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Enhancing the Value of the BfArM's DiGA Directory: Strategies for Improved Usability and Stakeholder Satisfaction

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Abstract. Germany's Digital Healthcare Act allows doctors to prescribe digital health applications (DiGAs) for reimbursement. DiGAs must demonstrate safety, data security, and a "positive impact on care" to be listed in the official directory. Previously, data for permanently listed DiGAs was analyzed. The work presented here evaluates additional data fields for the currently listed DiGAs (both provisionally and permanently included) and aims to assess the completeness, details and consistency of the information. The data for this analysis was scraped from the directory and evaluated to identify potential shortcomings in the information provided.

Keywords. Digital health applications, DiGA, reimbursement, meta-information

1. Introduction

In Germany, the Digital Healthcare Act (DVG) allows doctors to prescribe "Digital Health Applications" (Digiale Gesundheitsanwendungen, DiGA) to patients enrolled in statutory health insurance. DiGAs are low-risk medical tools aiding diagnosis, monitoring, or treatment. Only approved DiGAs from the German DiGA Directory [1], curated by the German Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM), are reimbursable. Manufacturers must prove the safety, data security, and positive care impact for inclusion. Provisional inclusion may be granted for 12 months if evidence is lacking (extendable to 24 months).

In previous work [2], the data on permanently listed DiGAs was analyzed, particularly regarding the scientific evidence provided for obtaining permanent status. In this context, limitations were identified in several scientific studies provided for the corresponding apps, similar to the findings of Kolominsky-Rabas et al. [3]. This time,

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the aim was to obtain a more comprehensive picture of the information available for listed apps, regardless of their status, by evaluating additional data fields in the directory. As the regulatory process dictated much of the structure and type of information presented in the directory, it was of interest to see how well manufacturers provided the relevant information and if there were any inconsistencies in the listed data.

2. Methods

On March 10, 2024, using R (4.3.2, [4]), information for all provisionally or permanently listed apps was scraped from the BfArM's DiGA directory [1]. Data were gathered from each app's introductory and detailed sections. Altogether, 163 additional data fields were thus available. However, fields were not always filled for every app. The collected information was then merged into a table for analysis. The "information for professionals" part was not included in this analysis, as it seemed to be a compilation of a subset of the total data fields.

For the evaluation presented here, the primary focus was on data fields containing structured information. However, some data fields also contained unstructured, i.e., freely worded, information. Where necessary, these were examined manually for relevant aspects. A descriptive analysis of the available data was then performed using R [4]. For space reasons, only a selection of the results is presented below.

3. Results

The acquisition process resulted in data for N=56 DiGAs. Of these, 33 (59%) had achieved permanent status, while 23 (41%) were only provisionally included in the BfArM's directory. The manual examination revealed that the listed apps, regardless of their inclusion status, were more focused on therapeutic purposes (52; 93%), with only 4 (7%) designed for self-management. Regarding positive effects on care, most applications (48; 86%) stated only to provide medical benefits. One app aimed at improving patient-relevant procedural and structural improvements. Seven apps (13%) targeted both effects.

The provided information had a strong emphasis on covering regulatory requirements (i.e., related to data protection and security regulation such as the Medical Device Directive (MDD) / Medical Device Regulation (MDR) [5,6], General Data Protection Regulation (GDPR) [7]) and the fulfilment of further requirements for inclusion in the directory (as evidenced by 11 data fields related to positive care effects and 40 each concerning data protection and data security). There were also additional data fields related to general (6 items) and medical device-related questions (5 items), information on the DiGA and involvement of healthcare professionals (6 items), instructions for use (6 items), and pricing information (7 items). Technical aspects and consumer-facing aspects, e.g., related to interoperability (4 items), robustness of the application (4 items), consumer protection (8 items), user-friendliness and accessibility (3 items), or support for care providers (4 items) were included as well. Information was also related to the quality of the medical content (9 items) and patient safety (6 items).

The answers to the relevant regulatory questions were largely unremarkable. For questions with simple yes or no answers, and if the respective question was applicable to the application due to its functionality, the apps were acknowledged to conform with

the data protection and security requirements. For some data fields, information was lacking in several cases. Examples are statements related to the manufacturer's use of an information security management system (4 cases), whether penetration testing had been conducted (8 cases), or whether the application supports secure digital identities for patients enrolled in statutory health care by January 1, 2024, at the latest (20 cases).

Medical device status was given as class I (following the older MDD [6]) for 24 (43%), class I (MDR) [5]) for 28 (50%) applications, and class IIa (MDR) for a further 4 (7%) applications. However, these were named only in 3 of the 4 class II apps, where involving a notified body in the certification process is necessary. In 10 cases, this information was neither positively nor negatively included. Unsurprisingly, none of the applications indicated that they contained functions intended to be used as a diagnostic tool. This would have led to an assignment to a higher risk class, thus preventing the app from being included in the directory.

