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Implementation of guidelines – obstructive and beneficial factors¹

Executive Summary

¹ Translation of the executive summary of the final report *Umsetzung von Leitlinien – hinderliche und förderliche Faktoren* (Version 1.0; Status: 9 May 2016). Please note: This translation is provided as a service by IQWiG to English-language readers. However, solely the German original text is absolutely authoritative and legally binding.

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This report was prepared in collaboration with external experts.

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According to §139 b (3) No. 2 of Social Code Book (SGB) V, Statutory Health Insurance, external experts who are involved in the Institute's research commissions must disclose "all connections to interest groups and contract organizations, particularly in the pharmaceutical and medical devices industries, including details on the type and amount of any remuneration received". The Institute received the completed *Form for disclosure of potential conflicts of interest* from each external expert. The information provided was reviewed by a Committee of the Institute specifically established to assess conflicts of interests. The information on potential conflicts of interest provided by the external experts is presented in Appendix J of the full report. No conflicts of interest were detected that could endanger professional independence with regard to the work on the present commission.

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Executive summary

With its letter of 11 October 2012, the German Federal Ministry of Health (BMG) commissioned the Institute for Quality and Efficiency in Health Care (IQWiG) to prepare a systematic review on the obstructive and beneficial factors for the implementation of guidelines. Details of the commission were specified with the BMG on 25 January 2013.

Aims of the investigation

The aim of the present report was divided into 3 subgoals:

Subgoal 1 was to provide an overview of measures for the dissemination and implementation of clinical guidelines, as well as of factors that can influence the targeted implementation of clinical guidelines, that is, can obstruct or promote them.

Subgoal 2 was to investigate determinants of the successful implementation of tailored interventions.

On the basis of the results of subgoals 1 and 2, subgoal 3 was to compile suggestions for the targeted dissemination and implementation of clinical guidelines within the German healthcare system.

Methods

Subgoal 1: overview of dissemination and implementation measures as well as of factors that can influence the targeted implementation of clinical guidelines

For this subgoal systematic reviews were included that

- investigate measures for the dissemination and implementation of clinical guidelines (or their main content) as a single measure or as a combination of several measures (multi-component intervention), or
- describe the characteristics of obstructive and/or beneficial factors of guideline dissemination and implementation

To obtain an overview of measures, systematic reviews with at least one randomized and/or non-randomized controlled study were included that reported results on process quality indicators (e.g. consistency of actions of players in the healthcare system with the guideline recommendations in terms of guideline-compliant behaviour).

To obtain an overview of influencing factors, systematic reviews of randomized and/or non-randomized controlled studies were included as well as observational and/or qualitative studies containing any form of description or classification of influencing obstructive and/or beneficial factors, including exemplary presentations.

The target population comprised members of all healthcare professions in the inpatient or outpatient setting.

This report included systematic reviews published in or after 2003. In addition, only systematic reviews were included that largely (at least 80%) investigated measures for guideline dissemination and implementation in Germany or in countries basically comparable to Germany. The classification of countries in the World Health Report 2003 by the World Health Organization (WHO) was used to operationalize results.

A systematic literature search in the following databases was conducted to identify relevant systematic reviews: MEDLINE, Embase, the Cochrane Database of Systematic Reviews (Cochrane Reviews), the Database of Abstracts of Reviews of Effects (Other Reviews), and the Health Technology Assessment Database (Technology Assessments). The last search was conducted on 21 October 2015.

The relevance of information retrieved from the bibliographic literature search was assessed by 2 reviewers independently of one another.

The methodological quality of the systematic reviews was assessed using the Assessment of Multiple Systematic Reviews (AMSTAR) instrument.

The checklist of the Cochrane Effective Practice and Organisation of Care Review Group (EPOC) was used as orientation for the analysis and categorization of the dissemination and implementation measures identified in the systematic reviews. In addition, the results on process quality indicators reported in the systematic reviews were presented, as were those on indicators of the quality of results (as supplementary information).

The analysis and categorization of factors influencing guideline dissemination and implementation was conducted taking into account the 5 levels of Titler's und Everett's implementation model, which we modified.

Subgoal 2: Determinants of the successful implementation of tailored interventions

As a second basis for inferring recommendations on guideline implementation for the German healthcare context, it was investigated what distinguished successful tailored interventions from unsuccessful ones.

