Digital Healthcare Empowering Europeans
R. Cornet et al. (Eds.)

doi:10.3233/978-1-61499-512-8-637

Draft Guideline for the Development of Evidence Based Medicine-Related Apps

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Abstract. Evidence based recommendations can significantly aid decision processes in medicine and mobile apps are starting to enter this domain. Considering the rapid access to and quick processing of information made possible by such apps, it is especially important to ensure the quality and structure of the provided data and to also keep the limitations of the information sources in mind. A draft guideline meant for implementing appropriate standards for such apps is outlined in this contribution.

Keywords. Evidence Based Medicine, Information Dissemination, mHealth, app

Introduction

Evidence based recommendations, founded on well-researched clinical trials can help health care personnel with managing their patients. Physicians are encouraged to consider the available evidence in their decisions. Patients often use the same information for deciding to go along with or reject the planned treatment [1].

Nevertheless, due to the overwhelming amount of available information, maintaining the overview over is not an easy task [2]. One reason for conducting systematic reviews (SR) that are a core element of evidence-based medicine [3] is to alleviate this situation. SRs use established and well-evaluated guidelines for summarizing individual studies. A key element is the systematic and structured process of searching for and reviewing appropriate studies [4].

Providing evidence based data by presenting a concise and comprehensive overview of the available clinical studies and their deductions is an attractive concept. If a mobile reference, e.g. on a device such as a smartphone, were readily available for health providers, this may positively influence the outcome of a treatment. Recently, a number of promising apps addressing this have been made available. The development of applications tailored to the needs of specific user groups that present key data of clinical trials is generally welcomed by the community. However, ethical concerns may arise when such projects do not explicitly name their limitations, conflicts of interest or other issues. To alleviate such issues, apps and other electronic media targeting this area should undergo a peer-review process before they are offered online. Systematic reviews of (clinical) studies that cover specific areas of indications are an integral part of this process. Often, but this is not mandatory, they contain meta-analyses where data are statistically aggregated [5, 6]. The selection of included papers follow a study

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protocol with clearly defined inclusion and exclusion criteria. The inclusion or exclusion of information and collaboration between experts play a significant role.

For rating apps and web pages that specify that their area of application covers evidence based medicine, we will present a draft guideline APPRECIEM [7] for the development of mobile apps with a focus on EbM-related content.

1. Methods

In order to compile a thorough and ready-to-use guideline, it makes sense to reference already existing and well-established guidelines and use them as a basis. When dealing with apps, different aspects apply and these depend not only on the context, but also on the different "levels" one needs to consider. Therefore, the proposed guideline is subdivided into three sections:

Level 1 considers the global app level. It covers aspects that have so far not been adequately included in other guidelines. An app that (due to its stated purpose) is rated as a medical device – currently only true for a negligible subset of all available medical apps – is subject to regulatory measures which ensure a certain level of quality control for such apps. For non-regulated medical apps, there are a number of private companies and initiatives that offer app certification programs. A potential shortcoming of such efforts is that the certification processes are often not disclosed and one can thus not be sure about their quality. This became apparent when Happtique, a company that had aimed to provide such certification, had to cancel their program [8]. Lately, there have also been efforts to implement standard reporting in the form of an app synopsis that can be applied to regulated and non-regulated mobile medical apps alike [9]. This synopsis guides developers and distributors in compiling information about themselves (imprint and extensive information about of all parties involved in the development, potential conflicts of interest), their product and its content (area of application, functionality, risks and limitations, studies that were performed etc.) as well as data protection and privacy. Once the compiled information is made available to users, it can serve to simplify their decision making processes on whether they want to use an app or not.

Level 2 focuses on content. A pre-selection of studies provided by an app should not be classified as a systematic review (SR), but as an alternative tool to find relevant studies in a specific medicinal field of interest. Aspects that are recommended in the context of SRs are therefore applicable for apps as well: Appropriate studies are identified, information is selected and probably extracted and distributed in a summary that is supplemented by a "take home" message. Nevertheless, the compiled information can be highly biased by personal interest (own hypothesis of results) or by the selective availability of information (publication bias). This emphasizes the need for a transparent distribution of information. For conducting SRs, the PRISMA-statement is a well-established guideline for the collection and processing of information [10]. This instrument was adopted in level 2. As the app aims to provide information "to go", additional links to more detailed information can and should be recommended in this context.

Level 3, i.e. the study level (or information source level), addresses aspects on which developers and distributors only have little if any influence: Information provided by a study or other sources should be presented in a clear and structured manner. Especially when only a shortened overview is given, aspects that are necessary

for understanding and assessing the provided information are of utmost importance. This is also an aim of the CONSORT statement [10]. Since there are already a number of guidelines or recommendations that extensively cover this level, we refrained from adding additional points and simply reference them for level 3.

