

Evolution of the HELEN Representation for Managing Clinical Practice Guidelines

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Abstract

Adaptation is a central process in the life cycle of clinical practice guidelines (CPGs), if a broad acceptance is to be achieved. Currently, there is no fully integrated solution for this process available. Due to the risk of introducing errors or compromising the evidence base, users and persons in charge often hesitate. To overcome these problems, we present a manageable pathway for the adapters and a control mechanism for the authors of generic CPGs which is fully integrated into a methodological and technical framework for developing, authoring, and implementing CPGs, called HELEN. We have extended this framework by functions to support a structured process of adaptation; there is first evidence that the quality of the adapted CPG can be enhanced by our solution. However, further evaluation is still to be done.

Key words: Clinical practice guidelines, implementation, local adaptation, execution

1 Introduction

Recent research in the field of clinical practice guideline (CPG) representations has a.o. come to the conclusion that a life cycle is an essential part of every conceptual model (1, e.g.). As an example for a CPG representation we introduced the HELEN framework (2), which provides such a life cycle,

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and the methods and tools to support its usage. Our life cycle consists of the following seven steps:

- (1) Estimation of value or usefulness for clinical practice
- (2) Authoring on a national or international level
- (3) Critical appraisal of the quality by an independent organization
- (4) Dissemination to standardized networks
- (5) Guided adaptation to local needs
- (6) Implementation within local institutional systems or environments
- (7) Evaluation of successful transfer

Based upon this life cycle we developed several methodologies and processes and also tools to support them.

Figure 1 gives an overview of the architecture of the supportive technical framework which basically consists of three parts:

- Authors of generic guidelines use the Authoring Environment to create CPGs and encode them into the HELEN XML format. Adaptation teams use the same environment with some restrictions.
- The encoded guidelines are prepared and presented by the Guideline Viewer whilst algorithms are processed and executed by the Guideline Execution Engine.
- Users (physicians, nurses, students etc.) of the system can use various clients to access the contents of the guidelines.

Presently, steps 2, 3, 4, and 6 of the life cycle presented above have already been investigated intensely and integrated (2) into the HELEN framework. The tools supporting the development, appraisal, dissemination and the implementation have reached a stable version.

Ollenschlaeger (3) suggests that research within this area should now deal with the implementation. A prerequisite for successful implementation is the adaptation to local needs (4; 5; 6). Environments in which the CPG is to be implemented differ between institutions, therefore adaptation can increase the acceptance by future users. Another beneficial side-effect of the adaptation process is the clear definition of processes, responsibilities and resource usage. Thus, we focus on step five of our life cycle – the adaptation process, which is the subject of this paper.

