



Manual

Developing recommendations within the “Deciding Wisely Together” Initiative

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Editorial Board/Contact:

AWMF – Institute for Medical Knowledge Management (AWMF-IMWi)

c/o Philipps-Universität
Karl-von-Frisch-Str. 1
35043 Marburg, Germany

E-mail: imwi@awmf.org

Please submit comments and change proposals to this email address

Authors

Nothacker M, Gaebel W, Gogol M, Hasenfuß G, Helms U, Klemperer D, Kreienberg R, Lynen P, Meyer H-J, Muche-Borowski C, Raspe H, Schaefer C, Scherer M, Strech D, Werdan K, Kopp I.

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“Deciding Wisely Together” – an initiative of the AWMF and its Scientific Medical societies

Under the auspices of the AWMF, the Scientific Medical Societies have been working for a number of years on how to better transfer recommendations from high-quality guidelines and other high-quality sources of systematically reviewed knowledge into practice. Originating in the USA, international campaigns are being promoted that strongly focus on public relations to disseminate prioritized lists of the "top 5/top 10" particularly relevant recommendations—above all, to avoid overuse, underuse and misuse of health care services^{1,2}. Considering these international approaches, their critical discussion³, the real potential of interdisciplinary collaboration across the Scientific Medical Societies established in Germany over the past 20 years under the auspices of the AWMF⁴ and the fact that not only overuse, but also underuse and misuse of health care services are addressed^{3,5} (see Annex 1 for definitions), the AWMF presidential board launched the “Deciding Wisely Together” initiative 2015 and set up an Ad Hoc Commission to shape the framework and methodological principles of the initiative. This manual is designed as a guide to a systematic approach for the Scientific Medical Societies that develop “Deciding Wisely Together” recommendations. Additionally, addressees of “Deciding Wisely Together” recommendations should be able to use this manual as a tool to test their methodology. The manual is continuously updated.

The Ad Hoc Commission issued the following mission statement:

"Deciding Wisely Together"

- is a **quality campaign of the Scientific Medical Societies under the auspices of the AWMF**
- is aimed at **improving the quality of care through identification and focused implementation of recommendations on topics** which are particularly relevant to health care
- highlights the **commonality and unity of the Scientific Medical Societies in the AWMF, the joint cross-disciplinary and interprofessional provision of care**
- focuses on **patient- and care- related aspects of diseases**, not specialties
- helps **focus and systematize conversations between patients and physicians and thus shared decision-making**
- promotes a **scientifically and ethically grounded decision-making process also in response to an increasingly market-oriented health care system.**

This manual is designed as a guide to framing reliable “Deciding Wisely Together” recommendations that uphold the standards of scientific rigor, transparency of the development process, consensus among stakeholders and those affected while achieving target group orientation. In the end, wisely chosen recommendations based on cross-disciplinary and interprofessional agreement and incorporating input from patient representatives should stand as the pillars of decision-making processes.

“Deciding Wisely Together” recommendations emphasize topics that doctors, patients, other health care providers, third-party payers and decision-makers within the health care system should discuss more intensively. Therefore, versions for lay persons or patients to support these conversations are an integral part of these recommendations and can be utilised to support in the entire treatment team in keeping patients informed and educated. Whether a "Deciding Wisely Together" recommendation is applicable in the individual case has to be weighed mutually by doctor and patient. Thus, the “Deciding Wisely Together” recommendations should under no circumstances be misinterpreted as regulatory instruments or standards that could replace individualized decisions.

2019 Update (Version 1.2) – what’s new?

The 2019 Update focussed on accurately gauging the essential need on the part of patients for informational and conversational input. This estimated need was included as a criterion in this manual. Moreover, a note on the framing of the identified need for research was included in the criterion’s explanation box “Evidence basing” and editorially updated.

Development and outline of the manual

The contents of the manual were agreed within the Ad Hoc Commission in an informal consensus. The criteria for selecting “Deciding Wisely Together” recommendations were determined in an online survey using the Delphi method. The results and comments from the survey were pooled and conclusively discussed with all committee members. The draft manual was sent to all scientific medical societies for comments before final editing. The update 2019 has been agreed on within the Ad hoc Commission.

