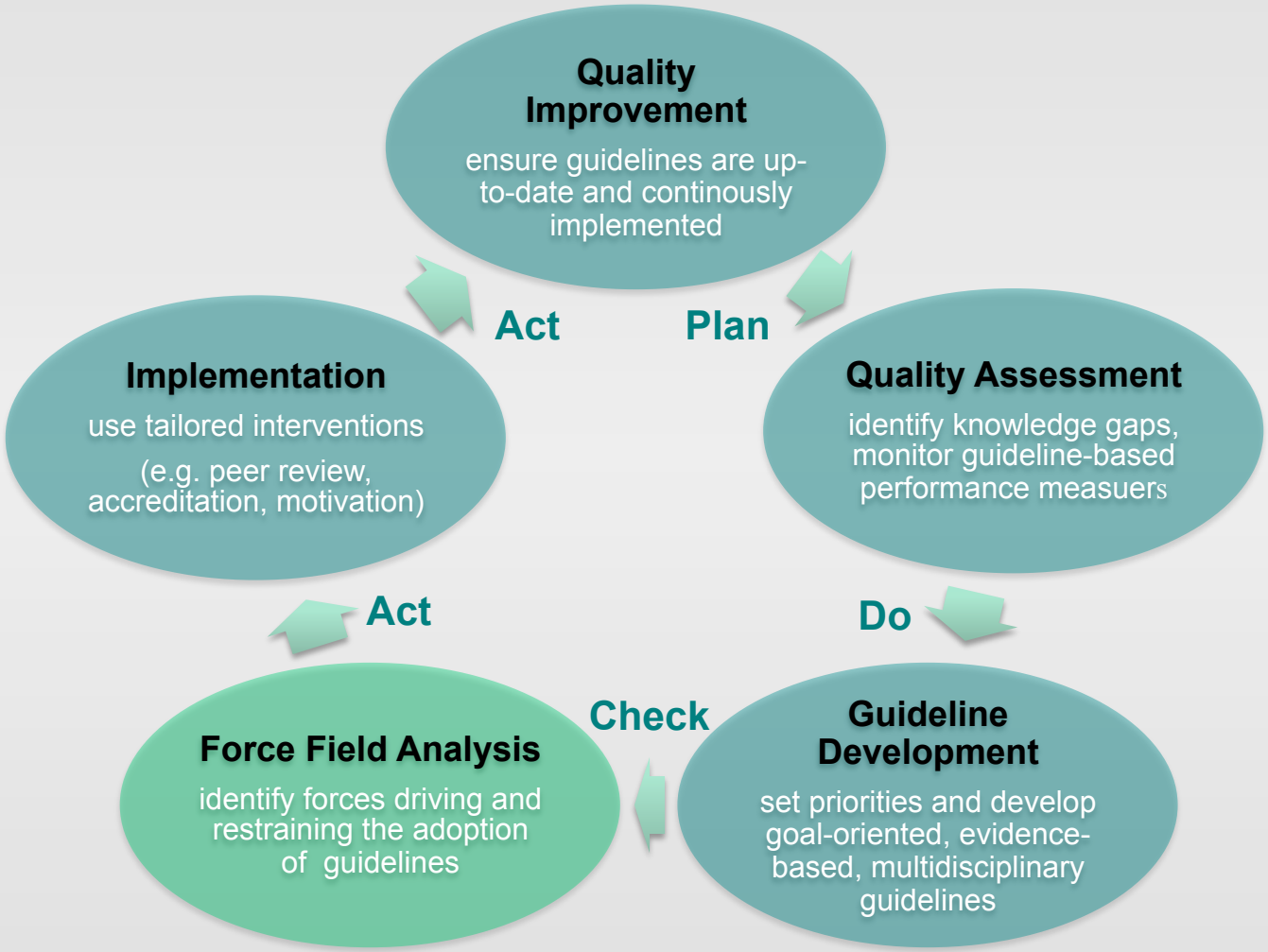
Editorial Independence
Manangement of Conflicts of Interest

- *Source(s) of funding*
  - declare sources of funding
  - make sure funders have no role in CPG development and can not influence the content of the guideline

