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A Method for the Classification of Digital Health Architectures as Medical Devices; a Digital Health Research Perspective

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Abstract. It is typical for many digital health research projects to develop IT architectures that will implement integrated care services that may also deliver interventions. As part of compliance with the requirements of the regulation, the components that are considered as a medical device will need to be classified to a medical device category. This is often seen as task that may increase the business risk and a major barrier of the project, particularly during the earlier stages when not all information is available. The paper offers a method assisting with classification of such architectures in the context of the Medical Devices Rregulation, offering a structured way to identifying how the initial deliverables of a project can be used to provide assurance to the justification of the classification.

Keywords. Digital health, patient safety, Medical Devices Regulation (MDR), SaMD

1. Introduction

Application of state-of-the-art informatics technologies are increasingly being used to create IT infrastructures that support healthcare, often providing interventions. Numerous research projects offer new capabilities, such as, implementing integrated care to provide a patient-centered services [1]. Failures in their operation may cause harm to patients, something that as part of the EU Medical Device Regulation, is considered a medical device. This is a significant risk for projects, as any exploitation will need to have a roadmap to comply with regulation. Projects need to evaluate the classification of their infrastructure or constituents modules, which are a medical device. This is challenging, as the reconfigure-ability of software makes contextual information as well as critical more fluid and often obscure. The paper presents a method that facilitates the classification assessment of such interventions, in the context of explicitly identified hazards, based on an exploratory hazard identification approach.

2. Overview of the Method

Table 1 shows an overview of the steps of the method. Each step provides a description of the purpose, along with typical (minimum) information that will be necessary, and

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guidance, which when complying with, will produce the necessary information. It should be noted that guidance does not guarantee quality of the produced information, albeit it does provide a well-reviewed and widely adopted body of knowledge and good practice likely to increase the quality of the artefacts of a project.

Table 1. Overview of the classification method.

1 | Identify architectural modules, dependencies and intended use.
2 | Describe clinical scenarios and use cases.
3 | Perform exploratory hazard analysis and hazard identification.
4 | Examine criticality and classify the system.

2.1. Identification of intended use and architectural context.

Description of intended purpose is a requirement for medical devices, as it sets the context for which, the evidence gathered during the assurance process will result in a convincing safety justification. A system may be acceptably safe in one context, but not in another. For example, a consumer application mainly offering information about a condition, will most likely not be suitable to be used as a diagnosis tool, unless it has been validated for that specific context. Changes of the context for which a device has been validated, may change the relevance of the assurance justification. Clearly capturing this information is necessary to ensure the long-term validity of a system. This would typically include information that would be found in a clinical study report, such as how it intervenes to a condition (e.g., diagnosis, risk stratification, prediction), users, as well as the population (subsets) for which the intervention is intended. Additionally, the technical scope of the system should be understood. It is important to understand the overall architecture and dependencies amongst components. In many cases, such dependencies will affect safety classification. For example, seemingly innocuous data used by much more critical decision making. Table 2 summarizes the information needed for this step.

Table 2. System context information and intended purpose information and guidance sources.

1 | Identify architectural modules, dependencies and intended purpose.
Information needed: Type of intervention, condition for which it is designed, users, target population, indications, contra-indications use, architectural dependencies, communication interfaces**.**
Sources: Intervention description, study protocol, including sample description and context of use.

2.2. Describe functionality as clinical scenarios and use cases

This step elaborates on the intended use by identifying the high-level requirements of the system. This is necessary, as ultimately, it is the functionality of a system that may contribute to hazardous conditions for patients. Understanding the requirements will allow a) to understand how the functionality of the system will result in the required intervention, b) offer a basis that can be reviewed by all stakeholders, and c) allows technical requirements to be associated and traced to the clinically relevant functionality, thus offering interpretation of effects of potential technical failures. A scenario-based approach can be very useful for this stage, as it offers a good balance between functional detail and comprehensibility by all involved stakeholders. Scenarios, can be associated with personas, offering further context, as well as more explicit participation of stakeholders, and elicitation of elusive tacit knowledge. For example: "*As a Health Professional, I want the support of Clinical Decision Support Modules for identification of diagnosis based on recent lab results based on clinical guidelines*". Additionally, more

detailed functional description can be described in the form of structured use cases. These offer significantly more information including a breakdown of activities, as well as guarantees that may need to be met such as pre-conditions, post-conditions, as well as identification of exceptions.