The outline below presents the factors that should be included when developing “Deciding Wisely Together” recommendations:

- 1. Selecting the care aspect / clinical condition with regard to its potential for improvement**
- 2. Composition of a representative panel**
- 3. Criteria-based selection of “Deciding Wisely Together” recommendations**
- 4. Structured consensus finding**
- 5. Target group orientation**
- 6. Dissemination and implementation**
- 7. Evaluation**

1. Selecting the care aspect/clinical condition

Explicit criteria (reasons for prioritisation) should be applied to identify a care aspect/clinical condition that may be applicable to the development of “Deciding Wisely Together” recommendations, such as

- Potentials for improvement in health care provision that can be exploited by “Deciding Wisely Together” recommendations
- Frequency of the disease (prevalence/incidence)
- Burden of the disease (morbidity, mortality, quality of life)

- Differences in the provision of health care services across clinical practice (variations), accounting for disparities and geographical (regional or local) differences, no different preferences
- Economic relevance
- Ethical and social significance
- Need for informational and conversational input into decision-making
- Coordination requirements (interdisciplinary, interprofessional, cross-sectional) ⁶

Reasons for the choice of topic may also be cases (see also chapter 3.),

- where it has been established that current, high-quality S3 guideline recommendations have not been sufficiently implemented, or
- where current, high-quality S3 guidelines (recommendations) are missing and “Deciding Wisely Together” recommendations ought to be drawn up from other high-quality sources of systematically compiled knowledge.

2. Composition of a representative panel

A “Deciding Wisely Together” recommendation should be developed by a panel which is representative of the recommendation's addressees. A single Scientific Medical Society that frames the task takes the initiative to develop “Deciding Wisely Together” recommendations and select the care aspects/clinical condition and then assume a leadership role. First, the lead Scientific Medical Society should determine the addressees, including representatives of potentially affected patients/citizens, for a potential “Deciding Wisely Together” campaign in order to form an appropriately representative panel. The additional involvement of methodologists such as AWMF guideline advisors can be useful.

If the development of "Deciding Wisely Together" recommendations is planned in line with a pre-existing guideline in the AWMF Registry, the representatives of the guideline panel used for that purpose can also constitute the lead contacts for setting up the "Deciding Wisely Together" panel. It is not necessary to convene the entire guideline panel; rather, the addressees affected by a specific recommendation are of pivotal importance. The initiative to develop a "Deciding Wisely Together" recommendation should also be initiated by the guideline group itself.

3. Criteria for selecting “Deciding Wisely Together” recommendations

The selection of “Deciding Wisely Together” recommendations should be predicated on multidisciplinary, formally agreed, evidence-based, up-to-date S3 practice guidelines or – when lacking – on other high-quality sources of processed knowledge that are to be systematically compiled (e.g. other high-quality guidelines, systematic reviews such as current Cochrane reviews, data from health care research).

The drafting of "Deciding Wisely Together" recommendations should already be planned during guideline development and carried out in parallel (see “Helpful tips” in Annex 2).

For selecting suitable "Deciding Wisely Together" recommendations, the Ad Hoc Commission explicitly recommends that the appraisal be underpinned by criteria. The first two criteria (3.1 clarity of recommendation and 3.2 indications suggesting the overuse, underuse or misuse of health care) ought to be fundamentally appraised, being defined as exclusion criteria, respectively. It is the opinion of the Ad Hoc Commission that criterion (3.3. indications suggesting an elevated informational and conversational need) newly introduced in 2019 should likewise be given priority in the appraisal. The other criteria *can* be appraised or be used (some partially) for purely descriptive purposes. However, it is advisable that reliable recommendations be prioritized, i.e. those with a sound evidence base (criterion 3.4.) and/or a strong grade of recommendation (criterion 3.5.).

Each criterion (3.1. – 3.8.) has an explanation and a key statement that is evaluated. The Ad Hoc Commission proposes the following procedure: The rating is based on a 4-point scale with response categories 1 (strongly disagree) to 4 (strongly agree). Criteria rated 3 or 4 are considered positive ratings. Finally (see 3.9), the raters may give an overall appraisal of the suitability of a recommendation for a “Deciding Wisely Together” campaign.

