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Health professionals' routine practice documentation and its associated factors in a resource-limited setting: a cross-sectional study

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ABSTRACT

Objectives Documenting routine practice is significant for better diagnosis, treatment, continuity of care and medicolegal issues. However, health professionals' routine practice documentation is poorly practised. Therefore, this study aimed to assess health professionals' routine practice documentation and associated factors in a resource-limited setting.

Methods An institution-based cross-sectional study design was used from 24 March up to 19 April 2022. Stratified random sampling and a pretested self-administered questionnaire were used among 423 samples. Epi Info V.7.1 and STATA V.15 software were used for data entry and analysis, respectively. Descriptive statistics and a logistic regression model were employed to describe the study subjects and to measure the strength of association between dependent and independent variables, respectively. A variable with a p value of <0.2 in bivariate logistic regression was considered for multivariable logistic regression. In multivariable logistic regression, ORs with 95% CIs and a p value of <0.05 were considered to determine the strength of association between dependent and independent variables.

Results Health professionals' documentation practice was 51.1% (95% CI: 48.64 to 53.1). Lack of motivation (adjusted OR (AOR): 0.41, 95% CI: 0.22 to 0.76), good knowledge (AOR: 1.35, 95% CI: 0.72 to 2.97), taking training (AOR: 4.18, 95% CI: 2.99 to 8.28), using electronic systems (AOR: 2.19, 95% CI: 1.36 to 3.28), availability of standard documentation tools (AOR: 2.45, 95% CI: 1.35 to 4.43) were statistically associated factors.

Conclusions Health professionals' documentation practice is good. Lack of motivation, good knowledge, taking training, using electronic systems and the availability of documentation tools were significant factors. Stakeholders should provide additional training, and encourage professionals to use an electronic system for documentation practices.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Although routine practice documentation is a legal obligation and crucial for the continuity of patient care, health professionals' documentation practices are poor, contain errors that further affect patient outcomes and create distorted health information.

WHAT THIS STUDY ADDS

⇒ This study assesses routine practice documentation in resource-limited setting including all types of health professionals, and identify associated factors.
⇒ Additionally, whether health professionals' documentation of education and counselling they give to patients and use an electronic system was assessed.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ This study is crucial for health policy formulators, planners and implementers to enhance health professionals' motivation for better documentation practice.
⇒ This study may motivate health professionals to use an electronic system for documentation practice as much as possible.
⇒ The evidence would serve as input for future similar studies.

INTRODUCTION

In routine healthcare practice, evidence about the care and treatment of patients, progress notes, assessments and care plans,[1] laboratory tests and results, medication and drug prescription information, patient education and counselling[2] are some of the routine practices of health professionals. Therefore, documenting the health professionals' routine practices are important for various purposes.

Documentation is a standard way of keeping ongoing patient care information. It is the relevant facts of routine health information and patient care plans,[3] such as professionals' evaluation and judgement about the

patients, evaluation charts, tests, reports, subjective notes or professionals' reflections.[4]

Documenting routine practices is essential for the continuity of patient care, legal defence, reimbursement, communication among healthcare professionals and better patient diagnoses and treatments.[5] Maintaining routine practice is part of the health professional obligation. Healthcare facilities' by-laws or policies should require health professionals to complete patient records.[6] Whether the documentation is a paper-based or electronic system, it should be patient-focused, accurate, relevant, clear, permanent, confidential and timely. Electronic patient record systems are better for reducing the time spent on documenting patient information and enhancing the quality of documentation.[7]

Poor documentation practice affects patient management, continuity of patient care and medicolegal issues, which arise from incomplete and inadequate documentation, lack of accuracy and poor quality.[8] It leads to adverse patient outcomes, medication errors and patient deaths.[9] Distorted health information may influence health professionals' decision-making capabilities due to inappropriate and misleading documentation practices.[10]

Globally, poor communication between health professionals is a reason for medical error and patient mortality.[9] Many health professionals' documentation practice is incomplete, inaccurate and of poor quality. According to evidence from the USA, documentation errors are a cause of at least one death and 1.3 million injuries annually.[11] Moreover, health professionals' documentation practice is inadequate such as 33.3% in Indonesia,[12] 47% in England[13] and 50% in Iran.[14]

In the low-income and middle-income regions, a qualitative study undertaken in Uganda stated that documentation practice is limited by constraints and poor support from the administration.[15] In Ghana, 46% of care is provided, and progress notes are not documented after the first day of patient admission.[16] In Nigeria, only 44% of health professionals had good documentation knowledge and practice.[17]

In Ethiopia, documentation is poorly practised and has been reported as being left undone.[3] Health professionals' documentation practice is 47.8% in the Tigray[18] and 37.4%[3] in Amhara regions. Surprisingly, 88% of the medication provided has been wrongly documented.[19] A study report in the Amhara region states that 87% of the medications had documentation errors.[19]

Age, sex, experience, income, levels of education, health professionals' knowledge and attitude,[3 12 18] motivation, workload and training about documentation[20] are factors associated with routine practice documentation.

Documenting health professionals' routine activities is valuable for sharing knowledge and learning from history. This has a significant impact on better decision-making and accuracy in patient diagnosis and treatment. As per our literature review, studies have not been undertaken in the current study setting. Few studies in similar settings have been carried out with only nursing as a study participants, education and counselling given to the patient were not assessed. So, assessment documentation practice in both medical and non-medical practices, including all health professionals is crucial. Therefore, this study aimed to determine health professionals' routine practice documentation and associated factors.

