Scottish Charity
No: SC 034047

Can Guidelines Protect From Overdiagnosis?

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Preventing Overdiagnosis Conference, Sept. 01-03 2015, NIH, Bethesda

Guidelines International Network (G-I-N)

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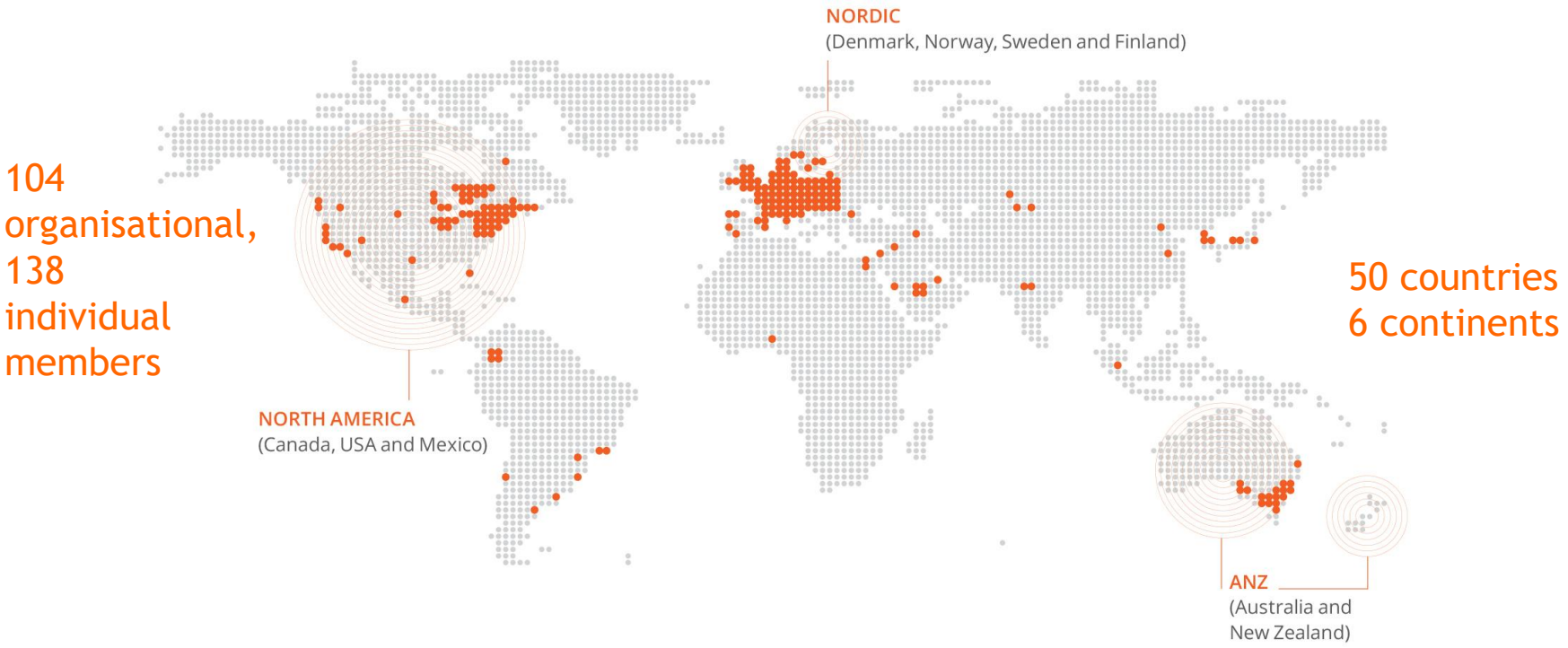
- Background:
  rapid increase in publications of guidelines – perceived inflation, uncertainty about validity, duplication of efforts
- Mission:
  to lead,strengthen and support collaboration in guideline development, adaptation and implementation



104 organisational, 138 individual members

50 countries
6 continents

Can Guidelines Protect From Overdiagnosis?

In Principle, Yes.

