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Patient Safety Informatics: Criteria Development for Assessing the Maturity of Digital Patient Safety in Hospitals

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Abstract. With the start of the 21st century, patient safety as a topic of special interest has attracted increasing attention in both academia and clinical practice. As technology has continued to develop since then, questions and focal points surrounding the topic have also shifted. In particular, questions regarding the impact of digitalization on patient safety and its measurement are now of high interest. This work aims to develop a maturity assessment instrument in the form of a criteria set for measuring structural requirements for digital patient safety in hospitals. Based on the results of a literature review and a derivation of maturity objects (MO) from known maturity models, 64 criteria across 11 categories were developed. Written comments of two digital patient safety experts as well as subsequent interviews were used to evaluate and refine the criteria catalog. The resulting catalog offers hospitals guidance for detecting possible areas of structural improvements in their information systems with regard to patient safety and represents a unique instrument for assessing digital maturity in this particular area.

Keywords. Patient Safety, Hospital Information Systems, Digital Maturity Models

1. Introduction

"To Err is Human", published by Kohn and colleagues in 2000, marked the beginning of renewed focus by healthcare providers and researchers to find ways of ensuring and improving patient safety [1, 2]. The report highlighted serious problems related to a high level of medical errors and pointed to potential solutions, including calls for better information systems. However, two decades later, low patient safety continues to be a pressing concern, and many developments in this domain have happened unexpectedly slowly [3]. At the same time, healthcare providers have continued to digitize their care delivery processes and information systems [4]. While digitalization is generally expected to have positive effects on both costs and quality of care [5], it can also induce various unintended consequences [6]. It may solve old familiar problems in terms of medication errors by introducing clinical decision support that intervenes at the point of care, but also has the potential to create new ones [6, 7]. Unintended consequences such as alert fatigue or adverse effects such as misidentifications of patients can arise when

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the requirements for health IT (HIT) systems are ill-defined, or as clinicians take time to adapt to new workflows and processes.

It is therefore of utmost importance for policy makers and hospitals to not just blindly push for higher degrees of digitalization for its own sake but instead work against a set of goal-orientated criteria that increase the likelihood of reducing medical errors. Despite the unequivocal importance and potential of ensuring patient safety by means of well-designed HIT systems, no standardized measures exist that gauge their maturity regarding their patient safety performance in particular. Existing maturity models such as the Electronic Medical Record Adoption Model (EMRAM) tend to focus on the availability of various, rather generic IT functions (such as nursing documentation) as well as the order in which they are implemented. These models are criticized, among other things, for invoking misguided incentives by enforcing a predetermined path to digitalization [8].

To provide comprehensible guidance as to how patient safety can be ensured when digitalizing hospital care processes, this research aims to develop a set of criteria that can point health care organizations such as hospitals, policymakers and vendors towards creating a safer environment for patients.

2. Methods

A three-stage development process comprising the following steps was carried out: First, we conducted a literature search in the databases Pubmed Medline, Wise, CINAHL, Scinos, and Google Scholar. The search sought to identify publications that were related to patient safety in the form of a condition, trigger, adverse event, or outcome. The combination of the two search terms "patient safety" AND "hospital" was linked with each of the following terms "digit*", "high risk company", "risk management", "management of adverse events", "adverse event", "error", "maturity model", "German Hospital Future Act[2](KHZG)[3]". The search was performed between March and August of 2021 and was limited to English and German publications from 2010 to 2021.

In the second step, five maturity models (CHECK-IT [9], EMRAM [10], WCS [11], KIT-CON [12], and MOST WIRED [13]) as well as the KHZG's eligibility criteria were reviewed for maturity objects (MOs). They are criteria for assessing digital maturity (e.g. "vital signs monitoring of emergency patients using medical devices") [12]. MOs that were unrelated to patient safety were removed. Based on the topical structure of the German Hospital Future Act, a categorial system, consisting of categories like “digital medication management” or “digital documentation” was developed, and the identified MOs were then assigned to these categories. This procedure was repeated for patient safety items (PSI), like “time pressure/ high workload” or “incomplete communication”, that were extracted from the literature review. The PSI and MOs were logically assigned to each other. If MOs could not be assigned to a PSI and vice versa, they were excluded from further use. For example, the PSI “informal standards” could not be reasonably matched to a corresponding MO and was therefore excluded. The criteria were then formed from the remaining MOs and adapted in wording according to [14, 15].

At last, two experts (physicians with a background in patient safety work and health informatics) were asked to comment on the criteria for validation purposes. The

[2] Act for funding the digitization process in German hospitals with a total volume of 4.3 billion Euros

[3] In the actual search, the German word “Krankenhauszukunftsgesetz” (KHZG) was used.

comments were then discussed in individual digital interviews (average duration 20 minutes). The criteria were subsequently updated by the authors (JOK, AJH, ME) and adjusted where necessary.