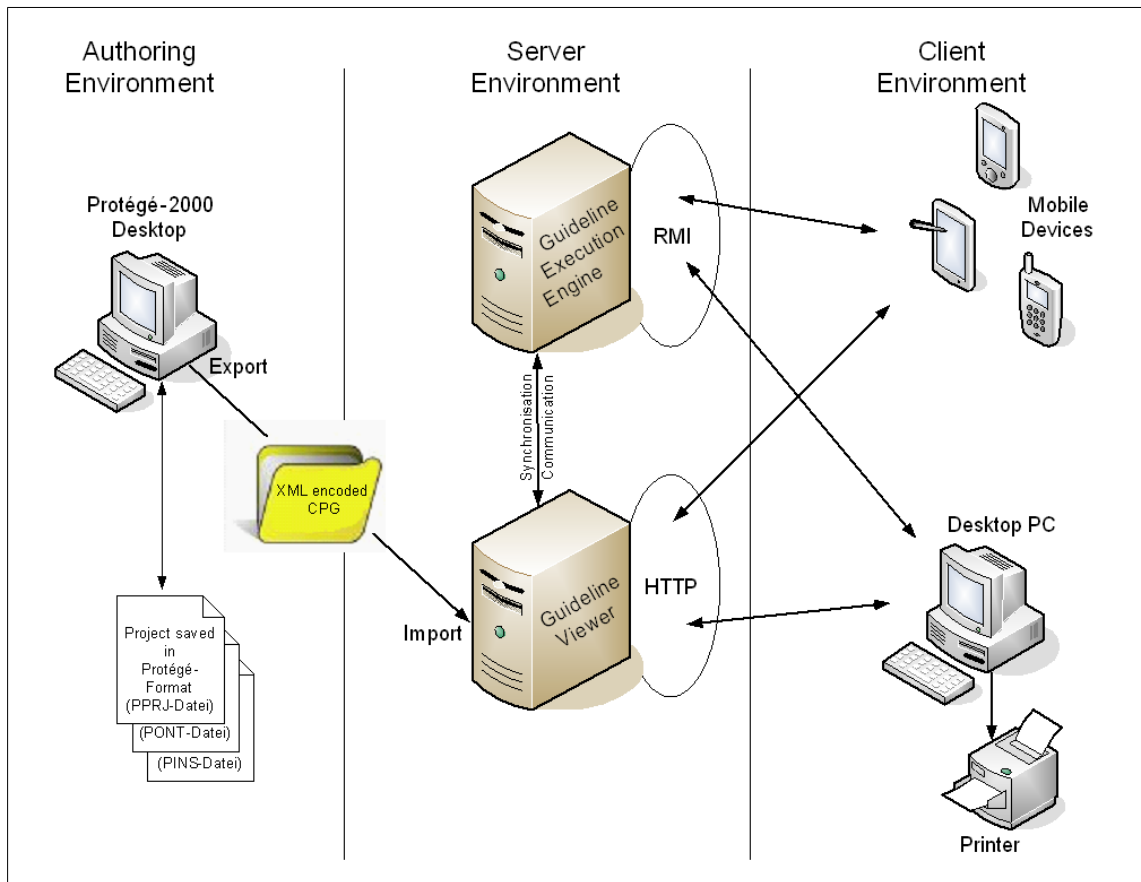


Fig. 1. Overview of the HELEN architecture

2 Background

2.1 Fundamentals

Adaptation (some authors also called this custom tailoring or localization) is a pivotal process in a CPGs life cycle if a broad acceptance is to be achieved (4; 5; 6). The settings in which guideline usage may be beneficial for quality of care differ in various aspects; therefore the adaptation process has to tailor the guideline recommendations to take into account variations such as:

- Lack or availability of resources
- Local policies for treatment options or drug doses
- Different patient population
- How the CPG is accessed (e.g. paper-based, on a desktop PC or handheld)
- Workflows, pathways, task assignments and qualifications

Although adaptation has many benefits and improves the acceptance of guidelines, tailoring guidelines to local needs on the other hand also raises several problems (7). We will now try to discuss the pros and cons.

The first obvious aspect is the expenditure of time and resources: Adaptation is a time-consuming process and many people have to be involved into the creation of the site-specific version. However, compared to the work of developing a CPG from scratch, adaptation requires less effort. Lauterbach (8) reported the costs for developing one CPG in Germany to about 250,000 Euros.

On the other hand, if all future user groups are involved in the process, the acceptance of the CPG can be improved considerably (9; 10; 11).

Another critical aspect of the adaptation is the availability of expertise and the management of several site-specific versions. Authors of generic CPGs may lose control over their intended implementation because the adaptation process contains the risk of introducing errors. By changing essential parts of the CPG, the evidence base created by the medical experts may be compromised. If changes of the generic guideline have to be made, multiple (adapted) versions of this guideline are hard to manage. Only if we succeed to offer a straight forward transparent process from a generic (e.g. national) CPG to site-specific guidelines, a common evidence base maintained by medical and CPG methodology experts can be guaranteed.

That is why future work shall focus on systematic evidence representation and propagation. An essential advantage of adapted CPGs over separately developed ones is that they can rely on the evidence that has been systematically assessed and incorporated in the original guideline.

The fact that generic guidelines also eventually undergo revisions adds another dimension to the maintenance and versioning problem: Not only validity/expiration of local guideline versions need to be traced and logged; easy to use tools are also required for tracking the impact of changes of the generic CPG to its local versions.