You only need to mind the steps.

- The topic chosen
- The group composed
- The methodology applied
- The health care system and target users addressed
- The factors driving and restraining implementation on the system and individual level
- The structures in place to network with in terms of implementation and evaluation

The Status Quo

- Clinical Practice Guidelines (CPGs) have been introduced to health care systems as tools to promote knowledge transfer, to assist individual decisions and thus to promote appropriate healthcare.

But

- CPGs in many areas do not achieve their intended goals, especially when it comes to the formulation and implementation of negative recommendations to prevent overdiagnosis and overtreatment.

The Status Quo

- Slow uptake of new research findings
- Specialist Bias
- Loss Aversion
- Peer Pressure
- Multiple barriers on the individual and system level

RESEARCH LETTER

LESS IS MORE

Responses of Specialist Societies to Evidence for Reversal of Practice

Medical reversal—when a current practice is found to be no better than, or inferior to, a prior standard—is common[1] and inconsistently translated into practice.[2] Continuing use of ineffective treatments wastes resources and harms patients.[3] There may be multiple reasons for persistence of reversed practices. Commercial entities may resist evidence of reversal that threatens profitability.[4] Academic and/or specialist biases

Invited Commentary page 809

Related articles pages 801

LESS IS MORE

On the Undiffusion of Established Practices

Frank Davidoff, MD, MACP

Everett Rogers' classic monograph on the diffusion of innovations represents the process by which we adopt new ideas and practices as a smooth S-shaped curve. In this curve, the percentage of adoption increases incrementally over time, then shoots up exponentially and begins to level off as it approaches 90%.[1] The path of diffusion in Rogers' model progresses in the following order: innovators, early adopters, an early majority, a late majority, and laggards. More recent work has deepened the general understanding of the inherently complex psychological and social processes by which innovations are adopted and ultimately incorporated into routines by persons[2] and service organizations.[3]

Related articles pages 801, 835, and 845.

Rogers' use of the word *diffusion* implies that, once started, the adoption of innovations becomes a continuous, self-sustaining process. But his text makes it abundantly clear that adapting to the "shock of the new" is hard work and that, in practice, the path of adoption is rarely smooth. Particularly in complex organizations, the knowledge that drives diffusion "is socially constructed and frequently contested, and must be continually negotiated by members of the organization."[3(pp405)] More generally, the pace and extent of diffusion depend on the characteristics of the innovations themselves, the goodness of fit between innovations and adopters, and the social, economic, and political contexts in which diffusion happens.[4]

The Abandonment of Established Practices

Once established, clinical practices can be extraordinarily hard to abandon if subsequent evidence and experience find them to be ineffective, disruptive, or the cause of net harm—or when better practices come along.[5] Intuition points to many factors that make it hard to abandon well-worn practices: preference for the familiar, shame at having used a discredited or obsolete practice, regret at leaving behind the sunk costs of training and equipment, potential loss of revenue, and simple inertia. But abandonment commands little attention as a topic for serious study and, as a consequence, our understanding of abandonment is limited. A recent elaborate theory of implementation has only this to offer: "If contribution cannot be sustained, then embeddedness of a complex intervention will be threatened as agents' efforts diminish."[2] Empirical studies of abandonment are few and far between; an extensive 2004 systematic review[3] found only a single published empirical study of abandonment among 200 studies of diffusion.

In short, there is no coherent, detailed, formal model for abandonment that characterizes the people involved in the process, the factors that drive it, and a curve describing its progress over time. Even a specific term is lacking that identifies the abandonment of established practices in the same technical sense that diffusion has come to identify the uptake of innovative practices. Many words could serve that purpose (eg, discontinuation, deadoption, deimplementation, reversal, rejection, or withdrawal). Because abandoning established practices is, at least to a first approximation, the mirror image (negative image) of diffusion, the term *undiffusion* arguably becomes the most appropriate choice.