Randomized controlled trials (RCTs, including cluster RCTs) were considered that investigated tailored interventions as dissemination and implementation strategies of guidelines (or their main content) as a single measure or as a combination of several measures (multi-component intervention). The control intervention consisted either of other measures for guideline dissemination and implementation or no measures.

The target population comprised members of all healthcare professions in the outpatient or inpatient setting.

The investigation analysed outcomes recorded with objective instruments. These referred to the process quality indicators mentioned under subgoal 1.

For this purpose, a systematic literature search was conducted in the following databases: MEDLINE, Embase, and the Cochrane Central Register of Controlled Trials (Clinical Trials). The last search was conducted on 21 October 2015. The relevant systematic reviews for subgoal 1 were used as a further information source for identifying published and unpublished studies. The relevance of information retrieved from the bibliographic literature search was assessed by 2 reviewers independently of one another. The relevant systematic reviews identified for subgoal 1 were searched for further potentially relevant studies for subgoal 2 and their relevance was assessed by 2 reviewers independently of one another.

To evaluate the certainty of results, the risk of bias was initially classified as “low” or “high” across outcomes. If classified as “high”, then it was also classified as “high” for the individual outcome. If not, an additional outcome-specific risk-of-bias assessment was performed.

For the present report, studies were rated as successful if a significant result had been reported for at least 50% of the outcomes considered. A comparative description was then presented of the influencing factors reported in the successful and unsuccessful studies and of the measures subsequently undertaken.

In addition, it was evaluated whether shifting the cut-off showed a difference in the influencing factors in connection with the success of studies.

Subgoal 3

On the basis of the results of subgoals 1 and 2, proposals for a better implementation of guidelines in the German healthcare system were compiled descriptively. For this purpose, it was in particular evaluated whether the dissemination and implementation measures described were also available in the German healthcare context and whether results obtained from studies conducted in Germany were available for subgoals 1 and 2.

Results

Subgoal 1

A total of 46 relevant systematic reviews were included for subgoal 1, of which 33 included information on guideline dissemination and implementation measures, 11 included information on influencing factors, and 2 included both types of information.

The systematic reviews differed strongly in their healthcare topics, their settings, as well in the designs of the studies included. Their methodology quality was assessed with the AMSTAR instrument and was classified as high for 16, as average for a further 16, and as low for 14 systematic reviews.

Measures for guideline dissemination and implementation

The measures for guideline dissemination and implementation were divided into single and multi-component interventions. In the systematic reviews included, multi-component

interventions were often described by means of their single components; this approach is followed in the presentation of results in this report.

The systematic reviews included results on the following EPOC categories as a single intervention and/or a component of a multi-component intervention:

- “distribution of educational materials” in the form of postal, electronic or personal distribution of guidelines
- “educational meetings”: participation of healthcare providers in training/workshops/further education measures etc.
- “educational outreach visits”: training of guideline users by external experts (or another well-trained person)
- “local opinion leaders”: support of guideline implementation by local opinion leaders
- “audit and feedback”: feedback of performance data or results (recommendations for action, healthcare data)
- “reminder systems”: measures designed in a way that they prompt healthcare professionals to recall specific information or remind them to perform certain actions
- “interventions tailored to local circumstances”: interventions where a barrier analysis is conducted before guideline implementation to tailor the implementation accordingly (tailored interventions)
- “organizational interventions”: strategies consisting of a reorganization of previous working procedures, and
- “ensuring continuity of care”: clinical care pathways consisting of various components securing the continuity of patient care in a specific healthcare context

Independently of the EPOC criteria, the category “quality management” was formed for the single interventions. In this category all interventions are summarized that introduce new quality assurance measures or are named as such by the authors of the systematic reviews. Not all implementation strategies investigated could be allocated to one of the categories named above; this applied both to the single interventions and to the multi-component ones. Due to the heterogeneity of results and insufficient data in the systematic reviews, the effectiveness of the interventions cannot be reliably assessed for any of the single and multi-component interventions identified.

Assessment of the effectiveness of the single interventions

Distribution of educational materials

In the 8 systematic reviews investigating the strategy “distribution of educational materials” as a single intervention, positive changes were reported only for single outcomes of process quality.

Educational meetings

Four of the 7 systematic reviews investigating the strategy “educational meetings” as a single intervention reported consistently positive and in part significant changes; 3 reported inconsistent results.

Educational outreach visits

All 4 systematic reviews investigating the strategy “educational outreach visits” as a single intervention reported consistent improvements.