- *Competing interests of guideline development group*
  - declare all interests and activities potentially resulting in COI (commercial, academical and institutional)
  - document measures taken to minimize the influence of competing interests on guideline development or formulation of the recommendations

Clinical Practice Guidelines at the Core of the PDCA Cycle



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Force Field Analysis

Driving Forces	Restraining Forces (Barriers)
1. Learning Theory	
Knowledge transfer to target group improves motivation	Information is not evidence-based, not communicating absolute numbers (NNT, NNH), not useful in the individual encounter
2. Behavioral Theory	
External audit / objective review based on performance measures Incentives	Benefit for individual professionals unclear, no reimbursement for documentation of performance measures
3. Social Theory	
Communication, Quality Circles Opinion Leaders	Lack of communication between professionals – especially transsectoral (primary/specialised care; ambulatory/in-hospital care)

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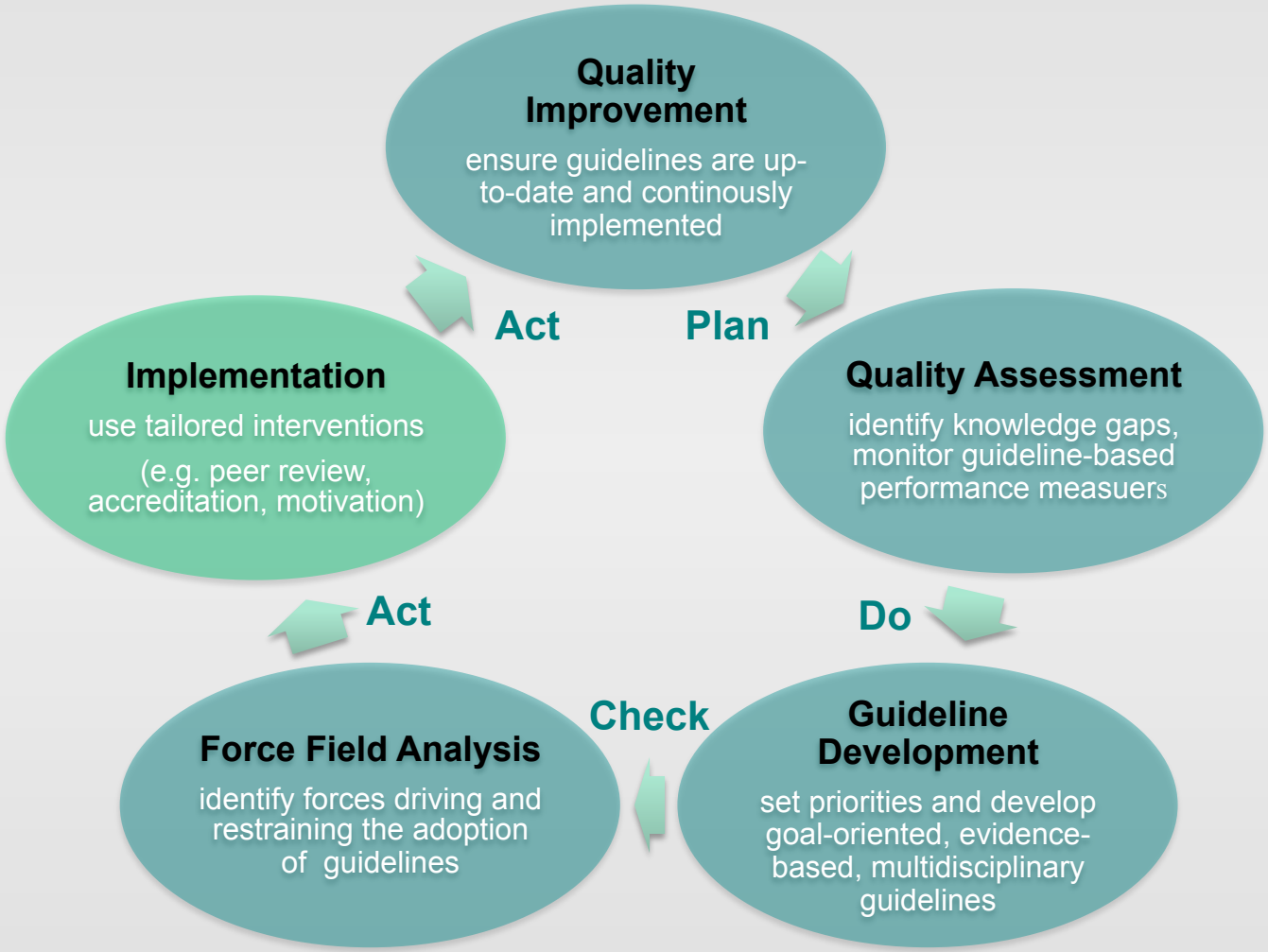
Clinical Practice Guidelines at the Core of the PDCA Cycle