New Evidence Related to Undiffusion

Three studies in this issue[5-7] contribute usefully to our understanding of undiffusion as a process. Niven et al[5] begin by reporting "slow but steady adoption of tight glycemic control" in a large national cohort of patients in the intensive care unit following publication of a 2001 article (the Leuven I study) that demonstrated reduced mortality rates among patients whose blood glucose levels had been tightly controlled. Although these observations are consistent with the possibility that publication of Leuven I was responsible for the increasing adoption of this innovation, a lack of meaningful baseline data (ie,

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31% vs 62%; $P = .003$) and were more likely to recommend the reversed practice for all or some patients (recommend, 54% vs 29%; not recommend, 31% vs 57%; $P = .01$) (**Figure**). Resistance to reversal of practice by specialist societies was greater when the reversed practice was assessed to be very important to its members ($P < .001$). No interaction was found between resistance to reversal, source of response, and either level of prior supporting evidence or type of intervention.

Discussion | Specialist societies are moderately resistant to medical reversal. The notion that "specialist bias" favors continuation of reversed practices is supported by our findings because journal responses were less resistant to changing practice and specialist societies' resistance to reversal was related to importance of the reversed practice to members of the re-nding society. Publications favorably disposed toward re-ed practices are predominantly found in specialty journals.[2] rnal responses may also be susceptible to bias: selection of torial authors might favor endorsement of the reversing pub-tion, thus reducing resistance, or editorial authors might e academic investment in the reversed practice, thus fa-ing resistance.

Our findings might reflect inherent conservatism among sicians, but physicians were not conservative in adopt-most of the reversed practices without rigorous support-evidence (Table). Interpretive biases favoring greater ngency in evaluating evidence that challenges estab-ed ideas, discounting of data by selective criticism of thods, and adherence to arguments of plausibility[6] may enhanced among specialists. Academic and commercial flicts within specialist societies[5] may also contribute to istance to reversal. Within specialist societies, greater olvement of methods experts and nonspecialists in luating new evidence and minimization of commercial flicts might improve the translation of reversing evi-ce into clinical practice.

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or Contributions: Dr Grey had full access to all the data in the study and s responsibility for the integrity of the data and the accuracy of the data sis.

y concept and design: Wang, Grey.

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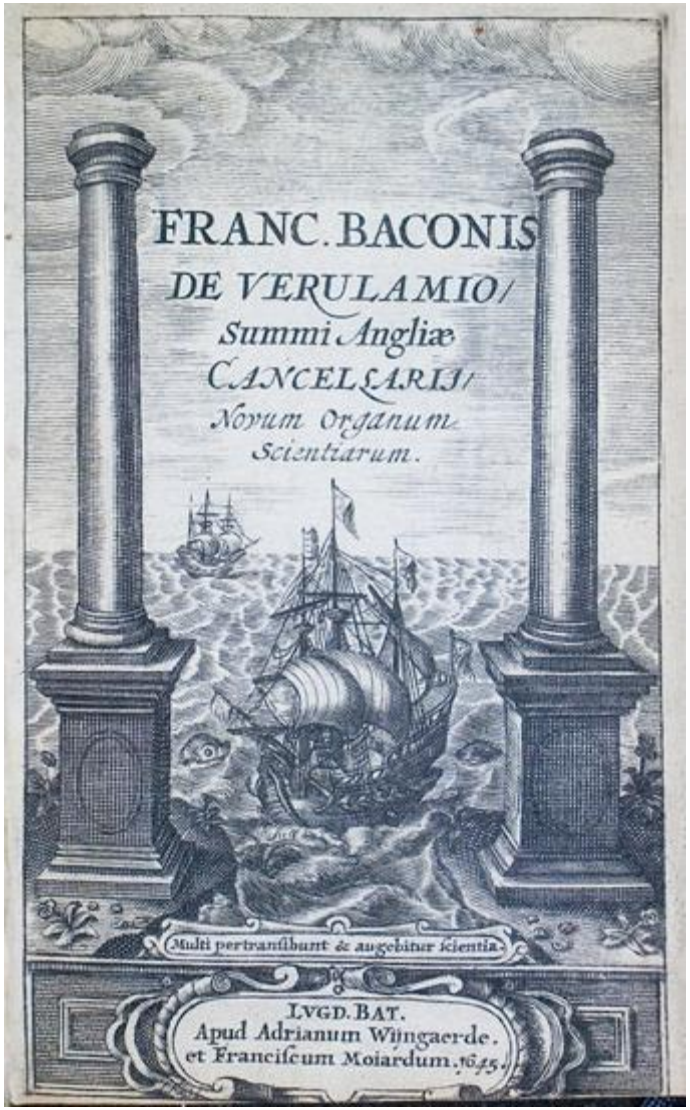
What we need to face