In order to keep their generic guidelines under control, the authors need several control mechanisms that can protect essential parts of a CPG. By providing the adapters with a helpful tool for the adaptation process, we try to reduce the resulting overhead in case that the original CPG is updated.

There still remains the risk that the overall evidence of the adapted guideline is weaker than the original. It has to be carefully evaluated if such tools can help to reduce this risk and if additional steps are necessary to verify the adapted guideline. Submitting the adaptation to the original authors or applying formal criteria have both been suggested. But existing solutions focus on plausibility and consistency within one CPG rather than across two or more variants of one CPG (7; 12; 13; 14; 15; 16). Furthermore, automatic verification processes will most likely be limited to the algorithm parts of a guideline.




Symbol	Name	Description
	<i>Must_be_adapted</i>	The object must be adapted in the local CPG
	<i>Can_be_adapted</i>	The adaptation team can choose whether to adapt the object
	<i>Must_not_be_adapted</i>	The adaptation team is not allowed to change the object

Table 1

Adaptation constraints

There have been various publications describing the need for adaptation (e.g. 17; 18; 19; 20) and the development of generic guidelines at (inter-) national level(21). In any case, all future user groups of the guideline have to be included into the structured process of local adaptation. In the past decade a sophisticated process of guideline authoring, representation, and linking evidence to recommendation has emerged in various places (22; 23)(evtl. Quellen SIGN, AGREE, NBO, weitere, die Sie wichtig finden). There is a need, too, for a defined process of adaptation, which starts at the (inter-)national level. In order to support local adaptation with a comparable degree of sophistication, the authoring process will have to be enhanced by introducing constraints that delimit and hints that guide local adaptation. With such information becoming part of future (inter-)national guidelines, the efforts required and the amount of errors introduced by local adaptors should be minimized.

2.2 Concepts

Some groups proposed different ways to solve one or more of these problems (20; 24; 25, e.g.). To minimize the risk of introducing errors, generic guidelines must be enhanced by metadata influencing the adaptation process. At the national or international level, where the generic CPG is created, the authors must be able to enforce, permit or inhibit changes on particular parts of a CPG. Within the *HELEN_Guideline* representation, a specialized attribute for certain objects¹ is necessary to specify how the object is to be treated in the adaptation process. Table 1 shows the possible values for this attribute along with its symbol in the authoring environment and a short description.

Additionally, institutions adapting guidelines should be provided with hints for the adaptation by the original authors. By using a free-text field along with the constraints from table 1, authors of generic guidelines have the possibility to explain exactly the intention of certain parts of the CPG thus avoiding misunderstandings.

To translate these two concepts into action, the authoring environment must

¹ An object can be a knowledge module, a variable or a constant.

be enhanced as well. Besides the minor changes for the authoring process, a tight integration within the adaptation process and a sophisticated support for the adapters is necessary. This can be achieved by providing a pathway in form of a synoptic view of the generic and the site-specific version (see figure 3). The adapters can see at one glance which constraint applies to each part of the CPG (i.e. whether they are allowed or even requested to modify it).

As a consequence of these conceptual changes it will likely be helpful for the authors of the generic guidelines to get a feedback from the adaptation teams. Frequently occurring adaptations that touch upon core parts of the generic CPG suggest themselves to be incorporated into future versions of the generic CPG. Therefore a protocol is created during the adaptation process which contains each action (creation, removal, adaptation) performed by the adapters. By means of this protocol, the authors are able to analyze and review the adaptations made. A similar feedback mechanism from the users to the adaptation teams should in the future be considered. This will give the adapters the chance to better adjust their adaptation for daily clinical practice.

3 Implementation

Based upon the existing HELEN framework (representation, methods and tools) described in (2), we developed an adaptation pathway and a control mechanism for the authors of the CPG. The required amendments to the HELEN version as of (2) were incorporated in the method and wherever necessary in the HELEN tools in the ways described below.