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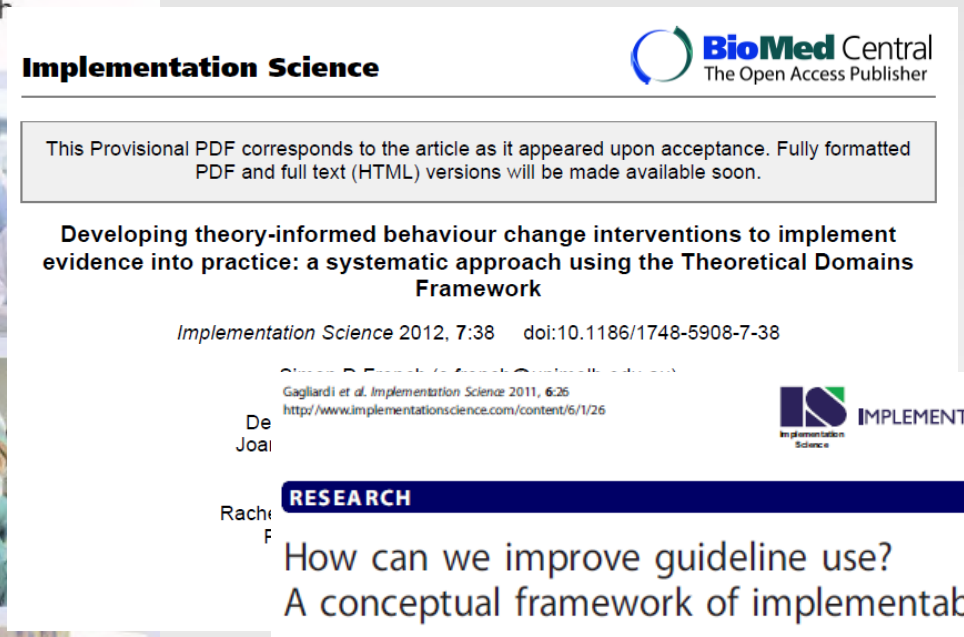
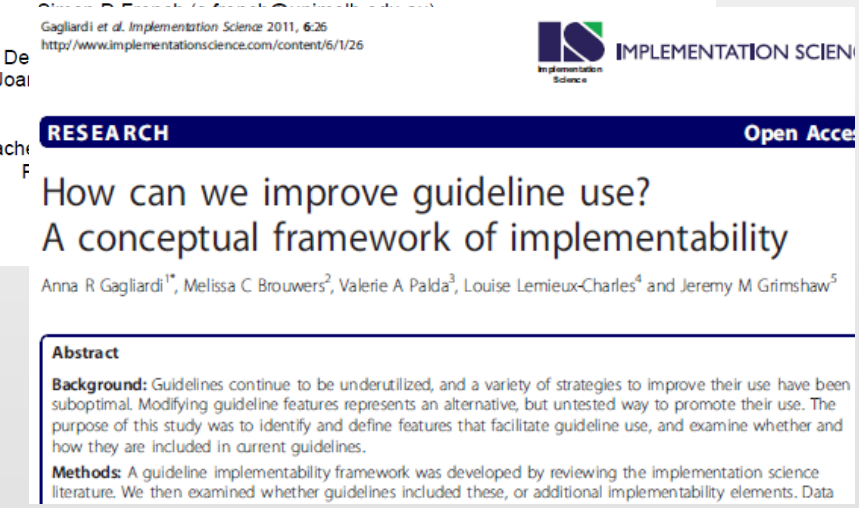
Implementation: evidence-based strategies (e.g. audit and feedback, professional peer review)