Local opinion leaders

One systematic review investigating the strategy “local opinion leaders” as a single intervention mainly reported improvements.

Audit and feedback

Four of the 9 systematic reviews investigating the strategy “audit and feedback” as a single intervention consistently reported improvements. Relevant heterogeneity existed for 2 of these reviews; 3 reported inconsistent effects and 2 could not show an improvement for any of the process quality outcomes investigated.

Reminder systems

All 13 systematic reviews investigating the strategy “reminder systems” as a single intervention mainly reported positive changes; 3 of these reviews showed heterogeneity, one of which also reported inconsistent results.

Interventions tailored to local circumstances

One systematic review investigating the strategy “interventions tailored to local circumstances” as a single intervention reported a statistically significant effect in favour of the intervention.

Organizational interventions

Of the 3 systematic reviews investigating the strategy “organizational interventions” as a single intervention, one reported positive changes, a further review reported negative changes, and the third one reported a statistically significant effect in favour of the intervention, with relevant heterogeneity.

Quality management

The 2 systematic reviews investigating the strategy “quality management” as a single intervention mainly showed positive changes.

Further single interventions

For the further single interventions presented in the 4 systematic reviews, no clear indications on their effectiveness could be inferred, due to the only partly positive changes or missing statements.

Assessment of the effectiveness of multi-component interventions

Distribution of educational materials

All 3 systematic reviews investigating multi-component interventions with “distribution of educational materials” as a single intervention showed mainly positive changes.

Educational meetings

All 7 systematic reviews investigating multi-component interventions with “educational meetings” as a single intervention showed (partly statistically significant) positive changes. One systematic review additionally reported a negative effect of the intervention. A further systematic review reported a relevant heterogeneous effect for the considered outcome of process quality; another showed relevant heterogeneity for the studies included.

Educational outreach visits

Both systematic reviews investigating multi-component interventions with “educational outreach visits” as a single component reported positive changes with regard to process quality indicators. However, one of them also reported a negative change with regard to a process quality indicator.

Local opinion leaders

One systematic review investigating multi-component interventions with “local opinion leaders” as a single component in part reported improvements.

Audit and feedback

Five out of 7 systematic reviews investigating multi-component interventions with “audit and feedback” as a single component in part showed positive changes; 2 showed no effect of the intervention.

Reminder systems

Three out of 4 systematic reviews investigating multi-component interventions with “reminder systems” as a single component largely showed positive changes; one showed no effect of the intervention.

Ensuring continuity of care

Both systematic reviews investigating multi-component interventions with “ensuring continuity of care” as a single component showed significant improvements through the intervention. However, in one of them the significant improvements referred only to one of the outcomes considered.

Multi-component interventions without separate presentation of the components

In 13 systematic reviews results on multi-component interventions were reported in such a manner that an allocation to a multi-component intervention including a certain single component was not possible. These results could thus not be used to make a clear statement on multi-component interventions with a certain single component.

Influencing factors

A total of 13 systematic reviews (Carlsen 2007, Cochrane 2007, Ebben 2013, Flodgren 2013, Flottorp 2013, Gurses 2010, Moe 2014, Heselmans 2009, Hollmeyer 2009, Sachs 2006, Sadeghi-Bazargani 2014, Simpson 2005, Swennen 2013) described factors that can obstruct or promote the targeted implementation of clinical guidelines. In these reviews 28 different influencing factors were identified that could be allocated to the modified 5 levels according to Titler and Everett.

The following influencing factors were identified at the guideline level: guideline format, specificity of guideline recommendations, their local applicability, the quality and strength of the evidence underlying the recommendations, the assessability of guideline recommendations, and the authorship of a guideline.

The following influencing factors were described for the level of conditions of the context of service provision at the system level: regulation of the healthcare system, economic framework, coordination of care, and support by external opinion leaders.

The conditions of the context of service provision at the organizational level also influence the implementation of guideline recommendations. The following factors were allocated to this level: processes of change, type of implementation strategy, provision of necessary resources, information management and evaluation, hierarchic administrative support, as well as further training and other supportive measures.

The level of knowledge and opinions of the guideline users comprises the largest number of different influencing factors. These include the guideline users' opinions on guidelines, their knowledge of guideline recommendations, the consistency of their actions with the recommendations, their willingness to implement recommendations, as well as their competence and further characteristics. The doctor-patient relationship and financial incentives also play a role.

