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Descriptive analysis of patient involvement in the development of German clinical practice guidelines: A meta-research study V.1

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Stefanie Pfisterer-Heise[1], Clara Orduhan[1], Mai Nguyen[1], Käthe Gooßen[2], Jessica Breuing[2], Sebastian Von Peter[3], Corinna Schaefer[4], Dawid Pieper[1]

[1]Institute for Health Services and Health System Research, Center for Health Services Research Brandenburg, Brandenburg Medical School Theodor Fontane;
[2]Institute for Research in Operative Medicine (IFOM), Faculty of Health, School of Medicine, Witten/Herdecke University;
[3]Department of Psychiatry and Psychotherapy, Brandenburg Medical School Theodor Fontane;
[4]German Agency for Quality in Medicine (AEZQ)

Patient Involvement in th...

Stefanie Pfisterer-Heise
Medical School Brandenburg

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Abstract

Clinical practice guidelines include recommendations to optimize patient care. As patients are "experts by experience" for their medical conditions, their involvement in the development of clinical practice guidelines is essential. Accordingly, many organizations worldwide require patient involvement in the development of clinical practice guidelines. However, in 2018 a German study found that patient involvement in the development of German clinical practice guidelines still lagged significantly behind international requirements. This meta research-study is an update on the status of patient involvement in German clinical practice guidelines. It examines whether and how patients have been involved in the development of currently valid German clinical practice guidelines as well as the current status of patient versions of German clinical practice guidelines. Furthermore, this meta-research study investigates in how far German clinical practice guidelines follow the RIGHT Checklist with respect to the reporting of patient involvement. To this aim the German clinical practice guidelines register will be searched for currently valid S3 clinical practice guidelines which will be screened by two independent reviewers. Relevant data on patient involvement will be extracted and analyzed descriptively. The results will be compared to the previous German study.

1 **Research team**

Stefanie Pfisterer-Heise, Clara Orduhan, Mai Nguyen, Käthe Gooßen, Jessica Breuing, Sebastian von Peter, Corinna Schaefer, Dawid Pieper

2 **Objectives**

The aims of this meta-research study are twofold: first, to investigate whether and how patients have been involved in the development of currently valid German clinical practice guidelines; second, to explore the current status of patient versions of German clinical practice guidelines, particularly with respect to their availability and patient involvement in their development.

3 **Research question**

Clinical practice guidelines are statements that include recommendations intended to optimize patient care (1). As patients are considered “experts by experience” for their medical conditions and may offer unique insights into treatment and outcomes, it is essential to involve them in the development of clinical practice guidelines.Patient involvement thus refers to clinical practice guidelines being developed “with” or “by” patients rather than “to”, “about” or “for” them (2).

Organizations and working groups worldwide such as the Guidelines International Network (3)or the British National Institute for Health and Care Excellence (4) require patient involvement in the development of clinical practice guidelines. Explicitly, the US-American Institute of Medicine states that clinical practice guidelines should “be developed by a knowledgeable, multidisciplinary panel of experts and representatives from key affected groups” and “consider important patient subgroups and patient preferences, as appropriate” (1).

Based on these recommendations several appraisal tools for the development of clinical practice guidelines, i.e. AGREE II (Appraisal of Guidelines for Research & Evaluation) (5), GIN-McMaster Guideline Development Checklist (GDC) (6) or DELBI (Deutsches Instrument zur methodischen Leitlinien-Bewertung, German instrument for the methodological evaluation of clinical practice guidelines) (7),include the consideration of patient perspectives as a quality dimension, i.e. the “consideration of views and preferences of the target population in the guidelines development process” (8). The RIGHT (Reporting Items for practice Guidelines in HealThcare) checklist provides guideline developers with extensive guidance for the reporting of clinical practice guidelines, also with respect to patient involvement (9) and includes statements with respect to patient involvement in greater detail than i.e. AGREE II and DELBI.

Despite all ethical reasoning and methodological grounding for patient involvement in the development of clinical practice guidelines, a 2017 US-American study found that five years after the introduction of the Institute of Medicine standards, patient involvement

was still poor (10). One year later Ollenschlaeger and colleagues reached the same conclusion with respect to the development of German clinical practice guidelines: “The results show that patient involvement in guideline development in Germany still lags significantly behind international requirements for trustworthy guidelines” (11).