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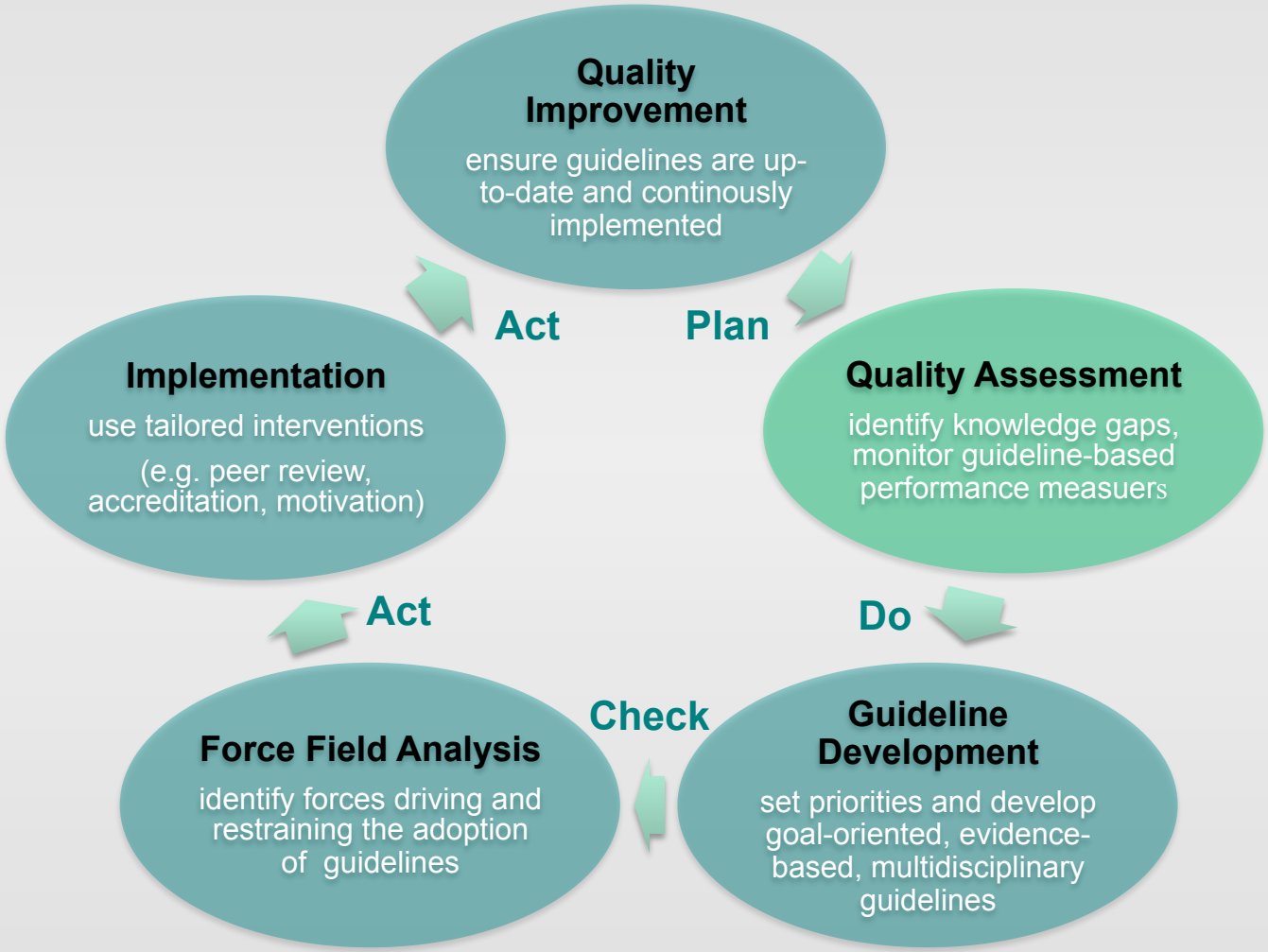