3.1 Clarity of the recommendation

Strongly disagree

1	2	3	4
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 Strongly agree

This criterion looks at the use of consistently clear definitions to avoid misunderstandings among the addressees.

The following statement is evaluated:

All aspects of the recommendation are clearly defined.

The use of the **PICO** scheme* can be helpful in guiding the assessment. Relevant factors for a recommendation are **P** (patient characteristics) and **I** (intervention), meaning the clear description of the patients to whom the recommendation ought to apply (for example, the clinical condition and any other characteristics such as age and sex) and the unequivocal description of the investigation method or method(s) of the treatment addressed.

Information on **C** (comparator intervention) and **O** (patient-relevant outcomes) are important in addition to weighing the potential benefits / harms of the recommendation. Such information should be found in the sources relied on for the recommendation (for example, background text from current S3 guideline recommendations or corresponding chapters of other sources that have been systematically selected and used). *PICO: Helpful tips for framing well-focused PICO questions, Patient – Intervention – Comparison – Outcome. Practical example presented in Annex 3.

3.2 Indications suggesting the overuse, underuse or misuse of health care

Strongly disagree

1	2	3	4
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 Strongly agree

This criterion aims to identify what is required for a "Deciding Wisely Together" recommendation.

The following statement is evaluated:

There are health care data or a well-founded expert consensus suggesting a relevant problem exists in terms of the overuse, underuse and misuse of health care.

Ideally, indications suggesting the overuse, underuse and misuse of health care services should be based on care provision data or, alternatively, on expert consensus. Care provision data should be assessed with respect to their clinical relevance and plausibility in identifying overuse, underuse and misuse. Relevant qualitative data can also be helpful. An accepted quality standard for patient care should be available.

Indications suggested by care provision data or by experts may be taken from data provided by the source(s) used for the recommendation (current S3 practice guidelines or other systematically selected sources); if these data are not available therein, then they can be derived from proprietary research or consensus-finding by the "Deciding Wisely Together" panel. The assessment ought not only be from the perspective of the individual patient but, if appropriate, from that of the general public as well (example: antibiotic resistance).

3.3 Indications suggesting an elevated informational and conversational need

Strongly disagree

1	2	3	4
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 Strongly agree

This criterion aims to identify what is required for a "Deciding Wisely Together" recommendation framing the extent of the need on the part of patients for informational and conversational input

The following statement is evaluated:

Health care data or well-founded assumptions (expert consensus) suggesting a relevant informational and conversational need on the part of patients relating to decision-making and/or their competency, e.g. for self-management.

Ideally, such suggestive indicators should be based on quantitative and/or qualitative data; alternatively, on a consensus among participating experts and patient representatives (expert consensus). Any extant data should be checked for clinical relevance and plausibility. An accepted quality standard for patient care should be available. If no data are available on the provision of care and the evaluating experts consider the care provision to be inadequate, this may constitute the best available evidence. Indications suggested by the provision of care data or by experts may be taken from data provided by the source(s) used for the recommendation (current S3 practice guidelines or other systematically selected sources); if these data are not available therein, then they can be derived from proprietary research or consensus-finding by the rating panel. The assessment should not only be from the perspective of the individual patient but also from the total group of affected patients.

3.4 Evidence base for the recommendation

Strongly disagree

1	2	3	4
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 Strongly agree

This criterion focuses on the certainty and credibility of the knowledge underlying the recommendation.

The following statement is evaluated:

The recommendation is based on reliable evidence of clinical studies.

The assessment may be based on summarizing information about the quality of the evidence from the source(s) used (current S3 guidelines or other systematically selected sources).

The study design as a sole criterion is not sufficient for this appraisal. The quality of the conduct of studies included and their consistency and transferability to the target patient group, in the context of the health care system, ought to be assessed as well.

The certainty and credibility of knowledge should be presented in relation to patient-relevant benefit and harm outcomes—for interventions, whenever possible, the effects should be reported in absolute terms like absolute risk reduction (ARR), number needed to treat (NNT), and/or number needed to screen (NNS) and number needed to harm (NNH).