4 **Method**

This study is an update of the work by Ollenschlaeger and colleagues (11). It examines whether and how patients have been involved in the development of currently valid German clinical practice guidelines and the current status of patient versions of German clinical practice guidelines, particularly with respect to their availability and patient involvement in their development. This meta-research study also investigates in how far German clinical practice guidelines follow the RIGHT Checklist with respect to the reporting of patient involvement. For this purpose, a descriptive analysis of all S3 guidelines disseminated by the Association of the Scientific Medical Societies in Germany (Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften, AWMF) will be performed using the items of the Ollenschlaeger publication, self-constructed items based on the RIGHT checklist (9) as well as some other self-constructed items, e.g. total number of members in the guideline development group.

The AWMF defines S3 guidelines as evidence- and consensus-based guidelines that include all elements of systematic guideline development. Thus, German S3 clinical practice guidelines are characterized by a representative guideline development group, the systematic search, selection and appraisal of the evidence as well as a structured consensus process. The scientific legitimation of the method and legitimation for implementation of German S3 clinical practice guidelines are both described as high (12). Other types of German clinical practice guidelines do not use a systematic search (S2k, S1 guidelines) or consensus process (S2e, S1 guidelines), and will not be evaluated in this study.

5 **Searches**

We will search the clinical practice guidelines register of the AWMF in Germany using the advanced search function (https://register.awmf.org/de/suche).

Inclusion criteria: Currently valid clinical practice guidelines in their comprehensive version, with development status S3 produced by any scientific medical society in Germany, with involvement of any organization. This will be operationalized in the advanced search by defining the status (“valid guidelines”), document type (“clinical practice guideline (long version)”), development status (“S3”), society (“All”) and organization (“All”).

Exclusion criteria: Clinical practice guidelines not valid on 31 March 2023.

All retrieved guidelines with development status S3 and their corresponding guideline reports will be independently screened by two researchers.

6 **Data extraction**

The research team will develop a data extraction table including items used in the Ollenschlaeger study (11), self-constructed items based on the RIGHT Checklist (9) as well as self-constructed items. Two members of the research team will then independently extract study data using this standardized data extraction table. Specifically, the data extraction table will contain the following items:
a)Name of the medical guideline (text)
b)Register number (number)
a)Version (number)
b)Date last edited (date)
c)Valid until (date)
d)Currently valid (yes/no)
e)Leading professional society in guideline development (text)
f)Classification of leading professional society to subject area (pediatric/surgical/nervous and emotional disorders/infections and environment – prevention and therapy/general and internal medicine/oncology without pediatrics/other)
g)Medical indication of guideline (acute/chronic/other)
h)Information on patient representative/patient advocate being a member of the guideline development group (yes/no)
i)Patient representative/ patient advocate was a member of the guideline development group (yes/no/not applicable)
j)Patient representative/patient advocate/family/patient representative and family/ patient advocate and family/unclear/not applicable
k)Patient representative/patient advocate had medical background (yes/no/unclear/not applicable)
l)Information on name of patient representative/patient advocate (yes/no/unclear/not applicable)
m)Information on name of patient organization(s) (yes/no/unclear/not applicable)
n)Name(s) of patient organization(s) (text)
o)Total number of members in guideline development group in the current version of guideline (number)
p)Total number of patient representatives/patient advocates in the current version of guideline (number)
q)Prior training for patient representative(s)/patient advocate(s) (yes/no/unclear/not applicable)
r)Payment for patient representative(s)/ patient advocate(s) (yes/no/unclear/not applicable)
s)Information on selection process of patient representative/patient advocate (yes/no/unclear/not applicable)