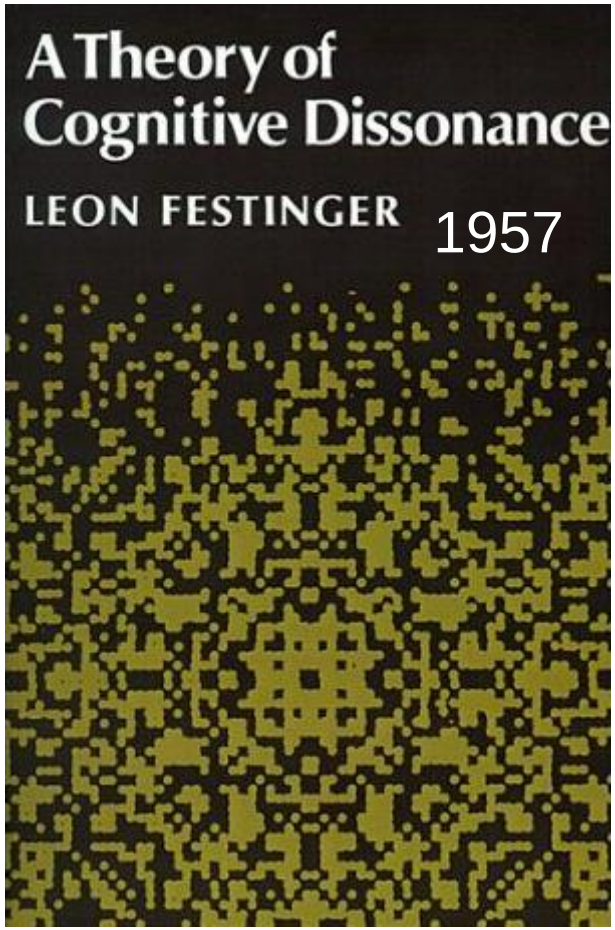
The human understanding draws everything else to be in harmony with, and to support, those things which once please it….

And, though it must be admitted that the force and the number of instances that occur to the contrary is greater, it either does not heed them or …
it distances itself from them…
-and that not without great …prejudice -

so that the authority of those previous beliefs remains inviolate.

Francis Bacon 1645

What we need to face



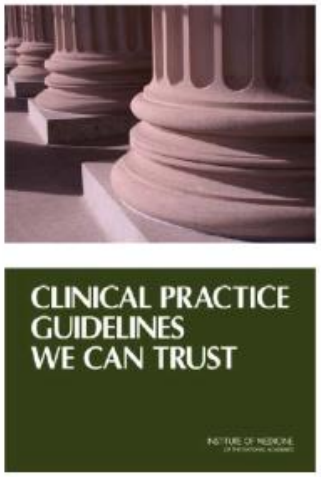
Attitudes once adopted and decisions once made
are extremely resistant against change.

This applies when we address knowledge as well as attitudes and behaviour.

The Potentials

- International consensus about guideline methodology
- Implementation research is aligned with (Social) Psychology
- Opportunities for networking with other quality improvement initiatives do exist

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.