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Kötter et al. Implementation Science 2012, 7:21
http://www.implementationscience.com/content/7/1/21

IMPLEMENTATION SCIENCE

SYSTEMATIC REVIEW Open Access

Methods for the guideline-based development of quality indicators–a systematic review

Thomas Kötter[1,2*], Eva Blozik[1] and Martin Scherer[1]

Criteria for the extraction of guideline recommendations

- impact on patient outcome
- ***level of evidence, grade of recommendation***
- ***potential for improvement***
- ***measurability***
- relevance
- ….

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trolled trial or other
pment to generate
s to guideline-
ions. Only a few

studies reported patient involvement.

Conclusions: Further research is needed to determine which elements of the methodological approaches identified, described, and compared in this review are best suited to constitute a gold standard for guideline-based QI development. For this research, we provide a comprehensive groundwork.

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Implementation and Monitoring / Evaluation: Networking with existing quality initiatives

- **National Network of Certified Centers /Reference Centers**
  support implementation, transfer of guidelines into practice

- **National Network of Registers**
  assess and report processes and outcomes, provide feedback

- **External quality assurance**
  (Germany: implemented in the Social Code book, carried out by a central institution)
  assess and report processes and provide feedback

- **Outlook: Networking with international initiatives?**

OECD Health Indicator Project

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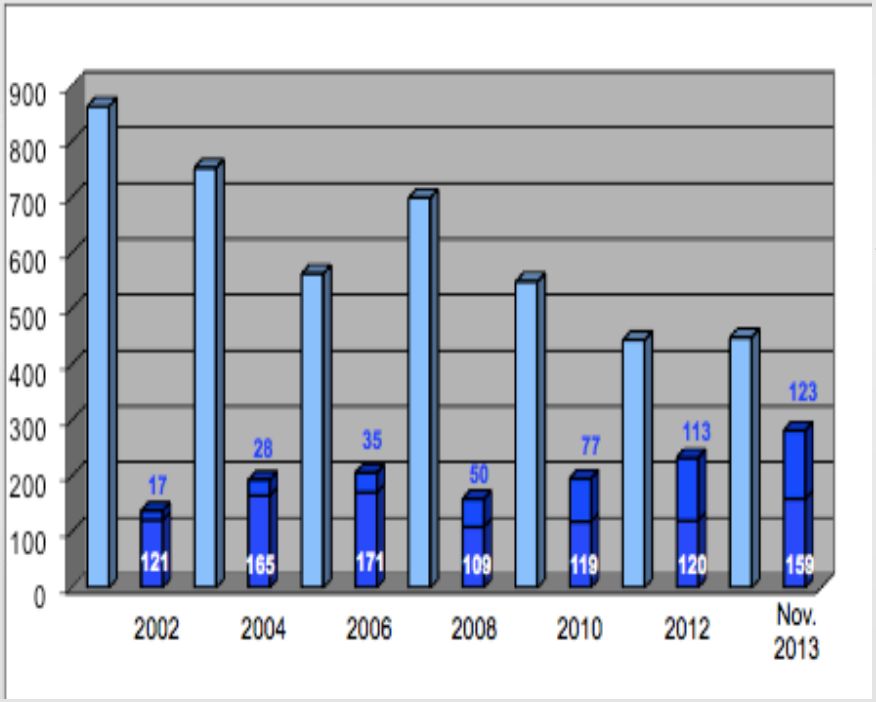
Enhancing
Medical Professionalism and Interdisciplinarity: is the German bottom-up approach successful?