If no reliable evidence base on patient-relevant outcomes available for a recommendation deemed relevant, **this will frame to declare the need to conduct research on that recommendation.**

3.5 Strength of the recommendation

Strongly disagree

1	2	3	4
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Strongly agree

This criterion focuses on the strength of a recommendation (grade of recommendation) under selection, and thus on the certainty of the benefit-harm balance assigned to an intervention.

The following statement is evaluated:

The strength of the recommendation is high and justified.

It is recommended that the justification for the recommendation also be included in the assessment. This should cover not only an evaluation of the certainty and credibility of the evidence base, but also other aspects such as clinical relevance of endpoints and effect sizes, applicability to the patient target group, extent of the benefit-harm balance as well as ethical, legal and economic considerations.

3.6 Influenceability of the health care problem

Strongly disagree

1	2	3	4
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Strongly agree

This criterion is used to appraise whether the potential "Deciding Wisely Together" recommendation relates to a health care problem that can be influenced by the stakeholders addressed.

The following statement is evaluated:

The recommendation refers to a health care problem that can be influenced.

Primary addressees are individual physicians, patients as well as the Scientific Medical Societies. An extended group of stakeholders can also be included, such as politicians, municipal providers (e.g. cities/communities in relation to healthy school lunches). The influenceability of the recommendation is to be considered and outlined in relation to its designated addressees.

3.7 Implementability of the recommendation in routine care

Strongly disagree

1	2	3	4
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Strongly agree

This criterion considers barriers, but also enablers.

The following statement is evaluated:

The recommendation is implementable in routine care.

Barriers, but also enablers can be of an organizational, staff-related or financial nature and include patient-related factors as well. A system perspective ought to be adopted when determining implementability. The chances as to whether a recommendation can be implemented ought to be assessed after considering barriers and enablers.

3.8 Risk of unintended consequences when using the recommendation in the "Deciding Wisely Together" initiative

Strongly disagree

1	2	3	4
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Strongly agree

This criterion focuses on the extent of potential unintended consequences if the recommendation is disseminated by the "Deciding Wisely Together" initiative.

The following statement is evaluated:

There are no known risks or the known or suspected risks of using the recommendation in the "Deciding Wisely Together" initiative are described and taken into account as appropriate.

For instance, a recommendation might be used too hastily as a control tool for changing resource allocations or be applied thoughtlessly and thereby prevent individualized clinical decision-making between doctor and patient. The perspective of the various addressees should be taken when assessing risks. Potential strategies or measures to avoid unwanted effects ought to be considered and included in the evaluation.

3.9 Overall appraisal: The recommendation is suitable for the "Deciding Wisely Together" initiative

Strongly disagree

1	2	3	4
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Strongly agree

In aggregate, after reviewing the results on the aforementioned criteria, an overall appraisal of the recommendation can be given of its suitability for the "Deciding Wisely Together" initiative. A consensus on a recommendation as suitable for the "Deciding Wisely Together" initiative is assumed when >75% of all participants give a 3 or 4 rating.

4. Structured consensus-finding for the final selection (prioritized Top lists)

In order for them to identify with the recommendation, it is relevant to the implementation of a “Deciding Wisely Together” recommendation that all those participating in the implementation reach a consensus. The more participants identify with the recommendation, the more likely it is that it will be disseminated and implemented. The representative panel described under item 2. above should reach a consensus on a recommendation or on a selected list of prioritized (top 5 or top 10) recommendations. Scientifically founded formal consensus procedures like the nominal group process, the structured consensus conference or the Delphi method should be used for this purpose⁵. It is recommended to assume that a consensus is reached on the suitability of any recommendation for the “Deciding Wisely Together” initiative or on a selected list of prioritized recommendations (top 5 or top 10) if >75% of the participants in the process give their approval.

5. Target group orientation

The format of “Deciding Wisely Together” recommendations should be available to all target groups as brief information, i.e. a recommendation with a brief justification. “Deciding Wisely Together” recommendations should also be issued in a language understandable to patients and laypersons. Formats that enhance communication between doctors and patients (e.g. reliable patient education leaflets or other material for patients (e.g. option grids, flyers) are critical for patient participation and can be utilized or re-invented. The mission of the “Deciding Wisely Together” initiative also continues to be to provide the public and institutions with specific and understandable information.

