Manual

Developing recommendations within the “Choosing Wisely Together” Initiative

Version 1.0 of 15 September 2015 (consultation version)

Publisher:

Ad Hoc Committee on “Choosing Wisely Together” — An Initiative of the Association of the Scientific Medical Societies in Germany (AWMF)

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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, Klemperer D, Kreienberg R, Lynen P, Meyer H-J, Muche-Borowski C, Raspe H, Schaefer C, Scherer M, Strech D, Werdan K, Kopp I.

Version 1.0 (consultation version)

Adopted by the AWMF's Presidential Board on DD-MMM-2015

The manual is continuously updated; a complete revision is planned after conclusion of the consultation phase

Please cite as follows
Association of the Scientific Medical Societies in Germany (AWMF) –
Ad Hoc Committee on "Choosing Wisely Together". A manual on developing recommendations within the "Choosing Wisely Together" Initiative. Version 1.0 (consultation version) 2015. Available at: http://www.awmf.org/medizin-versorgung/gemeinsam-klug-entscheiden.html (Accessed on DD-MMM-YY)

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Preface

“Choosing 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 into practice recommendations from high-quality guidelines and other high-quality sources of systematically reviewed knowledge. Originating in the USA, international campaigns are currently 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 of health care services[1,2]. Considering these international approaches, their critical discussion[3], the real potential of interdisciplinary collaboration across the Scientific Medical Societies established in Germany over the past 20 years under the auspices of the AWMF[4] 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 “Choosing Wisely Together” initiative and set up an Ad Hoc Committee 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 “Choosing Wisely Together” recommendations. Additionally, addressees of “Choosing Wisely Together” recommendations should be able to use this manual as a tool to test their methodology. The manual is continuously updated.

Kommentiert [DS1]: the methodology of the recommendations....

The Ad Hoc Committee articulated the following mission statement:

"Choosing Wisely Together”

- is a **quality campaign of the Scientific Medical Societies under the auspices of the AWMF**
- aimed at **improving the quality of care through selected recommendations on prioritized topics**
- highlights the **community of Scientific Medical Societies in the AWMF, the joint cross-disciplinary and interprofessional provision of care and shared decision-making between patient and physician**
- focuses on **patient- and care- related aspects of diseases**, not specialties
- helps **focus and systematize the dialog between patient and physician and their mutual contribution to shared decision-making**
- strives for **scientifically and ethically grounded decision-making in response to an increasingly market-oriented health care system.**

Kommentiert [DS2]: https://www.choosingwisely.org/our-mission/: " to promote conversations between clinicians and patients" Use "conversations" versus "dialog"?

This manual is designed as a guide to framing reliable “Choosing 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. Ultimately, 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.

“Choosing 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. This is predicated on the question whether a "Choosing Wisely Together" recommendation is applicable in the isolated case is established in a personalized conversation between doctor and patient. Therefore, the “Choosing Wisely Together” recommendations should under no circumstances be misinterpreted as regulatory instruments or standards that could replace individualized decisions.

Evolution and outline of the manual

The contents of the manual were agreed within the Ad Hoc Committee in an informal consensus. The criteria for selecting “Choosing 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 outline below presents the factors that should be included when developing “Choosing Wisely Together” recommendations:

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

1. Selecting the care aspect/clinical picture

Explicit criteria should be applied to identify a care aspect/clinical picture that may be applicable to the development of “Choosing Wisely Together” recommendations, such as

- Potentials for improvement in health care provision that can be exploited by “Choosing 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
- Economic relevance
- Ethical and social aspects
- Information requirements relating to new technologies
- Coordination requirements (interdisciplinary, interprofessional) [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 “Choosing Wisely Together” recommendations ought to be drawn up from other high-quality sources of systematically compiled knowledge.

2. Composition of a representative panel

A “Choosing 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 can initiate a campaign to develop “Choosing Wisely Together” recommendations and to select the care aspects/clinical pictures and then assume the leadership role. First, the lead Scientific Medical Society should determine the addressees, including representatives of potentially affected patients/citizens, for a potential “Choosing 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 "Choosing 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 "Choosing 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 "Choosing Wisely Together" recommendation can also be initiated by the guideline group itself.