3.1 Technical Changes

In order to meet the mentioned requirements, minor changes within the guideline representation as well as several additional widgets for the authoring and adaptation environment were necessary.

The initial framework had been developed using the Model-based Incremental Knowledge Engineering Process (MIKE) (26). This is a method for developing knowledge based systems based on the Spiral Model of Software Development (27). In this model, the development consists of four tasks:

- Analysis of requirements
- Design or refinement of the ontology
- Implementation of an initial knowledge acquisition tool and its extensions

- Evaluation by entering examples and test usage of the encoded information.

In our case the second task focused mainly on the extension of the existing ontology to meet the new requirements. To be able to test the encoded information, we only had to adapt the authoring environment because the processing of adapted CPGs had already been sufficiently implemented in the other tools (viewer and execution environment) to meet the new requirements. By changing only the authoring environment and leaving the language untouched, all evidence about processing HELEN-encoded CPGs reported in (2) remains valid.

Consequently, the additional functions were also developed using an additional MIKE cycle. Thus, we first refined the ontology and subsequently adjusted the authoring environment and the widgets.

In HELEN, CPGs are split in so-called *Knowledge_Modules*, which represent either text, images or algorithms. A guideline is assembled of these three module types. For the present investigation, each of these objects was equipped with metadata fields regarding the adaptation. An adaptation constraint is used for controlling the change of each module. It contains one of the three symbols described in the concepts section (see table 1). The other field contains hints for the adapters in form of narrative text. These two fields enable the authors to control the adaptation process and the adaptation teams to structure their work.

Protégé-2000 generates its user interface dynamically, changes in the ontology are adapted automatically. Thus, we could focus on the implementation of the two modes (generic authoring and local adaptation) of the authoring environment. Therefore, additional plug-ins were developed for

- protecting adaptation constraint and hint fields by a password and
- visualizing the pathway to the adaptation teams.

In figure 2 the control of the adaptation process is shown. The authors define the constraints (in the lower left) and give a hint to the adapters (in the lower right). At the time of the adaptation, this interface is used as well, but only the hint is shown and none of the two meta-fields is editable by the adapters. The constraint is not shown as separate field but individually displayed with every HELEN-module by the respective symbol of table 1.

Figure 3 illustrates the structured adaptation. The three lists on the left contain all elements of an original guideline, whereas the lists with the elements of the local guideline are presented on the right. This view can act as a work list for the adaptation team: The constraint defined by the authors of the CPG is represented by the colour of the icon, so the adapters can see at one glance what to do with each of the elements. Only if the constraint is