The envisaged plan is to design a template that can be used for the various projects.

6. Dissemination and implementation

Quality promotion initiatives and health care research projects have employed various implementation strategies, albeit with varying degrees of success^{7,4}. “Deciding Wisely Together” recommendations should be publicized using a proactive dissemination strategy via

- a. Websites of the Scientific Medical Societies
- b. The central “Deciding Wisely Together” website of the AWMF
- c. Detailed views of the guidelines in the AWMF Guidelines Register (“Deciding Wisely Together” recommendations as documents linked to the relevant guidelines)
- d. Conferences, further education compendia, journal articles, continuing medical education (CME)
- e. “Deciding Wisely Together” joint events with self-governing organizations, third-party payers etc.
- f. Press, public, social media

The implementation of “Deciding Wisely Together” recommendations can be actively promoted by building concrete partnerships at hospitals and in clinical practice (for example, with representatives of physicians’ self-government, regional initiatives, local opinion leaders etc.).

7. Evaluation

Criteria-based accompanying research to analyse the effects of "Deciding Wisely Together" recommendations ought to form an integral part of the initiative's concept from the outset. Experiences and results from other countries are also of interest. So far, however, hardly any results have been published on the effects of "Deciding Wisely". In Germany, no documentation is available for many areas which would allow specific analyses of the use of diagnostic and therapeutic interventions in routine clinical practice. It is therefore important to initiate appropriate accompanying research and evaluation right from the start.

If data are available (e.g. in the context of external comparative quality assurance, at certified centres or in registers), analyses are usually possible in the form of rate-based indicators. The problem with aggregation may be that the proportion of "correct" interventions or the appropriateness of the indication cannot be proven for the individual case. In addition to rate-based indicators, case studies and qualitative surveys can therefore be helpful, meaning that those research initiatives should also be developed and promoted that answer these questions.

Annex 1

Definition: Overuse, underuse and misuse of health care

Extract from the Guidelines Glossary of the Association of the Scientific Medical Societies in Germany and the German Agency for Quality in Medicine (ÄZQ) ⁸:

"Overuse" is defined as health care services that are provided without or with insufficient justification of (additional) health benefits (e.g. due to lack of knowledge, as a favor, for marketing purposes or financial incentives).

"Underuse" means that health care services are refused or not provided (within reasonable effort) in the face of an individual's professionally and scientifically recognized need, although—in actuality—the services are available and have been proven to confer a health benefit with an acceptable cost-benefit ratio.

"Misuse" means that health care services provided or omitted often result in therapeutic harm (potential harm) or loss of benefit, according to medical evidence or experience. Here, it is possible to distinguish between the following combinations:

- The provision of services that are in themselves appropriate, but are not provided according to recognized quality criteria, which may imply avoidable health risks or damage to health.
- The omission of indicated and needs-appropriate services can also be interpreted as misuse, since lost benefit can be understood as harm. In this sense, underuse is also misuse.
- The provision of non-needs-appropriate health care services, meaning those that are not clinically indicated and/or do not have a sufficiently assured net benefit, constitutes misuse.

Annex 2

Tips for developing "Deciding Wisely Together" recommendations in line with guideline development

"Deciding Wisely Together" recommendations can also be developed as part of creating new and updating clinical guidelines. Therefore, before starting to develop a guideline, searches for and discussions about data on the overuse, underuse and misuse of health care services are required. Focusing on some questions can be helpful, such as:

1. Before starting the guideline development process: Do the guideline authors know of or suspect any areas of overdiagnosis/overtreatment or of otherwise known overuse, underuse or misuse of health care services? Are there any data to be found that plausibly indicate the expansion of certain services and/or the lack of other services? What negative impacts are known? Are there any "Deciding Wisely" top lists available on this topic from international initiatives? Are they also relevant in Germany in terms of health care provision?
2. During development: Carefully consider and justify the certainty and extent of benefits and harms when generating recommendations. Ask the guideline authors systematically for the perceived need for a "Deciding Wisely Together" recommendation by section/chapter. (Helpful tips, see Annex 4).