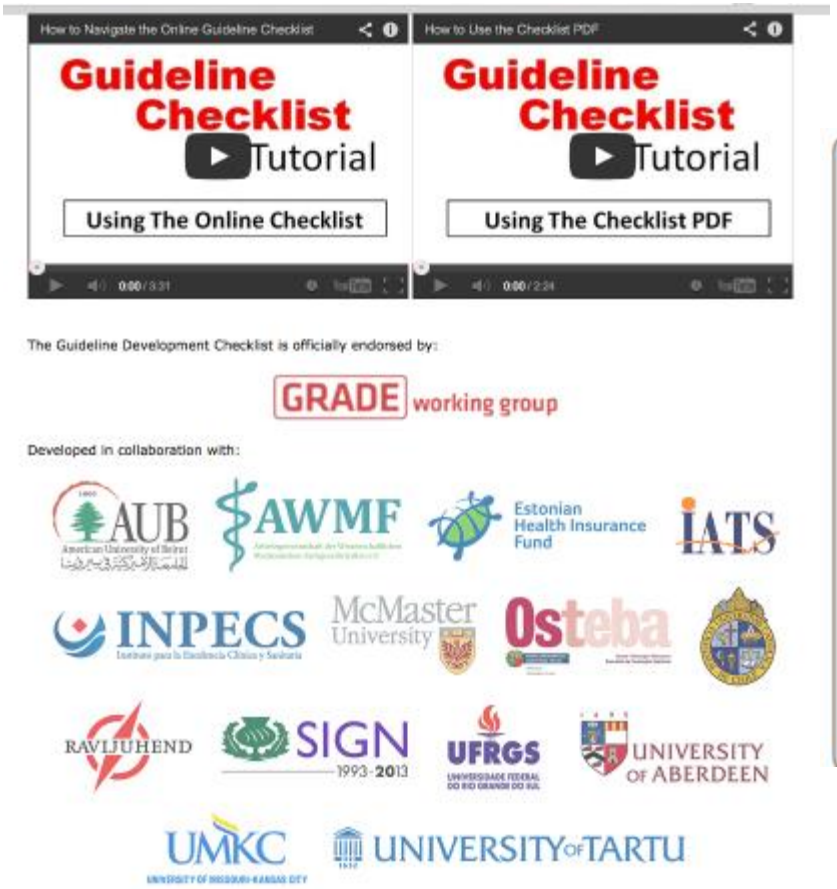
Founded in 2002, the Guidelines International Network (G-I-N) is a network of guideline developers that includes 93 organizations and 89 individual members representing 46 countries. The G-I-N board of trustees recognized the importance of guideline development processes that are both rigorous and feasible 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.

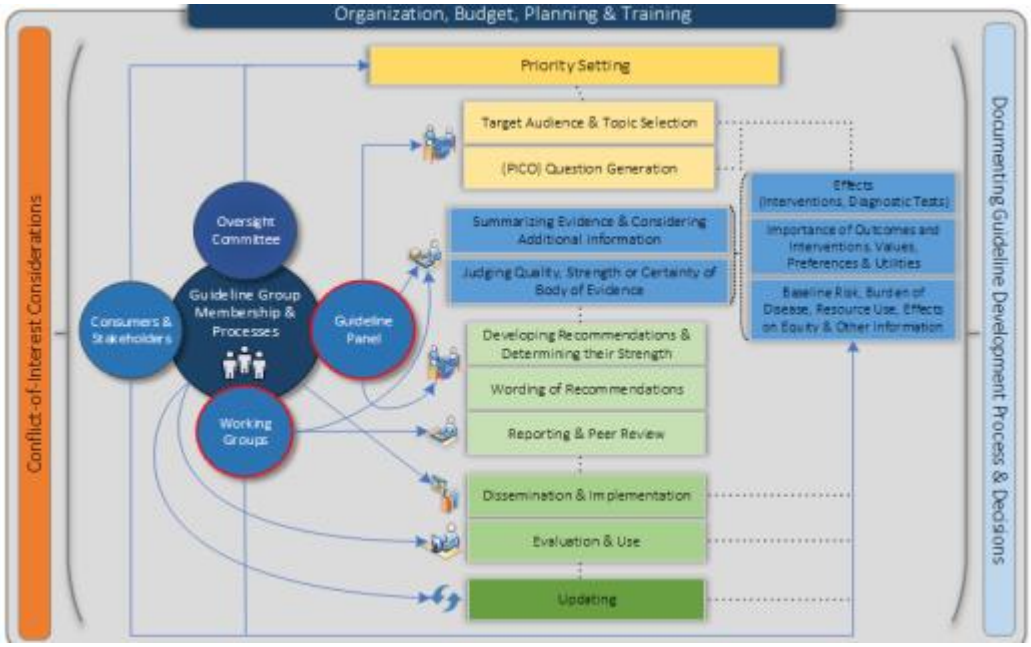
This article presents G-I-N's proposed set of key components for guideline development. These key components address panel composition, decision-making process, conflicts of interest, guideline objective, development methods, evidence review, basis of recommendations, ratings of evidence and recommendations, 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.