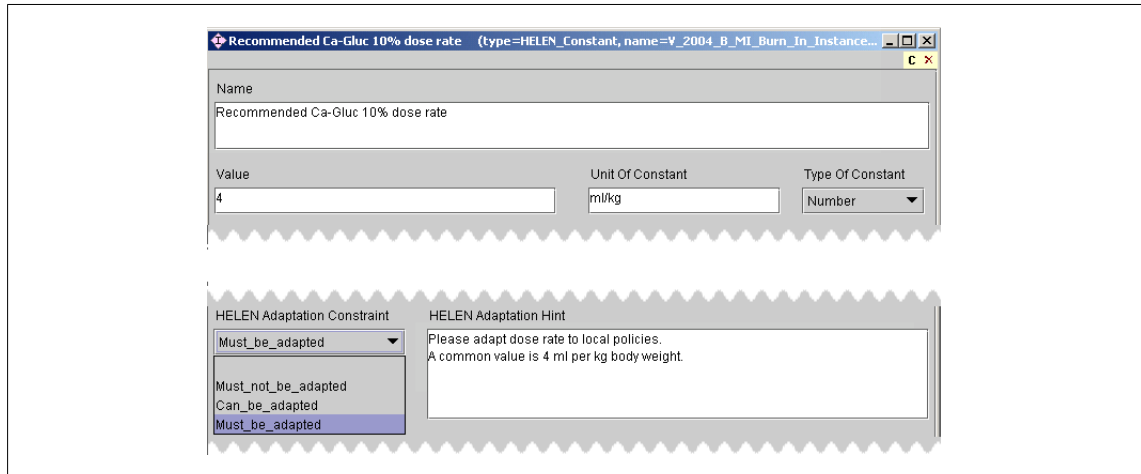


Fig. 2. Adaptation constraint and hint in the authoring environment

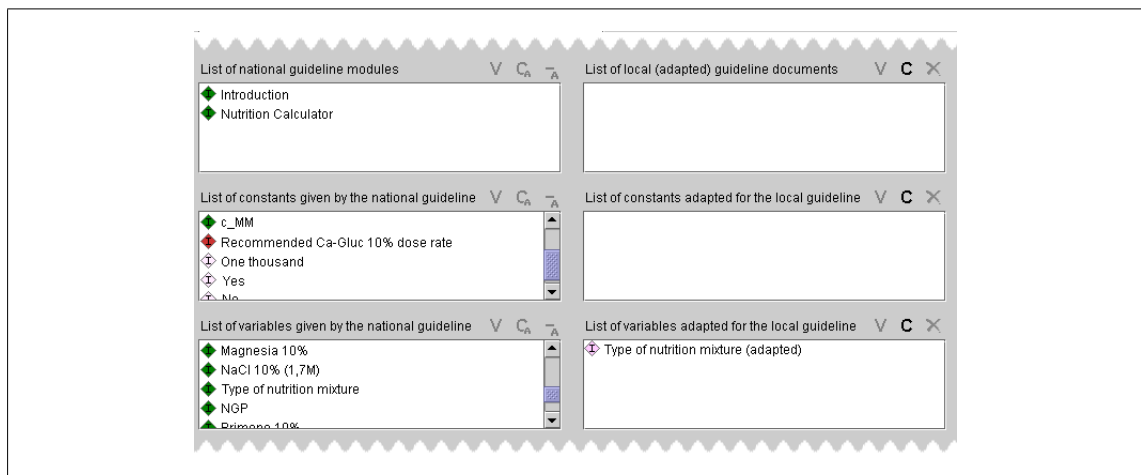


Fig. 3. Adaptation pathway overview

Must_be_adapted or *Can_be_adapted*, the object can be modified in the local version.

3.2 Methodological Changes

In addition to the technical changes we have to strengthen the methodological usage for authors and adapters. Besides proven concepts for collecting, synthesizing and formulating guideline recommendations by means of *Knowledge_Modules*, authors must additionally decide about adaptation by choosing the constraints applied to each module and giving hints to the adapters.

Since fixed rules for this decision are impossible to define due to the wide variety of topics, we gave rules of thumb for assistance. Authors of a generic guideline suitable for the guided adaptation must carefully consider the constraints for each part of the CPG. In being too restrictive (extensive use of

Must_not_be_adapted), adaptation can be made impossible because there is not enough range to tailor the recommendations to local needs. On the other hand, if the constraints are applied too generously (extensive use of *Can_be_adapted*), the potential of the new method is not utilized because applying *Can_be_adapted* to a module is literally the same as not using the control mechanism at all.

Authors must also try to put themselves in the position of the adapters when filling out the adaptation hints of each module. They have to consider potential misunderstandings and try to prevent them by explaining the intention as exactly as possible.

On the other hand, adapters should try to use the hints provided by the authors to adapt only those parts of the guideline which are really necessary. If the constraints seem too restrictive or hints are incomprehensible, a feedback to the authors should be made. General feedback about the adaptation process (i.e. a protocol of changes made) is also reasonable as it enables the authors to see if they were able to reach their intentions.

4 Evaluation

The support of adaptation by the HELEN system was assessed in a setting of quality assurance with a small simulated rather than with a large randomized trial. Reasons for this decision were that there are not any generic guidelines providing the necessary metadata to be used directly as input for our guided adaptation and that we wanted to find out whether the concept would work at all before planning a large trial.