Table 3. Clinical scenarios and use cases information, and guidance sources.

2 | Describe clinical scenarios and use cases.
Information needed: High level functionality in easy-to-read format, stakeholders and users associated with the functionality, sub-systems and components contributing to functionality. **Sources:** Intervention description, pathway description, requirements documents, sub-system/component specification documents.

2.3. Perform exploratory hazard analysis and hazard identification.

The task analyses the identified functionality for potential hazards. It allows us to establish a first causal link between the operation of the system, and how it can contribute to hazards. It is the management of (the risk associated with) these identified hazards are that is the reason why we need safety assurance. The criticality of a device, and hence its classification, depends on how a system is used in the health and care of a patient. Guidance offers a number of examples regarding the use of a system, based on which classification decisions can be made. These tend to represent common expected hazards that are considered of certain criticality. However, although the guidance needs to followed, a prescriptive approach to hazardous conditions may not be relevant for all cases, and does not contribute to identification of controls. Ultimately, completeness of this assessment relies on systematic and exhaustive identification and assessment of all potential hazards, in the specific context of (the functionality of a system). Identification of the causal chain allows to substantiate the contribution of software to hazards and can complement the guidance's more prescriptive approach (step 4).

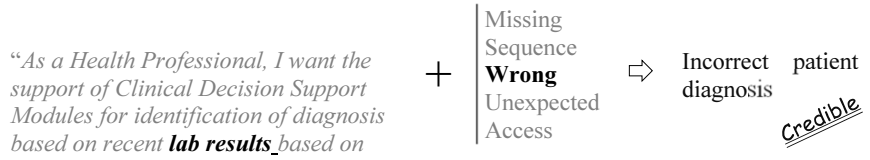

Figure 1. Example of exploratory (HAZOP-based) scenario hazard identification. The information *lab results* is selected out of a number of system elements (in this case the scenario provides mostly data elements such as, *identification of diagnosis*, *clinical guidelines, lab results*) and paired with *wrong* from a set of prompts indicating potential failures, to identify what was evaluated as credible hazard.

Figure 1 shows an example of a methods used to explore a system for hazard, and their effect on the users and the operation of a system. Such approaches have been used successfully in other industries are not uncommon in the healthcare domain, usually described as Failure Modes and Effects Analysis (FMEA), or Hazard and Operability Studies (HAZOPS). Table 4 summarizes the information needed in this step. It should be noted that this should be a multi-stakeholder exercise, allowing users to voice known concerns, their experience, and potentially challenge operational assumptions. Establishing an analysis that highly matches real practice, will improve the relevance of all hazard related decisions.

Table 4. Exploratory hazard identification information and guidance sources.

3 | Perform exploratory hazard analysis and hazard identification
Information needed: Functional description, clinical scenarios, use cases, exploratory hazard identification methods, user (past) experience and testimony. **Sources:** Requirements documents, safety management system and plan, Hazard workshops.

2.4. Examine state of patient healthcare and clinical significance of the system.

In general, the criticality of system is described by the risk associated with its hazards, consisting of a likelihood (e.g., probability) and severity (e.g., injuries). In healthcare the criticality assessment tends to focus on severity in terms of the condition of the patient using it, and the contribution it has in the intervention used, something that is reflected by guidance approaches such as MDCG 2019-11 and ISO 14971. MDCG 2019-11 annex III maps medical device classification (as described in the MDR) to the risk framework suggested by the IMDRF Software as a Medical Device guidance. A risk acceptability table assigns classification according to the state of a patient's healthcare (e.g., critical care, non-serious care), and the significance of the system to the intervention (e.g., direct treatment, driving clinical management).

Table 5. Classification assessment information and guidance sources.

4 | Examine criticality and classify the system.
Information needed: Hazard list (log), intended use, clinical scenarios/use cases. **Sources:** Requirements documents, safety management system and plan.

3. Conclusions

Classification of an architecture (or its components) as a medical device, needs to be supported by justification. Contextual information is important as it contributes to the relevance of the justification and will offer the operational assumptions for the system. Furthermore, identification of hazards and the mode in which the system may, through the designed intervention, harm the patient, will provide the basis for its classification. A number of expected sources have been identified to contain the necessary information, along with guidance that describes the methods, applicable to each step.

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