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

The Potentials

Open access to methodological support: The G-I-N McMaster Guideline Development Checklist





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

The Potentials
Excursion to the German Guideline 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 currently representing 171 members)
- AWMF strives for networking with national quality initiatives to promote implementation and evaluation of guidelines
- AWMF is a founder member of G-I-N

www.awmf.org

Quality Assurance for Guidelines: the AWMF Guideline Register

Content:

≈ 700 guidelines developed by the Scientific Medical Societies

Minimal inclusion criteria, assessed by two independent reviewers:

- registration and public announcement of guideline projects under development to improve interdisciplinarity
- existence of a guideline report describing methodology to ensure transparency of the development process
- documented declaration and management of conflicts of interest
- up-to-datedness; outdated guidelines are deleted by AWMF

Quality Assurance for Guidelines: AWMF Guidance - Manual and Rules for Guideline Development

Online pdf in English available open access via

www.awmf.org/filemin/user_upload/leitlinien/AWMF-Regelwerk/AWMF-Guidance_2013.pdf

Yes, we can!

Some examples from the AWMF-Register

- Declaration of CoI is a fully implemented standard
- Of 753 CPGs published via the AWMF Register (as per November 2014)
  - 61% CPGs are not developed by a single society, alone (range: 2-56 societies/organisations involved)
  - >100 self-help patient/citizen organisations involved
  - 17,4% (131) CPGs meet the AGREE-criteria reg. (1) systematic review of the literature and (2) formal consensus with involvement of all relevant stakeholders,
  - 24,2 % (182) CPGs meet the criteria for one of these two elements

Yes, we can!

Negative Recommendations

- Sample: 40 CPGs from the AWMF-Register
  - published 2006 - 2013, valid as per review date 11/2013
  - meeting AGREE criteria for systematic review of the literature and formal consensus with all rel. stakeholders
- Results:
  - 37 of 40 Guidelines provide negative recommendations
  - percentages range from 1,2 to 63,2 of all recommendations in a specific guideline
  - Top 2: Hormone Therapy, Unspecific Low Back Pain
  - the amount of negative recommendations is not dependent on the society/specialty but on the topic addressed