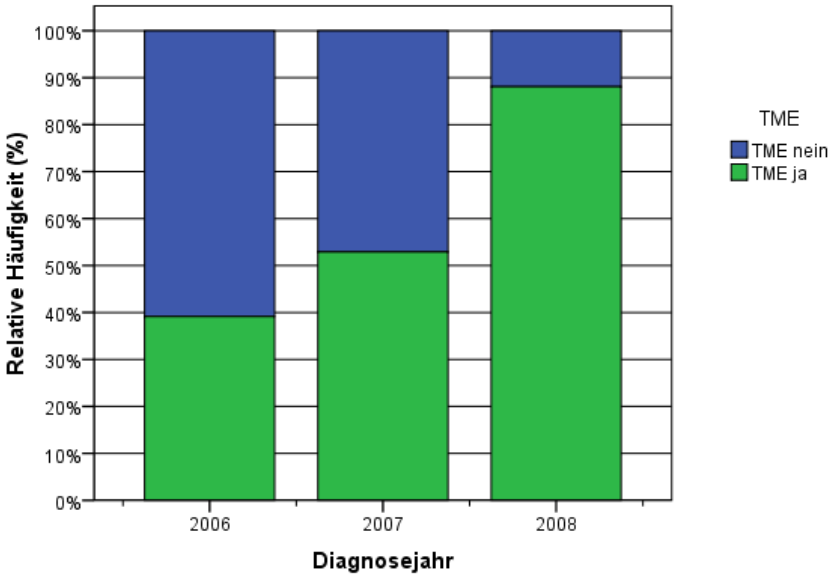


Enhancing Professionalism- improvement in systematic development: Quality Improvement of Guidelines in the AWMF-Register over time

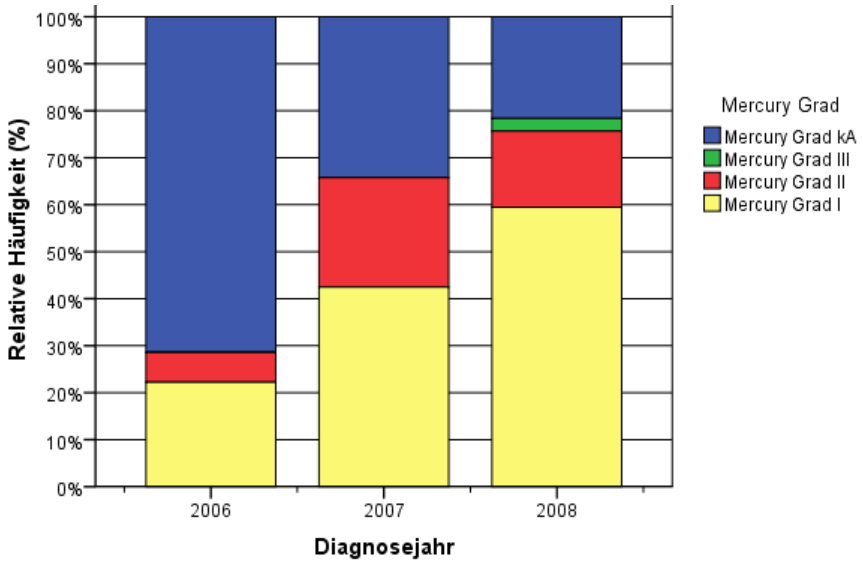
- S1 - expert recommendations
- S2 - guidelines based on a systematic review of the evidence or on structured consensus of a multidisciplinary group
- S3 – evidence and consenus

Enhancing Quality: Documentation of Guideline- based Performance Measures

Patients receiving TME



Documentation according to Mercury (n= 173)



Performance Measure: Total Mesorectal Excision in Patients with Rectal Cancer (LoE 2a)
Source: M. F. Hofstädter, M. Klinkhammer-Schalke 2008
Data base: German Cancer Registries

