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# Guidelines for Clinical practice guidelines

This document is intended to inform all stakeholders about the rationale, the development and the implementation of clinical practice guidelines.

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## Table of contents

1	Why develop and use appropriate guidelines?.....	2
2	Developing high quality guidelines, a fastidious process .....	3
3	Adapting high quality guidelines, an alternative approach .....	3
4	Implementing guidelines and monitoring their effectiveness are mandatory .....	4
5	Possible support of the Federal Quality Commission (FQC).....	4

## 1 Why develop and use appropriate guidelines?

Clinical practice guidelines are evidence-based recommendations for health and care. Their purpose is to foster appropriate care, attempting to reduce and control overuse, underuse and misuse of care. According to the USA Institute of medicine, Clinical Practice Guidelines are "statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options". Thus, guidelines aim to improve quality of care for patients, setting out the clinical care that is suitable for most patients with a specific condition. Guidelines have to be based on the best available research evidence and developed using a standard process. Although they are advisory, they should be taken into account by healthcare and other professionals as well as by patients. Indeed, patients' perspectives and the actual clinical situation (e.g., comorbidities) should also be considered when making health related decisions.

There is no national and coordinated structure developing guidelines in Switzerland. However, a few guidelines are produced by national bodies (e.g., vaccination recommendations). In addition, several medical associations or groups have produced guidelines. Nevertheless, the methods of development are often weak, lacking methodological support and resources, mostly based on expert consensus.

Guidelines are most useful when there is a need to improve quality of care, for instance in presence of overuse of care (e.g., smarter medicine or similar approaches), underuse of care (e.g., preventive or health promotion guidance), or large variations between and within geographical areas, medical or care specialty, or healthcare networks, for instance.

The rationale for the development of high-quality clinical practice guidelines includes several aspects:

1. Article 32 of the Federal law on health insurance indicates that medical interventions should be effective, i.e., based on scientific evidence.
2. The production of new knowledge in medicine and health sciences is increasing exponentially. For instance, in 2022, over 1,3 million citations were added to Medline, the USA National Library of Medicine journal citation database (which contains a total of about 30 million citations). Even if only a tiny minority of these publications could be useful in actual healthcare, searching and appraising scientific evidence constitutes a huge task.
3. Indeed, the amount of information is much too large to allow busy clinicians to stay aware of possibly important information.<sup>1</sup> Regularly updated systematic reviews are essential to assess effectiveness of interventions. However, the size, format and volume of systematic reviews precludes their actual direct use in daily clinical practice.
  - Thus, clinical practice guidelines based on systematic reviews of evidence are expected to be better tailored in healthcare.

Clinical practice guidelines should be supported by evidence and transparent explanations about the level of evidence and strength of recommendations, as explained below. Most often a guideline contains several recommendations concerning various aspects of care, such as dia-

gnosis, therapy, which may vary according to severity of disease or the presence of comorbidities for instance. Because most guidelines are conceived to target various healthcare professionals (e.g., physicians, nurses, other allied health professions) as well as patients and relatives there is a need to present the recommendations and related explanations in various formats suited to target groups' needs. Indeed, one objective of practice guidelines is to foster better coordination and implementation of care by providing similar information to all members of the care team, including patients.

The effectiveness of clinical practice guidelines has been evaluated in series of studies that were analysed in the framework of systematic reviews. Most interventions lead to slight to moderate improvements in quality of care. For instance, various formats of reminders could lead to small to moderate increases in outcomes related to adherence to clinical recommendations<sup>2,3,4</sup>. Audit and feedback generally lead to small but potentially important improvements in professional practice<sup>5</sup>. Furthermore, local opinion leaders alone, or in combination with other interventions, can be effective in promoting evidence-based practice, but the effectiveness varies both within and between studies<sup>6</sup>. Also, patient-reported health information and patient education probably improve professional practice by increasing healthcare professionals' adherence to recommended clinical practice<sup>7</sup>. Finally, the combination of two or several interventions or multifaceted interventions to foster guidelines use may also be helpful.