Likewise, influencing factors on the level of the patients' knowledge and opinions are described. These include the following factors: agreement of patients' opinions with the content of a guideline recommendation, their willingness to implement a recommendation, further patient characteristics, and financial aspects.

The following influencing factors were particularly common (i.e. were named in at least 7 of the 13 systematic reviews included):

- Guideline level
 - local applicability of the guideline
 - quality and strength of the evidence underlying the guideline
- Organization
 - material, financial and human resources
 - information management and evaluation
 - hierarchic administrative support
 - further training and other support
- Guidelines users
 - consistency with recommendations
 - willingness to implement recommendations
 - doctor-patient relationship

Subgoal 2

Subgoal 2 was to identify determinants of the successful implementation of tailored interventions. A total of 22 studies (25 publications) were classified as relevant.

The 22 studies were assessed with regard to risk of bias, initially at the study level. If classified as “high” at the study level, the risk of bias for an individual outcome was also classified as “high”. Otherwise, outcome-specific aspects were considered in studies showing a low risk of bias at the study level. The risk of bias at the study level was assessed as high for the majority of studies (n = 19).

On the basis of the degrees of barrier analysis and the subsequent tailoring, the studies could be summarized into 5 groups:

1. studies with their own preliminary study on barrier analysis and transparent and comprehensible tailoring (B1 / T1 [n = 6 studies])
2. studies with their own preliminary study on barrier analysis and a moderate degree of tailoring (B1 / T2 [n = 7 studies])
3. studies with their own preliminary study on barrier analysis and an intransparent or a missing description of tailoring (B1 / T3 [n = 5 studies])
4. studies with a specific literature search for barriers and a description of tailoring (B2 / T2 [n = 1 study])
5. studies with a general literature search for barriers and a moderate degree of tailoring (B3 / T2 [n = 3 studies])

The 22 studies were also examined to identify determinants that could have an influence on the success of a study.

1. Barrier analysis method applied: It did not make a difference which method was used. The majority (n = 18) of the 22 studies conducted barrier analyses as preliminary studies or within the framework of the study. However, this did not affect the results of guideline implementation.
2. Complexity of tailoring: No influence of the factor “tailoring” on the success of guideline implementation was detected.
3. Influencing factors according to Titler and Everett: The respective 5 levels according to Titler and Everett did not influence the success of the study.
4. Number of individual components of the implementation strategy: Only 5 studies investigated interventions consisting of 4 to 5 components; 4 of the 5 studies were successful. The other 17 studies investigated interventions consisting of 1 to 3 components; only 7 of the 17 studies were successful. Due to the small number of studies with 4 to 5 components no regularity can be inferred.
5. Setting: The setting did not influence the success of the study.

If the cut-off for distinguishing between successful and unsuccessful studies were shifted to 100% of the outcomes of process quality, then 4 of 22 studies could be classified as successful. If statistically significant differences were accepted as a cut-off for at least one of the considered outcomes of process quality, then 15 of the overall 22 studies would be classified as successful. The choice of cut-off alters the number of studies classified as successful/unsuccessful. However, by shifting the cut-off, no other influencing factors are addressed in the successful studies than in the unsuccessful ones.

If only studies with a low risk of bias at study level (n = 3) are considered, no associations are shown either.

Three studies considered the results of the barrier analysis in the development of the guideline; all were classified as successful for this report. Here too, due to the low number of studies, the influence of this approach on the success of guideline implementation cannot be reliably assessed.

Subgoal 3

The evidence analysed for subgoals 1 and 2 does not allow clear conclusions, and in particular no generalizable conclusions, on what implementation strategies are most likely to be successful or which influencing factors should be considered to ensure the success of guideline implementation. Only 2 of the 46 systematic reviews included for subgoal 1 originated from Europe/Germany (Sachs 2006, Weinmann 2007). In addition, the data from

these 2 systematic reviews did not allow specific conclusions on the application context in Germany. No studies investigating data from Germany were identified for subgoal 2.

The following recommendations, structured according to Titler's und Everett's modified implementation model (characteristics of the guideline, type of dissemination and implementation, conditions of the context of service provision, as well as knowledge and opinion of guideline users and patients), are thus based on general considerations and the results from the systematic reviews.