3. Results

The literature search yielded a total of 85 relevant articles that contained information about factors for HIT, patient safety or a combination of both. 43 patient safety items (PSI) could be derived from the literature. From the maturity models, 2350 maturity objects (MO) were extracted, which were reduced to 78 unique MOs related to patient safety over three iterations. Twelve categories were initially derived from the KHZG. After assigning the MOs and PSI to the categories and examining overlaps, 65 criteria (divided between eleven categories) remained which were used for the development of the criteria catalog. Following the interviews, the combination of three criteria was found to be necessary as well as the inclusion of a new one, resulting in the final catalog (Tab.1) that comprises a total of 64 criteria in eleven categories.

Table 1. Exemplary excerpt from the criteria catalog for assessing digital patient safety maturity in hospitals. The full catalog can be found here: https://1drv.ms/b/s!ApxR0mqhcuA1jf47WtS4xJOEcCfiVQ?e=YrYESo

Category	Criteria
Digital documentation	Digital documentation is standardized throughout the organization in terms of nomenclature, coding and form.
	All digital inputs are legible, clear and unambiguous for the user.
Digital file	All patient data of the current treatment as well as data of previous and external treatments (if provided by the patients), are available in the digital patient file.
	In the event of a system failure, it is ensured that health professionals continue to have full access to important patient data (allergies, problems, diagnoses, medication, lab results, progress logs, vital signs) at the point of care.
Digital medication management	The entire medication management process is carried out digitally in the form of closed-loop medication management (ordering, documentation, testing, positioning, administration, etc.).
	Systemic testing for medication errors, over/under doses, drug allergies, contraindications, drug-food interactions is possible and can generate alerts.
Digital treatment management	Pathologically deviating vital signs generate automatic alerts.
	The execution of complex and standardized activities for the treatment of patients (e.g. operations, hygiene measures, mobilization, etc.) is checked by medical professionals for complete and correct execution using digital checklists.
Digital discharge management	All information items provided to patients at the time of discharge is legible, unambiguous, correct, complete, and available to them in standardized digital and machine-readable form for all common platforms, as well as in paper form if required.
	A digital based assessment of discharge risk is performed, and alerts are issued in the event of increased risk potential for the patient.
Digital decision support system/ risk assessment system	The digital treatment and documentation software identifies potential risks based on the complete patient data (falls, pressure ulcers, multi resistant pathogens, nosocomial infections, malnutrition, pain, incontinence, injuries, death, etc.) and generates alerts to make health professionals aware of them.
	An automatic review of all prescriptions of clinical relevance is performed and recommendations regarding potential alternatives are issued. This is also done when patients are admitted with their existing orders (such as home medication).
Digital service request	Service requests are made digitally only and generate notifications for the service provider.

	Automatic warning messages are generated as soon as a service request is created twice, which are only requested once for comparable treatment processes (e.g. dialysis once a day vs. twice a day).
Robotics, hardware and software	The preparation of individual doses (medication) is robot/dispensing-machine controlled.
	Medical equipment used on patients without continuous supervision by health professionals (e.g. monitoring equipment) is connected and continuously as well as automatically checked for error messages or serious deviations.
Digital incident and error management	For patterns involving nears-miss events a continuous clinic-wide background check is performed, which is compared with near-miss events, errors and incidents of harm in order to issue appropriate warnings about possible correlations of causal chains.
	Employees have the opportunity to immediately report errors and undesired events digitally and anonymously.
Digital patient observation	Digital observation of patients can be performed remotely outside the point of care (e.g., by an on-call physician).
	Locating patients with a tendency to wander in or out (e.g., in the case of dementia) is digitally possible in certain areas (e.g., geriatrics).
Digital information transfer	The transmission of patient data between the actors involved in the treatment (external) takes place exclusively digitally.
	A uniform patient identification number is used in cross-sector and cross-organizational communication.

4. Discussion

Patient safety continues to be one of the key issues for providing high quality patient care. While digitalization can be used to reduce barriers for achieving maximum patient safety, it can also create hurdles if used inappropriately and missing adequate control. This study provides a categorial system and related criteria that is based on the international literature, existing maturity models and expert discussions. It provides a framework to evaluate the maturity of health IT systems regarding their compliance with structural patient safety requirements.

While previous studies on patient safety primarily focused on medication, this study includes the patient journey within a hospital covering any type to treatment, patient monitoring and transfer and discharge management. It also refers to accountability of patient safety measures in terms of documentation, incident management and (electronic) availability of information. In summary, it provides more details than other approaches and abandons the rationale of mere rank order of IT systems availability such as EMRAM.

However, some limitations have to be considered. Although, this study is based on 5 maturity models, it is recommended to include further models in future research. Also, the use of a systematic literature review could generate further results regarding patient safety items.

Nevertheless, this research is the first to provide a comprehensive set of practical requirements that must be placed on HIT systems to meet the promise of improved patient safety specifically. It could be used as an easily accessible list of items that hospitals can use to review their internal digital processes and structures to identify potential patient safety threats in advance. Additionally, it could be used as a basis for designing maturity assessment for policymakers on a national and international level. Being the first of its kind, the criteria catalog has yet to be tested and evaluated in practice. Future research could focus on validation and evaluation as well as the definition of an appropriate scoring scheme.

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