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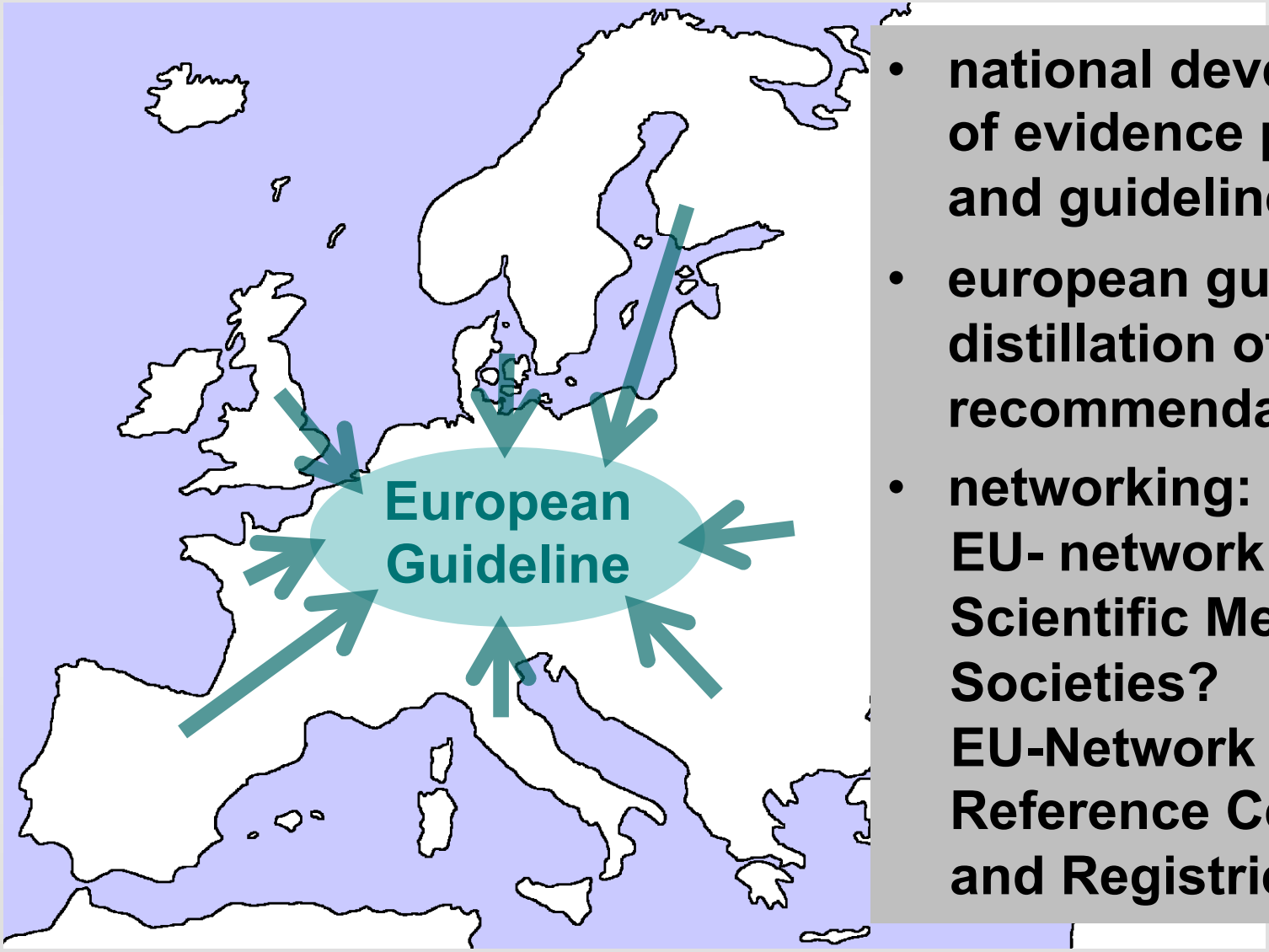
Moving forward towards networking with guidelines: conceptual suggestion



- national development of evidence profiles and guidelines
- european guidelines: distillation of key recommendations
- networking:
  EU- network of Scientific Medical Societies?
  EU-Network of Reference Centers and Registries?

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Conclusions:
how to move forward with networking to improve healthcare

- „For the future, systematic clinical practice guidelines of the highest quality is the way to go, to assure implementation of the right research results in clinical practice – so that EbM is used in each and every patient treatment, everywhere“

  (Implementation of Medical Research in Clinical Practice, www.esf.org)

- concept:
  national guidelines / evidence profiles as
  basis for european consensus on key points

- outlook:
  EU- Network of Scientific Medical Societies?
  EU- Network of Reference Centres, Registries?

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