2. Results

Table 1 summarizes items relevant for level 1 (app-level). Some of these seem self-evident, but are still mandatory, e.g. the name of app (A1) and information about the author(s) (A5). Others, e.g. the date(s) of initial release and updates (A2), responsibilities (A6), contact data (A8) and conflict of interest (A9) are also highly important and should be obligatory as well. Additional items of interest are the aim of the app and its limitations (A3). Altogether, this compilation of information is important for two reasons: Firstly, the reader receives important additional information pertaining to the app he is interested in. This can also include references to another search engine, or alternative libraries listing guidelines or systematic reviews or other guidance instruments. The information is also important for applying the guidelines mentioned for level three (see table 3), e.g. CONSORT [10] for single studies or PRISMA [11] for systematic reviews. Item A4 (target group) goes hand in hand with A3: If the aim of an app (and its limitations) are clearly defined, its target audience should be easily inferable and vice versa.

Listing the qualifications (A7) of those who are responsible for the app may also aid individual users in their judgment of the reliability of the information. It may also enable them to rate conflicts of interests and the individual influence of author(s).

Table 1. Guideline for level 1

Item number	What?	Why?
A1:	Name of App	Needed to identify, recommend or reference the app. For transparency reasons, if the app's name was changed, this should also be documented.
A2:	Date	Date of initial release, date(s) of last and previous updates (update cycle shows how well the app is maintained).
A3:	Aim of App/ Limitation	The aim of the app, i.e. is it meant as an alternative to other sources of information, guidance, EbM? Its limitations should also be specified (e.g. access or other limitations, incl. their causes). Useful for rating the relevance for one's own work.
A4:	Target group	Closely connected with A3: E.g., which group of users (MDs, patients?) or which country is targeted? There may be major differences in the needs of different target groups.
A5:	Author(s)	This item provides information about who is responsible for compiling the provided information. For example, an app solely built on an expert's knowledge may vastly differ from one sponsored or provided by the industry.
A6:	Responsibilities	Different persons or entities may be held accountable for different aspects of the app, e.g. contact person(s), author(s), developers (technical implementation), or those providing financing.
A7:	Qualifications	In order not to inadvertently ignore important information, recommending and selecting information should to be done by experts (or a team of experts) that are well qualified in the respective area. In this context, qualification is even more important in level 2 since selecting information or even the

		intention for creating the app may be influenced by an expert's specific area(s) of interest.
A8:	Contact data	Where can users turn with their questions or concerns? This avoids the impression of anonymity and contributes to the app's trustworthiness.
A9:	Conflict of Interest	Potential conflicts of interest that may lead to a bias in the provided content should always be stated.
A10:	Protocol and registration*	Specify whether the app is registered with or has been certified by any entity and if so, where and according to which protocols or regulations, e.g. FDA approval or CE label (in the case of a regulated app) or specific app certification programmes (for non-regulated medical apps).

For level two, aspects relating to the collection and selection of information come into focus. The PRISMA statement covers important points for SRs, and these were adopted here as shown in table 2. However, since some of the points mentioned in the PRISMA statement were already covered in table 1 (or included in the following section, table 3), only points not listed elsewhere are included.

Table 2. Guideline for level 2 (adopted from PRISMA [11])

Item number	What?	Why?
B1:	Title/Rationale/ Objectives	If the app is subdivided into sections, the title and/or subtitles should be specified.
B2:	Searching Process (Eligibility criteria, information sources, study selection)	All characteristics of the sources of information included in the app should be listed. For example, systematic reviews, RCTs or information by specialist organizations.
B3:	Data collection/ extraction process (additional analyses)	An app may use an own style of presenting information. The information collected out of studies (and other sources) should be specified here The data to be extracted should be made clear in advance.
B4:	Assessment of risk of bias in individual studies and across studies	If the authors aim to assess the quality of studies included, than how this was done should be mentioned. If only extraction of data was performed without further assessment, then this should be mentioned.
B5:	Summary and conclusion	This might not apply here as this would be a "real" systematic review and no meta-analysis is performed
B6:	Limitations	Review own work: Might there be additional information not considered? Potential influence of bias?

Level three makes use of already existing checklists and guidelines. Since the development of such checklists is an ongoing process and their applicability depends on the context, the items listed in Table 3 are only of an exemplary nature.

Table 3. Guideline for level 3

What?	Reasoning?
C1: CONSORT C2: CHERRIES C3: STARD C4: STROBE C5: REMARK C6: TREND C7: PRISMA CX: [*to be continued*]	While the information provided here cannot be influenced as such, applicable checklists (depending on the study design) should be used. Additional information should be marked as such. If any information was abbreviated, references and/or links to the full articles or information sources should be listed. Furthermore, if there have been any controversies relating to studies included here, this should also be mentioned.

Discussion

While, taken together, the list of items included in all three levels is quite extensive, and some of the items (such as authors, title of the app, date of publication etc.) seem self-evident and superfluous while other items are more complicated (but can in fact be easily resolved by applying flowcharts and the like), the compiled information may considerably contribute to an app's perceived quality and trustworthiness. Users' sensitivity towards established aspects may also profit.

Nevertheless, the guideline we propose can only be a stepping stone towards further developments of guidelines in this area. Many aspects will only surface once existing guidelines are applied in real word scenarios. The need for guidelines relating to mobile apps in this sector is also furthered by today's demand for quick retrieval of clinical trial information. One key question is how to combine the need fast access to such information with systematic approaches and we believe mobile technology offers just this: target group specific, timely and hassle-free access to relevant content; the proposed guideline can contribute to ensuring appropriate quality of such mobile solutions.

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