Regarding content curation and development, the involvement of medical institutions and organizations in developing the DiGAs was stated in 45 cases (80%). Almost all manufacturers indicated that they had processes in place to keep provided health information current. There was one case where this was denied with "Not applicable; the digital health application does not offer any health information.". For four applications, manufacturers did not confirm that health information contained in the product was up-to-date and reflected the state of the art. In 3 cases (a subset of the previous four apps), the provision of health information adapted to the situation and use case, target group-oriented provision of health information, as well as the availability of references used for the health information contained in the application was denied. The reasoning was the same in all these cases, i.e., no health information being offered in the application.

There were also inconsistencies in the context of the involvement of healthcare professionals in patients' use of the applications. Regarding whether information was provided to the professionals to facilitate explaining the use of the respective application to patients, in 39 cases (70%), an answer of "Not applicable; integration of service providers not required for using the digital health application" was given. In 41 cases (73%), manufacturers also denied providing information to healthcare providers regarding their role and their own (additional) use of the app in the care process. In 44 cases (79%), it was stated that users could not offer access to recorded data to professionals involved in their care, again because service providers were not required to use the app.

As in previous work [2], the manual analysis of statements about the studies for obtaining permanent listing status predominantly showed randomized controlled trials (32/33); only for one app (1/33) was there a higher level of evidence in the form of additional meta-analysis. For the provisionally included apps, the types of studies they employed were not evaluated. None of the related studies were scrutinized for bias, inconsistencies, or other problems at this time. However, answers related to whether the studies conducted for the apps had been published and were referenced in the application itself or on a related web page showed that even for apps with provisional status, a large percentage (21 apps, 91%) had already provided such information. Surprisingly, while permanent inclusion in the directory requires related studies to have been conducted, there were still 7 cases where the data indicated that this was not (yet) the case, with reasons given such as "studies will be published once they have concluded", "a study is currently underway", or "the study will start once provisional inclusion status in the directory is obtained".

4. Discussion

Besides regulatory aspects, the information covers many relevant elements for the stakeholders involved in developing, evaluating, or using digital health applications (e.g., [8–12]). As the BfArM already must collect the relevant information as part of its decision-making processes, providing this information to the informed public is very welcome, given the scarcity of information often lamented for health applications.

Nevertheless, the presented analysis highlights some shortcomings that, if rectified, might improve the usefulness of the provided information. Firstly, there is a high level of complexity, hampering the identification of the desired information by interested parties. The questions covering the >160 data fields frequently appear unnecessarily complicated and sometimes refer to legal paragraphs and regulations (or follow the wording these employ) that are sometimes hard to understand. These questions likely serve as the foundational inquiries for manufacturers during the application process. However, there is potential to refine their presentation to enhance comprehensibility for laypersons or medical professionals, many of whom may encounter challenges with legal terminology. Analogous to a medication package insert, adapting the questions for easier comprehension could benefit all stakeholders involved. This is regardless of whether they are already using the app or are still deciding whether and, if so, which of the apps they want to use for the respective use case.

Secondly, manufacturers sometimes also provide relatively long-winded or unclear answers to questions that could be answered with simple yes/no answers or brief descriptions of individual points. Typical examples of the lack of curation of the provided information are the statements related to the locations where data processing of acquired (health) data takes place (following the GDPR's requirements); in some places, lengthy assurances are given that the processing takes place in Germany (i.e., "Data processing in connection with the use of [...] takes place in Germany" or similar) where a short mention of the respective country might have sufficed. Altogether, 51 applications (91%) only used German or other EU data processing locations. Only in 5 cases was there at least some data processing outside the EU, e.g., in Switzerland, Sweden, Israel, or the USA (e.g., for push notifications). At times, the locations are not clearly specified, leaving it to the reader's interpretation to infer the country from the name of a city. For instance, in one case, the provided information suggests that data might at least partly be processed in French-speaking Switzerland.

Inconsistencies in the results suggest a lack of thorough assessment and plausibility checking by the BfArM. Problems, like referencing associated studies, may stem from inadequate data updates once an app's status changes from provisional to permanent. It is unclear whether manufacturers fail to provide necessary data or if it is provided but not transferred to the website's database. Other discrepancies, like statements about professional involvement being necessary for patients' use of the applications, could result from manufacturer oversight or misunderstandings during the application process.

The absence of data for specific data fields for some apps, e.g., related to using secure digital identities, suggests an ongoing evolution of the directory, with occasional additions of new data fields. Some fields appear to have been introduced after certain apps were submitted for inclusion, without subsequent addition of the corresponding data for these new fields. This is regrettable as such details may also be pertinent to older applications needing updates to adapt to new developments and requirements.

5. Conclusions

Improving the BfArM's DiGA directory is pivotal for stakeholders in digital health. Summarizing information, similar to a package insert for medication, along with providing technical and legal details, would aid both laypeople and medical professionals. This would enhance app discoverability and comparability, fostering competition among manufacturers. Standardizing answer options and addressing inconsistencies would further improve usability. Regular updates, including for permanently listed applications, would enhance accuracy and user-friendliness. Addressing these issues would significantly augment the value of the directory for all stakeholders.

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