3. Criteria for selecting “Choosing Wisely Together” recommendations

The selection of “Choosing Wisely Together” recommendations should be predicated on multidisciplinary, formally agreed, evidence-based, up-to-date S3 practice guidelines or, where appropriate, 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 "Choosing Wisely Together" recommendations can already be planned during guideline development and carried out in parallel (see “Helpful tips” in Annex 2).

For selecting suitable "Choosing Wisely Together" recommendations, the following seven criteria should be applied when appraising potential candidates. The first two criteria (3.1 and 3.2.) ought to be obligatory and are defined as exclusion criteria. The other five criteria can be appraised, but are classified as optional. They can be used for purely descriptive purposes to further characterize the recommendation. However, it is advisable that reliable recommendations be prioritized, i.e. those with a sound evidence base (criterion 3.3.) and a strong grade of recommendation (criterion 3.4.).

Each criterion (3.1. – 3.7.) has an explanation and a key statement that is evaluated. The following procedure is proposed: 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.

Finally (criterion 3.8), an overall appraisal of the suitability of a recommendation for a “Choosing Wisely Together” campaign is undertaken after appraising the ratings and descriptions in aggregate.

3.1 Clarity of the recommendation

Strongly disagree	1	2	3	4	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 picture 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, **P**atient – **I**ntervention – **C**omparison – **O**utcome. Practical example presented in Annex 3.

3.2 Indications suggesting the overuse or underuse of health care services

Strongly disagree	1	2	3	4	Strongly agree

This criterion aims to identify what is required for a "Choosing 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 or underuse of health care services.
Ideally, indications suggesting the overuse and underuse 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 or underuse. 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 "Choosing 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 Evidence base for the recommendation

Strongly disagree	1	2	3	4	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.
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 endpoints—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).

Kommentiert [DS3]: https://www.sciencedirect.com/science/article/pii/S089543561630703X

3.4 Strength of the recommendation

Strongly disagree	1	2	3	4	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.

Kommentiert [DS4]: https://www.uspreventiveservicestaskforce.org/Page/Name/grade-definitions

3.5 Influenceability of the health care problem

Strongly disagree	1	2	3	4	Strongly agree

This criterion is used to appraise whether the potential "Choosing 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.

3.6 Implementability of the recommendation in routine care

Strongly disagree	1	2	3	4	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.

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3.7 Risk of unintended consequences when using the recommendation in the “Choosing Wisely Together” initiative

Strongly disagree	1	2	3	4	Strongly agree

This criterion focuses on the extent of potential unintended consequences if the recommendation is disseminated by the “Choosing 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 "Choosing Wisely Together" initiative are described and taken into account as necessary.
For instance, a recommendation might be used too hastily as a control tool for changing resource allocations or be applied thoughtlessly and thereby prevent personalized 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.

3.8 Overall appraisal: The recommendation is suitable for the "Choosing Wisely Together" initiative

Strongly disagree	1	2	3	4	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 “Choosing Wisely Together” initiative. A consensus on a recommendation as suitable for the “Choosing 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 lists of top 5 / top 10)

In order for them to identify with the recommendation, it is relevant to the implementation of a “Choosing 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 purpose[5]. It is recommended to assume that a consensus is reached on the suitability of any recommendation for the “Choosing 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 “Choosing Wisely Together” recommendations should be available to all target groups as brief information, i.e. a recommendation with a brief justification. “Choosing 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 “Choosing 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 provision of care research projects have employed various implementation strategies, albeit with varying degrees of success[7,4]. "Choosing Wisely Together" recommendations should be publicized using a proactive dissemination strategy via

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

The implementation of “Choosing Wisely Together” recommendations should 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.).

Kommentiert [DS5]: https://www.gkv-spitzenverband.de/english/statutory_health_insurance/statutory_health_insurance.jsp

7. Evaluation

Criteria-based accompanying research to analyze the effects of "Choosing 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 "Choosing 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.

Kommentiert [DS6]: is "Together" missing?

If data are available (e.g. in the context of external comparative quality assurance, at certified centers 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 research initiatives should also be developed and promoted to answer these questions.

Annex 1

Definition: Overuse, underuse and misuse of health care services

Extract from the Guidelines Glossary of the AWMF and the Medical Center 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. from lack of knowledge, as a favor, for marketing purposes or financial incentives).