With the simulation, we initially aimed at the question if the adaptation process introduces errors to definitions of decisions, actions or clinical states within a CPG. We particularly posed the question if the process proposed earlier in section 3.2 can decrease the errors introduced during the adaptation of a guideline. For the simulation we used two international guidelines which were annotated using the HELEN tools:

- Management of Hyperbilirubinemia in the Healthy Term Newborn (German version from the GNPI)(28)
- Smoking Cessation from the Agency for Health Care Policy and Research² (29).

In the first step, the published guidelines were mapped to the HELEN representation straight forward as published i.e. without any enhancements that

² which is now the Agency for Healthcare Research and Quality

HELEN supports. Subsequently the fields regarding evidence base and the links between elements were completed.

In cooperation with medical experts, the HELEN versions of the CPGs were discussed and the constraints for the adaptation defined. Finally, we generated paper-based versions from the annotated guidelines. That step was necessary because we only wanted to assess the concept of the adaptation and not the influence of the tools in this first step of evaluation.

We recruited 27 physicians from different fields and institutions. Depending on their professional experience and their personal interests, they were assigned to an adaptation team with a specific subject. There were two groups for each of the following scenarios that the adaptations should be targeted at:

- Department of Gynecology in a general hospital,
- Department of Neonatology of a University Medical Center,
- Pediatrician in private practice,
- General Practitioner in a practice group.

Thus, there were eight adaptation teams. Each team adapted both guidelines summing up to 16 adaptation experiments. It was randomly assigned whether a team adapted both, one, or neither guideline with the use of adaptation metadata. In other words there were 16 team-guideline pairs each with randomly assigned “with” or “without” metadata condition. The instructions for all groups comprised the creation of an adaptation which would be useful for practice in their assigned environment, thereby enhancing respectively adapting the focus, the recommendations, the typical patients affected and the diagnostic and therapeutical options. In an adaptation protocol, all changes to the CPG broken down into clinical states, actions and decisions were documented.

Because it was hard to define an exact scope for the appraisal of the adapted guidelines, the adaptations produced were examined by experts from the Department of Neonatology within an expert colloquium. Using the adaptation protocol, an informal consensus was achieved for each of the entries, deciding if the applied changes lead to a corruption of the intention or to an illegal deviation from the original recommendations of the CPG.

Initially noticeable is the decrease of the number of changes to the individual parts of the CPG by 51% (see table 2). The satisfaction of the adaptation teams stayed constant (see table 4). From this evaluation and from the concluding discussions with the participants of the test, we can conclude that the constraints and hints for the guided adaptation did not delimit the users too much.

Looking at the central question of the trial, concerning the unwanted corruptions during the adaptation, we can see an effect which is obviously positive.

Evaluation criteria	without	with
	adaptation hints	
Changes to decisions	69	27
Changes to actions	58	28
Changes to states	32	22
Overall changes	158	77

Table 2
Evaluation of the adaptation protocols (number of entries)

Evaluation criteria	without	with
	adaptation hints	
Corruption of decisions	6.00	1.25
Corruption of actions	3.75	1.00
Corruption of states	0.75	0.50
Average corruption	3.5	0.9

Table 3
Appraisal of the adapted guidelines (means)

	without	with
	adaptation hints	
User satisfaction	1.88	1.88

Table 4
User satisfaction during the adaptation

Evaluation criteria	without	with
	adaptation hints	
Corruption of decisions	8.70%	4.63%
Corruption of actions	6.47%	3.57%
Corruption in states	2.34%	2.27%

Table 5
Relative portion of errors within the overall changes

For the results in table 4, all corruptions to the three types of modules in the 16 experiments were counted and within each condition divided by the number of team-guideline pairs in that condition (which is also 16). Averaged over all measured parameters (decisions, actions and states), the number of corruptions decreased from 3.5 with the unguided adaptation to 0.9 with the guided adaptation. To assure that this decrease did not only result from the reduction of the numbers of changes made, we calculated the number of the

identified corruptions by the number of the adapted elements (table 5) giving the rate of falsely adapted guideline modules. Although there is a decrease in the corruptions during the adaptation of clinical states from 0.75 to 0.50 when looking at the means, this effect is no longer visible when looking from the relative point of view (this comes up to a decrease from 2.34% to 2.27%). Therefore we must conclude for this trial that the smaller number of corruptions of the clinical states results mainly from the decreased absolute number of adapted clinical states.