1) Characteristics of the guideline

An essential precondition for successful guideline implementation is the existence of high-quality guidelines. In particular the local applicability of the guideline, as well as the quality and strength of the evidence, are paramount here. The studies examined particularly often mention the guideline characteristics as an influencing factor, that is, in at least half of the systematic reviews included (see subgoal 1).

To promote guideline application in Germany, it can thus be meaningful to support the development of guidelines that are of high methodological quality and are relevant to clinical practice.

2) Type of dissemination and implementation

Inadequate further training and other lack of support are often named as reasons for the insufficient implementation of guideline recommendations. Likewise, systematic reviews investigating the single intervention "educational outreach visits" or multi-component interventions with this intervention as a component, mainly reported positive changes when it was applied.

To achieve a more comprehensive application of guidelines in Germany, the promotion of educational measures thus seems meaningful.

Poor information management is often mentioned as a reason for insufficient implementation of guideline recommendations. Likewise, systematic reviews investigating the single intervention "reminder system" or the multicomponent interventions with reminder systems as a component mainly showed positive changes.

To achieve a more comprehensive application of guidelines in Germany, the promotion of reminder systems thus seems meaningful.

3) Conditions of the context of service provision

The studies included in the systematic reviews were conducted in different healthcare contexts. It is thus difficult to infer recommendations for Germany from these reviews.

But generally it seems meaningful to evaluate to what extent legal requirements (e.g. for disease management programmes) or an economic framework financially compensating

guideline-compliant behaviour can promote guideline implementation. For instance, the likelihood of the implementation of guideline recommendations increases if financial incentives for guideline-compliant behaviour exist. This would be the case if payers financially compensated guideline-compliant behaviour accordingly.

4) Knowledge and opinions of guideline users and patients

The potential guideline users' knowledge of guideline recommendations is an essential prerequisite for their implementation. In addition, the unwillingness of guideline users to actually implement the recommendations can be a major barrier to the implementation of guideline recommendations.

Whereas a poor state of knowledge can be improved, for example, by appropriate educational measures, it is much more difficult to influence personal opinions of guideline users. If, for example, these potential users see guidelines as an impairment of their autonomous professional decision-making, this can then negatively affect the implementation of guideline recommendations. To solve this problem, for example, strategies should be developed in collaboration with physicians' bodies.

Need for research

A robust conclusion on the targeted dissemination and implementation of clinical guidelines in the German healthcare system is not possible on the basis of the evidence identified.

The state of knowledge can be improved here by the promotion of suitable controlled studies. These studies should contain the development of quality indicators in guideline development and a subsequent evaluation of the effectiveness of the guideline. Likewise, the choice of the respective guideline implementation measures should be explained theoretically.

Conclusion

Subgoal 1

Overview of measures for guideline dissemination and implementation

A total of 16 different measures applied as single interventions or in combination as multi-component interventions were identified in the systematic reviews included. These could be classified into 10 categories according to EPOC.

For all single and multi-component interventions identified, the data are insufficient to be able to reliably assess the effectiveness of these interventions.

Overview of influencing factors

A total of 28 factors were identified that could be allocated to the modified 5 levels according to Titler and Everett.

Subgoal 2: determinants of the successful implementation of tailored interventions

It was evaluated to what extent the successful implementation of guidelines is influenced by the barrier analysis method applied, the complexity of tailoring, certain influencing factors, the number of components of the intervention, as well as the type of setting. It was also investigated whether the results of barrier analysis were considered in guideline development. No influencing factors could be identified that clearly promoted guideline implementation.

Subgoal 3: proposals for the targeted dissemination and implementation of clinical guidelines within the German healthcare system

No clear and generalizable conclusions on the targeted dissemination and implementation of clinical guidelines within the German healthcare system can be inferred from the results on subgoals 1 and 2.

The recommendations are thus based on general considerations and the results identified. In principle it can be assumed that the implementation of guideline recommendations can be supported in a meaningful way, by

- supporting the development of guidelines that are of high methodological quality and are relevant to practice
- promoting educational measures and reminder systems
- creating certain legal requirements or economic frameworks
- developing strategies to promote the implementation of guideline recommendations, for example in cooperation with physicians' bodies

In addition, by promoting suitable controlled studies, the state of knowledge on guideline implementation should be further improved. These studies should include the development of quality indicators in guideline development and a subsequent evaluation of the effectiveness of the guideline.

Keywords: guidelines as topic, guideline implementation, systematic review

The full report (German version) is published under
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