"Underuse" means that health care services are refused or not provided (within reason) 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.

Excerpt from the special report by the Council of Experts[9]

Table 3: On the definition of overuse, underuse and misuse of health care services

Service[a)] / Need	Rendered according to the standard of care	Not rendered according to the standard of care	Not rendered[b)]
Only objective, no subjective need (latent need)	Needs-based provision	Misuse	(Latent) underuse
Subjective and objective need	Needs-based provision	Misuse	Underuse (or misuse)
Only subjective, no objective need	Overuse (or misuse)	Overuse and misuse	Needs-based provision

a) Assuming that services are rendered with a verified net health benefit and reasonable benefit-cost ratio

b) Assuming that no alternative care is rendered either

Annex 2

Helpful tips for developing "Choosing Wisely Together" recommendations in line with guideline development

"Choosing Wisely Together" recommendations can also be developed as part of creating new and updating legacy 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. Here, focusing on some questions can be helpful:

1. Before starting the guideline development process: Do the guideline authors know of or suspect any areas of overdiagnosis/overtreatment or of otherwise known underuse 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 "Choosing Wisely" top 5 or top 10 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 (Helpful tips, see Annex 4).

Annex 3

Practical example: 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 Care 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.

Annex 4

Helpful tips for determining the benefit-harm balance and the plausibility of the justification

A benefit-harm balance assessment ought to be undertaken to assess whether the evidence base on the recommendation suggests it is suitable for "Choosing Wisely Together" campaign. What is the certainty of proof for benefit and/or harm? How pronounced is either benefit or harm? The overriding principle is "primum nihil nocere"—a justified suspicion is sufficient, while any benefit should be well proven (cf. German Drug Law, AMG).

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).

References

1. American Board of Internal Medicine (ABIM). Choosing Wisely - Lists. 2015; http://www.choosingwisely.org/doctor-patient-lists/. Zugriff 01.09.2015
2. Levinson W, Kallewaard M, Bhatia RS, et al. 'Choosing Wisely': a growing international campaign. BMJ Qual Saf. Feb 2015;24(2):167-174.
3. Strech D, Follmann M, Klemperer D, Lelgemann M, Ollenschläger G, Raspe H, Nothacker M. When Choosing Wisely meets clinical practice guidelines - Wenn "Choosing Wisely" auf Leitlinien trifft. Z Evid Fortbild Qual Gesundhwes. 2014;108(10):601-603.
4. Nothacker M, Muche-Borowski C, Kopp IB. 20 Jahre ärztliche Leitlinien in Deutschland - was haben sie bewirkt? [Reflections on 20 years of clinical practice guideline programmes in Germany: what is their impact?]. Z Evid Fortbild Qual Gesundhwes. 2014;108(10):550-559.
5. Deutsche Gesellschaft für Allgemein- und Familienmedizin (DEGAM). S3-Leitlinienprojekt (Anmeldung): Schutz vor Über- und Unterversorgung - Gemeinsam entscheiden. 2014; http://www.awmf.org/leitlinien/detail/anmeldung/1/ll/053-045.html.Zugriff 01.09.2015
6. Muche-Borowski C, Selbmann HK, Müller W, Nothacker M, Kopp I. Das AWMF-Regelwerk Leitlinien: Ständige Kommission "Leitlinien" der Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften (AWMF); 2012: http://www.awmf.org/leitlinien/awmf-regelwerk.html. Zugriff 01.09.2015
7. Selbmann HK, Kopp I. Implementierung von Leitlinien in den Versorgungsalltag. Psychiatrie. 2005;2(1):33-38.
8. Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften (AMWF), Ärztliches Zentrum für Qualität in der Medizin (ÄZQ). Leitlinien-Glossar. Begrifflichkeiten und Kommentare zum Programm für Nationale VersorgungsLeitlinien 2007; http://www.awmf.org/leitlinien/ll-glossar.html.Zugriff 01.09.2015
9. Gutachten 2000/2001 des Sachverständigenrates für die Konzertierte Aktion im Gesundheitswesen. Bedarfsgerechtigkeit und Wirtschaftlichkeit. Band III: Über-, Unter- und Fehlversorgung.