GUIDELINES FOR THE DEVELOPMENT OF NEW AND MODERN METHODS

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Annotation: The complexity and quality requirements for the development of clinical practice guidelines steadily increase. Internet technologies support this process by optimizing the development process.

An internet portal was developed allowing for a shared workplace to support clinical practice guideline authoring. It is based on a Content Management System and combines different tools for document handling and editing, communication as well as process and team steering.

Key words: heart, blood, clinical practice.

Clinical practice guidelines (CPGs) play an important role as treatment guidelines in daily clinical practice. A prerequisite of this trend was the development of rigorous quality criteria for such guidelines, which has been promoted by different national and international organisations. As a result, the requirements for the development process of clinical practice guidelines have been sharpened steadily. A modern evidence- and consensus-based guideline [1, 2], in Germany known as a S3 CPG [3], requires both the evaluation of highest possible evidence and the establishment of a consensus between all participants, from the specialized medical professional to patient organizations. To obtain acceptance, the finished guideline has to pass through an intensive reviewing process and assessment by instruments such as AGREE [4] or its German counterpart, DELBI [5]. Prerequisite for these steps is a comprehensive method report. Because of its limited lifetime moreover, the CPG also requires a cyclic update.

As a consequence, typical development time-periods for such guidelines quickly reach up to three years. At the same time, the development is expensive. There have been reported costs per guideline of $ 150.000 in the Netherlands or of $ 400.000 for British NICE guidelines [6]. Consequently, reduction of expenses represents one important objective in CPG methodology [7] as well as simplification of time and cost intensive steps in the development of CPGs should be considered.

Modern Information Technology (IT) techniques such as internet portals, content management systems or communication platforms have the potential to contribute to the solution of these problems. More remarkable, no specialized IT solutions have been described for accompanying support of the CPG development so far.

To fulfill these requirements, a content management system (CMS) with powerful web interface [8] and a large degree of configurability and extensibility has been chosen. As an optimal framework, the Plone CMS has been selected [9]. Plone, as a portal solution, already includes a full-developed subsystem for accounting and access control, which is relatively simple to extend to a full-fledged, LDAP-based participant management.

A decisive advantage is the application of the universal scripting language Python as an implementation language. This offers a high flexibility for the programming of server-side business processes, compared with solutions based on web-only languages such as PHP or on more complex Java environments. Accordingly, it is an excellent platform for rapid reaction on emerging user requirements, and it comes with a multitude of extensions.

One key component of the portal is a tool for the preparation, execution and evaluation of voting via Internet [10]. It applies a formalized description of questionnaires, based on XML Schema. Various scripts for automated generation of HTML implementations of questionnaires, for monitoring of voting and finally, the statistical analysis of results simplify online voting at a considerable rate. Some features, e.g. the possibility to comment answers, are specially tailored to the demands of consent establishment.

All data, describing a CPG and generated during its development are handled by an external database, using the relational database management system MySQL, with the exception of text documents, which are managed within Plone's internal repository. To ensure a high degree of availability, the portal is hosted on a virtualized Linux server on a VMware ESX cluster.

The client-side part can be kept very simple. As software configuration, it only requires a browser, possibly supplemented by some support for the handling of PDF and office documents. But the latter are optional, since the text editing mostly takes place with internal editors, supplied by the portal. To simplify the access to the Internet, all client-server communication exclusively uses HTTP/HTTPS. Furthermore, all tools are server-side applications, and no download of any executable code is required. Thus, even in secure environments like hospitals the access does usually not raise problems.

The experience, gained from different CPG developments hosted so far, indicates a high flexibility in adapting to individual methodology. Some early expectations, e.g. to fully substitute Nominal Group Processes by pure online votings, have been revised. On the contrary, skillful combination of online votings about CPG recommendations with their subsequent discussion and finalization during a consensus conference has remarkably increased the quality (accuracy, completeness) of their formulation. To optimize the interplay between those two steps, the voting tool has been completely redesigned during the test phase to improve the possibilities to comment answers.

So far, the full integration of tools, required for evidence appraisal, into the portal is not solved satisfactory. Thus, it is planned to extend the portal by a powerful Document Management System, which will support all aspects of literature work without the need of external tools.

The portal is available for further users at anytime. Detailed information can be found on the start page of the portal [8] and in an information brochure [13] available for download from the portal. Terms of portal use and prices can be inquired. The latter depend on the extent of the required tools. Referring to a CPG with up to 10 workgroups and a total of 50 participants, the cost of portal usage normally is below 10.000 $, which matches the minimum expense of a single one-day meeting of such a team.

The portal has shown its value in the development of CPGs. For developer teams it offers a high degree of flexibility in the organization. Especially, considerable parts of consensus finding, as yet often connected with numerous meetings, which are difficult to organize and very expensive, can be replaced by platform usage. In addition, the management and control of the development process can be simplified significantly. This includes measures for quality management, which are profoundly supported.

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The present manuscript does not report results from research including experiments on human subjects or animals.

As evidence-based recommendations for health professionals, clinical practice guidelines play an important role in their daily work. The aim of the portal, presented here, is to optimize the quality of these recommendations, by supporting their development. This increased quality also results in increased confidence in CPGs, connected with improved implementation into clinical practice.

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