Annex 3

Practical example 1: Using the PICO scheme to assess the clarity of a recommendation

"In acute low back pain, no imaging examination should be performed if serious pathologies have been clinically excluded by taking a medical history and physical examination." (*Recommendation 3-5: National Disease Management Guideline on Low Back Pain, Version 4*)

P= Patients with acute low back pain (maximum duration 6 weeks) after clinical examination excluded serious pathologies ("red flags" = defined in the guideline including necessary clinical examinations; Table 4).

I = No imaging In the recommendation and background information, a comparison is made with

C= Imaging.

The good prognosis of acute, nonspecific low back pain is mentioned in the background text

O= Outcome, good prognosis for pain within a short remission period.

Practical example 2: “Deciding Wisely Together” recommendation in geriatrics¹¹

A practical example is given in the following and characterised according to the assessment criteria. Ideally, authors of the manual carry out the assessment based on the pre-set assessment criteria 1 (strongly disagree) to 4 (strongly agree).

Recommendation: Neuroleptics for Behavioural and Psychological Symptoms of Dementia (BPSD) should not be prescribed to persons suffering from dementia without an assessment of the causes of such symptoms.

References (as per 9/15): American Geriatrics Society 2015 Beers Criteria Update Expert Panel, etc. American Geriatrics Society 2015 updated Beers Criteria for potentially inappropriate medication use in older adults. J Am Geriatr Soc 2015;63:2227-2246; National Institute for Health and Clinical Excellence and Social Care Institute for Excellence NICE-SCIE. National Collaborating Centre for Mental Health. Clinical guidelines 42: Dementia: Supporting people with dementia and their careers in health and social care. London 2006: Amended 2011. www.nice.org.uk/CG042 Maher A, Maglione M, Bagley S, Suttorp M, Hu JH, et al. Efficacy and comparative effectiveness of atypical antipsychotic medications for off-label uses in adults: a systematic review and meta-analysis. JAMA 2011;306:1359-1369.

Leadership roles: German Society of Geriatrics in cooperation with the German Society of Gerontology and Geriatrics (DGGG)

Recommendation selected based on an online survey of members followed by approval on a cross-disciplinary internal medicine panel (German Society of Internal Medicine and 10 scientific societies of internal medicine). Patients/patient representatives not participating.

Clarity of the recommendation 3-4, the terms “BPSD” and “Assessment” are defined in the supplementary text. Negative consequences when an assessment is lacking is obvious from the literature.

Data suggesting overuse, underuse or misuse : Assessment of the database: 2, Online survey of members (expert opinions), no care data on file

Evidence base of the recommendation: 2-3, indirect evidence, quality: “moderate” deriving from the US recommendation on strict indications for antipsychotics, recommendation on assessment in NICE, systematic review of the effects of antipsychotics in people with dementia, no evidence assessment,

Strength of the recommendation: 3, Strong recommendation, clinically sound, but no external evidence discussed in the supplementary text. Recommendation appears clinically sound..

Influenceability of the health care problem 4

Implementability of the recommendation in routine care: 2-3? Who in the leader team can undertake the assessment, time capacity?

Risk of unintended consequences when using a recommendation in the “Deciding Wisely Together” initiative: 1

Annex 4

Helpful tips for determining the benefit-harm balance

A benefit-harm balance assessment should be undertaken to assess whether the evidence base of the recommendation suggests it is suitable for the “Deciding Wisely Together” campaign. What is the certainty of proof for benefit and/or harm? How pronounced is either benefit or harm?

Several scenarios of a benefit/harm balance are possible including:

1. Uncertainty about both the benefits and harms of an intervention
2. Uncertainty about benefits, indications of harm
3. Uncertainty about benefits, certainty about harm
4. Indications of a benefit, uncertainty about harm
5. Indications of both benefits and harms
6. Indications of a benefit, certainty about harm
7. Certainty about benefit, uncertainty about harm
8. Certainty about benefit, indications of harm
9. Certainty about both benefits and harms.

In addition to the certainty of the statement, the effect size, i.e. the extent of patient-relevant benefits in relation to harms, is relevant. Effect sizes should be reported in absolute numbers and, additionally, as number needed to treat (NNT) and number need to harm (NNH). The overriding principle is “primum nihil nocere” – a justified suspicion is sufficient, while any benefit should be well proven (cf. German Drug Law, AMG).

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