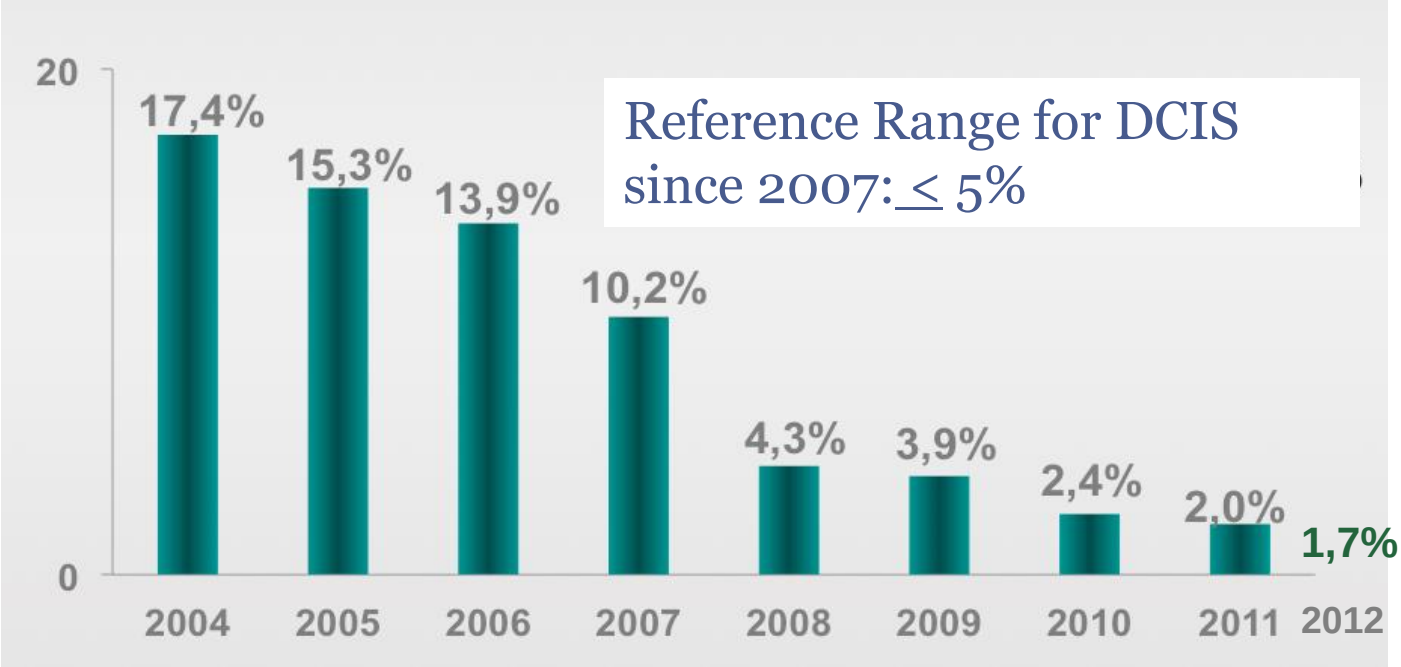
Analysis by Prof. Günter Ollenschläger, G-I-N Honorary Patron, Director Emeritus of the German Agency for Quality in Medicine, AQuMed, Personal Communication

Yes, We can!

Reducing Overuse through implementing Guideline based Performance Measures

DCIS: primary axillary dissection (definition until 2007: ...or papillary CIS)

Obligatory documentation, according to §37a Social Code Book
910 hospitals, 7. 347 DCIS cases (2012)



National Quality Reports, www.sqgg.de

Yes, We can!

Jointly Decide Wisely: an Initiative of AWMF and it´s Member Societies

- To adress over,- under,- and misuse
- In areas, where CPG recommendations are not adequately implemented or missing
- To ensure trustworthiness of recommendations through the implementation of guidance and methodological criteria:

1. clarity of the recommendation
2. indications for under- over- or misuse
3. quality of the evidence
4. strength of the recommendation
5. influencability of the topic/clinical problem addressed
6. implementability of the recommendation (barriers/facilitators)
7. Risk of unintended consequences associated with implementation

The Outlook

- Concerted action to improve appropriate healthcare, driven by networking between the various quality initiatives initiated and led by the medical profession and patient/citizen representatives:
  - Guidelines
  - Performance Measures
  - EBM/EBHC/HTA
  - SDM
  - Choosing Wisely / Preventing Overdiagnosis

  …

Conclusion

- Justified criticism of existent guidelines should not lead us to discard the concept of CPGs
- CPG recommendations might still be the best, but not the only instrument we have to promote changes on the individual and the system level
- Any quality improvement initiative will need manuals and rules to ensure transparency and trustworthiness
- I have a dream:
  concerted action to improve appropriateness of healthcare as a joint effort of current initiatives