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Conciliation and Approval of Quality Principles for the Self-Declaration of the Quality of Health Apps

Urs-Vito ALBRECHT^{a,1}, Evgenii PUSTOZEROV^a and Ute VON JAN^b

^aDepartment of Digital Medicine, Medical Faculty OWL, Bielefeld University, Bielefeld, Germany

^bPeter L Reichertz Institute for Medical Informatics of TU Braunschweig and Hannover Medical School, Hannover, Germany

Abstract. This poster describes the conciliation and approval process of the unified set of criteria for self-declaration of health app quality. The timeline underlines the necessity of transparency and open communication in regulations.

Keywords. Quality principles, quality criteria, health apps

1. Introduction

The unified set of criteria for self-declaration of health app quality we describe here is a set of nine quality principles (practicality, risk adequacy, ethical soundness, legal conformity, content validity, technical adequacy, usability, resource efficiency, and transparency), 18 features and 25 requirements that were developed in close cooperation with ehealth Suisse and approved by its associated committees in 2019 [1]. The goal was to develop a uniform set of criteria for self-declaration of the quality of health apps to make relevant information applications accessible to practitioners and the general public. This poster describes the conciliation and approval processes to illustrate the method and explains the process to the non-German and non-French speaking communities. The synthesis of the nine quality principles is not part of this work.

2. Methods

The quality principles were compiled through a literature search of PubMed, Google Scholar, and IEEExplore and by reviewing study protocols and non-scientific literature, such as international standards on software quality. The development of the quality principles and information of the self-declaration process is described in detail here [1],[2]. Three iterations were part of the coordination process between the mHealth

¹ Corresponding Author: Urs-Vito Albrecht, Department of Digital Medicine, Medical Faculty OWL, Bielefeld University, Universitätsstraße 25, 33615 Bielefeld, Germany; E-mail: urs-vito.albrecht@uni-bielefeld.de.

Core Group (CG), the Advisory Board (AB), and the mHealth Working Group (WG) of ehealth Suisse. The draft criteria catalogue (V.01) was released to eHealth Suisse, which forwarded the documents to the CG. The draft was presented to the CG and subsequently discussed with participants; suggested changes were agreed upon, and additional comments were included; further comments were also considered. The CG was presented with the follow-up version of the criteria document (V.02) for approval. The consented document was sent to the Advisory Board members in advance and discussed at the Advisory Board meeting. Following feedback from the Advisory Board, the updated version of the catalogue (V.03) was presented to the members of the Audit Committee and discussed at its fifth meeting. The revised catalogue of criteria (V.04) was then presented to the working group members for comment. Subsequently, the Steering Committee finalised and recognised the standardised criteria catalogue for self-development, version 1.1. Finally, version 1.2 was prepared for publication and released.

3. Results

A catalogue of nine quality principles, 18 features, and 25 requirements was developed on a scientific basis and agreed upon in multiple interactions across eHealth Suisse committees over a period of 5 months, between 29.01.2019 and 22.06.2019. Compared to other sets of criteria published for reporting app quality aspects, a concise set was developed that provides a flexible basis that is easily adaptable to the highly dynamic market and the particular interests of the stakeholders involved.

4. Discussion and Conclusions

The involvement of interdisciplinary experts at different levels and in an iterative process proved useful and led to a mutually acceptable agreement. With the approval process, an increased acceptance of the community was achieved. In Germany, the quality principles have been recommended by the AWMF [3] and are considered in appropulative assessments, e.g. by professional societies [4].

Lessons learned from the conciliation and approval process are that good preparation of the basis for discussion, good project management, and transparent communication significantly speed up the approval process.

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