However, based on the sum of the results, it is fair to conclude an effective reduction of corruptions results for the decisions and actions from the guided adaptation.

When trying to generalize the described effects, we carefully have to take into account that the results were produced from a simulation with two CPGs, which are structurally very similar. Because of the known wide variety of guideline topics and the resulting differences in the form, complexity and developed materials, further investigations are absolutely necessary.

5 Discussion

Independent from the drawbacks mentioned at the end of section 4, we could integrate and support the adaptation process within the guideline's life cycle by extending the ontology and the authoring tools. In the used examples the evidence base could be kept stable and corruptions could be reduced to a minimal rate during the adaptation process only by merely adding constraints and hints to the paper format of the original CPGs.

With our extension to the HELEN system we have achieved the aim of controlling changes of generic CPGs which are provided on a national or international level. A pathway for the adaptation process is provided in the authoring environment.

The results of our first simulation trial reflect our experience with implementing CPGs within the Department of Neonatology. Our results go into the same positive direction as those of other other researchers (30; 13; 31; 32; 33; 34).

Besides the positive experience we made dealing with the adaptation of CPGs, several problems remain which constrain the implementation and evaluation of our adaptation concept. First of all, there is a lack of generic guidelines which could be used as input; at the moment ³, in Germany ⁴ there are only 34

³ as of 06/06/2005

⁴ from the web site <http://leitlinien.net>

guidelines available of the development level "S3"⁵. Even in these qualitatively high grade CPGs, evidence is sometimes implicit and only few metadata are included, none of which concern adaptation constraints or hints.

Having not yet validated the benefit of the tools but only the methods, we plan to perform a second simulation trial like the one described in section 4 and consequentially assess the quality of our supportive tools in the near future.

Our approach of supporting the whole CPG life cycle requires that we do not only impose the requirement on authors of generic guidelines to mark them up for adaptation. Rather should we support them through tools that prompt and guide them in delivering the information that adaptation teams rely on. In other words, HELEN should further evolve into an authoring tool for developers of generic guidelines to enable them to make national or international guidelines more expressive and better adaptable. Besides requirements on the quality of the generic guidelines and their constraint and hint annotations this is also necessary for reasons of cost-effectiveness. Because if in the future guidelines only pass quality appraisals when their annotations are as well substantiated as their contents, the cost of authoring a guideline may by far exceed the value estimated (8) unless authoring support precisely matches authors' needs.

This means that the grading of evidence as well as the constraints have to be defined carefully to minimize the danger of compromising the evidence base during the adaptation process. There is a need for a standard format for CPGs which incorporates evidence references and adaptation metadata.

To further reduce the work for guideline authors and adapters/ implementers, we try to achieve a central repository for consistently graded literature references either on national or international level. There is work (partly in process) related to this topic by the GRADE working group(35; 36), the G-I-N⁶ and also the AGREE Collaboration⁷. We want to integrate a method for grading of evidence into our framework as soon as an international standard is established.

At the moment, it is not easy to evaluate whether the evidence base can be protected in general by our adaptation process because there are currently no CPGs which contain the necessary metadata (i.e. adaptation constraints and hints). But after having defined such metadata for the specifically developed

⁵ S3 means methods obtained from consensus and evidence based medicine are used during the development process. Results are stated in formal logic and decision and outcome analysis are included.

⁶ Guideline International Network, <http://www.g-i-n.net>

⁷ <http://www.agreecollaboration.org>

master guidelines of this investigation, the process of taking them into account while adapting the guideline proved straightforward and well structured.

After all, the availability of more generic CPGs with metadata and suitable methods and tools for the adaptation process along with proven concepts for the implementation suggests itself as an approach for further improving the quality of clinical care.

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