## **2 Developing high quality guidelines, a fastidious process**

Developing guidelines anew is a much demanding process, which starts with establishing the objectives, assembling stakeholders' representatives, including professionals performing and prescribing the intervention or treatment, primary care providers, nurses, other allied health professionals, and patients. The evidence should be based on systematically collected research results as indicated before (e.g., systematic reviews of evidence<sup>8</sup>). The evaluation of the level of evidence and strength of recommendations is crucial because, unfortunately, most studies are inconclusive, or have included too few individuals, and could be biased<sup>9,10</sup>. Evaluating the level of evidence and strength of recommendations requires skills and experience and should be done by trained individuals using an appropriate process (GRADE<sup>11</sup>). One should acknowledge that the available evidence is much too often weak, leading to uncertainty that must be properly considered. Failing to acknowledge uncertainty of evidence and relying essentially on expert opinion and consensus may lead to inappropriate guidance. Hence, developing proper guidelines requires much expertise, time and costs. Furthermore, regular updating of guidelines is necessary to adjust recommendations to new existing and sometimes conflicting evidence. Recommendations, guidance for developing guidelines, and examples, do exist internationally (NICE<sup>12</sup>, ÄZQ<sup>13</sup>, HAS<sup>14</sup>, SIGN<sup>15</sup>, GIN<sup>16</sup>, AGREE<sup>17</sup>). Potential conflicts of interest (financial but also intellectual) matter and should be identified and declared.

## **3 Adapting high quality guidelines, an alternative approach**

An alternative to the de novo development of guidelines is to adapt high quality updated guidelines developed by experienced and well financed agencies elsewhere. An adaptation process has been developed and tested, which is largely used worldwide (ADAPTE<sup>18</sup>). The adaptation has to

be made according to the context of the country and healthcare system where the adapted guidelines are intended to be implemented. The adaptation process still requires local capacities and skills, but is less demanding, and actually suited for countries and regions where actual resources and skills are lacking for the actual development of guidelines de novo. However, adapted guidelines should also be updated when needed as "dynamic" guidelines, when new evidence becomes available.

High quality guidelines could be obtained from experienced agencies and consortiums. For instance, the Guidelines International Network proposes a library of guidelines as well as tools and support (<https://g-i-n.net>). Also, NICE and SIGN, for instance, do have a long experience in developing high quality guidelines. The quality of existing guidelines can be evaluated using the AGREE tools<sup>17</sup> beforehand.

#### **4 Implementing guidelines and monitoring their effectiveness are mandatory**

Last but not least, clinical practice guidelines will not contribute to improve quality of care if they are not properly implemented. Guideline implementation needs also a rigorous and demanding investment. The implementation process could be facilitated by some tools (e.g., Gin's Guideline Implementation Planning Checklist<sup>16</sup> and the GuideLine Implementability Appraisal tool (GLIA)<sup>19</sup>). Actually, there is some evidence that implementation supported by appropriate tools could contribute to guidelines implementation<sup>20</sup>. Furthermore, improving the design and implementation of evidence-based practice depends on successful behaviour change interventions. This requires an appropriate method for characterising interventions and linking them to an analysis of the targeted behaviour. S. Michie et al. have performed a systematic review of frameworks tailored for this purpose, and proposed a "behaviour change wheel that could contribute to lead to more efficient design of effective evidence implementation interventions"<sup>21</sup>. Finally, the evaluation and monitoring of actual improvements in practices following the introduction of guidelines in the framework of an implementation project should be monitored.

#### **5 Possible support of the Federal Quality Commission (FQC)**

FQC may possibly support the development and implementation of clinical practice guidelines, **if**:

1. There is an important need to improve quality of care (e.g., documented overuse, misuse, or underuse of care).
2. Guidelines are developed following state-of-the-art guidance for developing guidelines.  
- Guideline adaptation to the Swiss context can be part of the project.
3. The project must describe how clinical practice guidelines will contribute to improve quality of care.
4. The implementation phase must be described in detail.
5. The impact of guidelines on quality of care must be assessed.
6. The sustainability of the intervention (after the end of the project) must be discussed.

FQC can grant financial aid to support national or regional quality development projects that include the development and implementation of guidelines (maximum 50% of the total budget).