t)Information on role and responsibilities of patient representative/patient advocate, e.g. steering group, guideline development group, etc. (yes/no/unclear/not applicable)
u)Information on whether patients' values and preferences were considered (yes/no/unclear/not applicable)
v)Methods to identify patients' values and preferences (none/literature search/survey/focus group/patient representative or patient advocate in guideline group/any combination of these/all)
w)Explanation in case that patients' values and preferences were not considered (yes/no/unclear/not applicable)
x)Information on whether patient representative/patient advocate was involved in decision-making/ had voting right (yes/no/unclear/not applicable)
y)Patient representative/patient advocate had voting right (yes/no/unclear/not applicable)
z)Patient representative/patient advocate exercised voting right (yes/no/unclear/not applicable)
aa)Information on limitations in the process of guideline development, e.g. if patients' values and preferences were not sought (yes/no/unclear/not applicable)
bb)Information on how the validity of recommendations might have been affected in case that patients' values and preferences were not sought (yes/no/unclear/not applicable)
cc)Availability of guideline methodology report (separate document/included in long version of guideline)
dd)Patient version of guideline available or planned as stated in guideline report (yes/no)
ee)Patient involvement in patient version of guideline (yes/no)
ff)Editorial coordination (text)
gg)Availability of the patient version of guideline on the internet (yes/no)
hh)Homepage of patient version of guideline (URL)

7 **Data analysis**

All gathered data will be analyzed descriptively. The results will be compared to those obtained in the Ollenschlaeger study (11). This appears feasible because the format of register numbers is unchanged.

8 **Research information**

Condition or domain being studied

Development of German S3 clinical practice guidelines

Data analysis

Descriptive analysis of all S3 guidelines disseminated by the Association of the Scientific Medical Societies in Germany (AWMF)

Anticipated or actual start date
1 March 2023

Anticipated completion date
15 April 2023

Protocol references

1.IOM (Institute of Medicine). Clinical Practice Guidelines We Can Trust. Washington, DC: The National Academies Press; 2011.
2.NIHR School for Primary Care Research. What is Patient and Public Involvement and Public Engagement? 2023 [Available from: https://www.spcr.nihr.ac.uk/PPI/what-is-patient-and-public-involvement-and-engagement.
3.Qaseem A, Forland F, Macbeth F, Ollenschlager G, Phillips S, van der Wees P, et al. Guidelines International Network: toward international standards for clinical practice guidelines. Ann Intern Med. 2012;156(7):525-31.
4.NICE National Institute for Health and Care Excellence. NICE's approach to public involvement in guidance and standards: a practical guide. Manchester; 2015.
5.AGREE Next Steps Consortium. The AGREE II Instrument [Electronic version] 2017 [Available from: https://www.agreetrust.org/wp-content/uploads/2017/12/AGREE-II-Users-Manual-and-23-item-Instrument-2009-Update-2017.pdf.
6.Schünemann HJ, Wiercioch W, Etxeandia I, Falavigna M, Santesso N, Mustafa R, et al. Guidelines 2.0: systematic development of a comprehensive checklist for a successful guideline enterprise. Canadian Medical Association Journal. 2014;186(3):E123-E42.
7.Kopp I, Thole H, Langer T, Selbmann HK, Ollenschläger G. Deutsches Leitlinien-Bewertungsinstrument (DELBI) - Fassung 2005/2006 + Domäne 8 (2008) Berlin: AWMF
ÄZQ; 2008 [Available from: www.delbi.de.
8.Siering U, Eikermann M, Hausner E, Hoffmann-Esser W, Neugebauer EA. Appraisal tools for clinical practice guidelines: a systematic review. PLoS One. 2013;8(12):e82915.
9.Chen Y, Yang K, Marusic A, Qaseem A, Meerpohl JJ, Flottorp S, et al. [A reporting tool for practice guidelines in health care: the RIGHT statement]. Z Evid Fortbild Qual Gesundhwes. 2017;127-128:3-10.
10.Armstrong MJ, Bloom JA. Patient involvement in guidelines is poor five years after institute of medicine standards: review of guideline methodologies. Res Involv Engagem. 2017;3:19.
11.Ollenschlager G, Wirth T, Schwarz S, Trifyllis J, Schaefer C. [Patient involvement in clinical practice guidelines is poor after 12 years of German guideline standards: A review of guideline methodologies]. Z Evid Fortbild Qual Gesundhwes. 2018;135-136:50-5.
12.Ärztliches Zentrum für Qualität in der Medizin. Leitliniengrundlagen Berlin2022 [Available from: https://www.leitlinien.de/hintergrund/leitliniengrundlagen.