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- <sup>1</sup> Straus S et al. Managing evidence-based knowledge: the need for reliable, relevant and readable resources. *Can Med Assoc J* 2009;180:942-945; DOI: <https://doi.org/10.1503/cmaj.081697>
  - <sup>2</sup> Pantoja T et al. Manually-generated reminders delivered on paper: effects on professional practice and patient outcomes. *Cochrane database of systematic reviews* 2019; <https://doi.org/10.1002/14651858.CD001174.pub4>.
  - <sup>3</sup> Arditi C et al. Computer-generated reminders delivered on paper to healthcare professionals: effects on professional practice and healthcare outcomes 2017; <https://doi.org/10.1002/14651858.CD001175.pub4>.
  - <sup>4</sup> Shojania KG et al. The effects of on-screen, point of care computer reminders on processes and outcomes of care 2009; <https://doi.org/10.1002/14651858.CD001096.pub2>.
  - <sup>5</sup> Ivers N et al. Audit and feedback: effects on professional practice and healthcare outcomes 2012; <https://doi.org/10.1002/14651858.CD000259.pub3>.
  - <sup>6</sup> Flodgren G et al. Opinion leaders Local opinion leaders: effects on professional practice and healthcare outcomes 2019; <https://doi.org/10.1002/14651858.CD000125.pub5>.
  - <sup>7</sup> Fönhus MS et al. Patient-mediated interventions to improve professional practice 2018; <https://doi.org/10.1002/14651858.CD012472.pub2>.
  - <sup>8</sup> For instance *Cochrane database of systematic reviews* -[www.cochranelibrary.com](http://www.cochranelibrary.com)
  - <sup>9</sup> Howing J et al. *J Clin Epidemiol* 2022; <https://doi.org/10.1016/j.jclinepi.2022.04.017>.
  - <sup>10</sup> Ioannidis JPA. Why most published research findings are false. *PloS Med* 2005;8:e124.
  - <sup>11</sup> Grading of Recommendations Assessment, Development and Evaluation (GRADE) - [www.gradeworkinggroup.org](http://www.gradeworkinggroup.org)
  - <sup>12</sup> National Institute for Health and Care Excellence (NICE) - [www.nice.org.uk](http://www.nice.org.uk)
  - <sup>13</sup> Ärztliches Zentrum für Qualität in der Medizin (ÄZQ), Leitlinien - [www.aezq.de/aezq/publikationen/leitlinien](http://www.aezq.de/aezq/publikationen/leitlinien)
  - <sup>14</sup> Haute Autorité de santé (HAS) [www.has-sante.fr/jcms/fc\\_2875208/fr/rechercher-une-recommandation-un-avis](http://www.has-sante.fr/jcms/fc_2875208/fr/rechercher-une-recommandation-un-avis)
  - <sup>15</sup> Scottish Intercollegiate Guidelines Network (SIGN)- [www.sign.ac.uk](http://www.sign.ac.uk)
  - <sup>16</sup> Guidelines International Network (GIN) - [g-i-n.net/](http://g-i-n.net/)
  - <sup>17</sup> Appraisal of Guidelines for Research and Evaluation (AGREE) - [www.agreetrust.org/](http://www.agreetrust.org/)
  - <sup>18</sup> Guidelines adaptation tool (ADAPTE) - [g-i-n.net/get-involved/resources](http://g-i-n.net/get-involved/resources)
  - <sup>19</sup> Guideline Implementability Appraisal tool, v. 2.0 (GLIA) - [www.cdc.gov/os/quality/docs/glia\\_v2.pdf](http://www.cdc.gov/os/quality/docs/glia_v2.pdf)
  - <sup>20</sup> Flodgren G et al. Tools developed and disseminated by guideline producers to promote the uptake of their guidelines 2016; <https://doi.org/10.1002/14651858.CD010669.pub2>.
  - <sup>21</sup> Michie S et al. The behaviour change wheel: A new method for characterising and designing behaviour change interventions. *Implementation Sci* 2011;6:42. <https://doi.org/10.1186/1748-5908-6-42>