METHODS

Study design and period

An institutional-based cross-sectional study design was employed among health professionals working in public health facilities in the Ilu Aba bora Zone, from 24 March up to 19 April 2022.

Study setting

Ilu Aba Bora Zone is found in Southwest Ethiopia. The zone is located 600 km away from Addis Ababa, the capital city of Ethiopia. In the zone, there are 44 total health facilities and 2 hospitals (1 general hospital and 1 referral hospital). The public health facilities provide different health services for more than a million of the population in southwest parts of the country coming from Gambela, Southern Nation Nationality and People's region.

Study population and eligibility criteria

All healthcare professionals working in the public health facilities of Ilu Aba Bora Zone and those who were found during the data collection period were the sources and study population, respectively. Healthcare professionals who were not permanently employed, those who were not present during the study period and who worked as data clerks were excluded.

Sampling size determination

A sample size (n) was determined by using a single population proportion formula, $N=(Z_{a/2})^2\times P(1-P)/d^2$, where n=the required sample size, $(Za_{/2})^2$=the value of standard normal distribution or 1.96, p=the prevalence of documentation practice among health professionals and so the default maximum value of 50% was used for P, d=degree of precision or 0.05. Taking this, the required sample size was calculated to be 384. After adding a 10% non-response rate, a total of 423 healthcare professionals participated in this study.

Sampling producer

A stratified simple random sampling method was used. Due to the limited resources, we have to cover all types of health facilities, we have included two hospitals directly and three randomly selected health centres. Once the sample was stratified based on the types of randomly selected health facilities, the sample was allocated to each stratum proportionally. Then, a simple random sampling technique was used to select the study subjects in each public health facility. The list of health professionals was taken from human resource departments. Accordingly, there are 1043 health professionals from 5 randomly

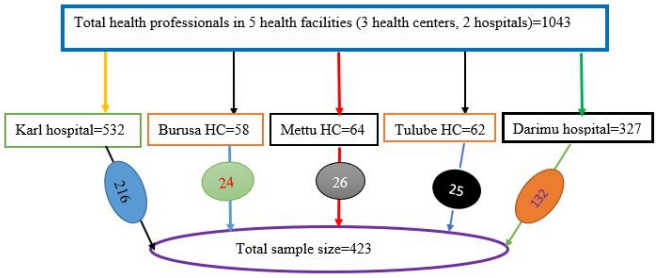

Figure 1 Sampling procedures of study participant selection. HC, health centres.

selected health facilities. The sampling procedure has been presented in figure 1.

Operationalisations and measurements

In the healthcare system, patient status, medical diagnoses, planned care, medical interventions or treatments, laboratory tests, result confirmations, medications, patient education and counselling, communication and delivering service are activities of health professionals. All the mentioned activities of health professionals are either medical or non-medical activities (patient education and counselling), but all are routine activities for health professionals. As a result, health professionals use standard documentation tools such as manual records and/or electronic systems to document their routine activities correctly and on time while respecting the rules of ethics.[21] Accordingly, health professionals' routine practice documentation was assessed by using 12 'yes' and 'no' questions.[3 22] The level of health professionals' routine practice documentation was determined using the mean value as a cut-off point. Hence, the level of health professionals' routine practice documentation is good if the score is above or equal to the mean value, and otherwise poor documentation practice.

Knowledge

The study participants' level of knowledge was measured by using 10 'yes' and 'no' options. Health professionals who scored above or equal to the mean score were considered to have good knowledge, and those who scored below the mean value had poor knowledge.[3]

Attitude

The study participants' level of attitude was measured by using nine Likert scale questions with responses ranging from 1 'strongly agree' to 5 'strongly disagree'.[3 18] Health professionals who scored above or equal to the mean score were considered to have a good attitude, otherwise, poor attitude.

Data collection tool and quality assurance

The tool used was developed based on reviewing similar studies.[3 18 22] A pretested, self-administered questionnaire was used. Two supervisors and three data collectors received 2 days of intensive training on the study objectives and how to approach study participants. A pretest was done outside the study area with 10% of the study subjects to check the readability and consistency of the questionnaire. The data obtained from the pretest were used to check the validity and reliability of the tool. The Cronbach's alpha was used to check the reliability of the tool with a value of 83.

Data processing and analysis

The data entry was performed using Epi Info V.7.1 software packages and analysed using STATA V.15 software. Descriptive statistics were computed to describe the sociodemographic characteristics of the healthcare professionals, their knowledge and their attitudes towards routine practice documentation. Bivariable and multivariable binary logistic regression analyses were conducted to measure the association between the dependent and independent variables. In the bivariable regression

Table 1 Sociodemographic characteristics of health professionals

Sociodemographic characteristics	Frequency	Per cent
Sex		
Female	199	48.0
Male	216	52.0
Educational status		
Degree and below	277	66.7
Master and above	138	33.3
Age (in years)		
21–25	65	15.7
26–30	244	58.8
31–35	59	14.2
>35	47	11.3
Month salary (Ethiopian Birr)		
Up to 4500	93	22.4
Between 4500 and 7500	235	56.6
>7500	87	21.0
Experience (in years)		
1–5 years	259	62.4
Between 6 and 10 years	88	21.2
>10 years	68	16.4
Training for standard documentation tools		
Yes	134	32.3
No	281	67.7
Availability of standard documentation tools		
Yes	333	80.2
No	82	19.8
Types of documentation tools used		
Electronic system	190	45.78
Manual form	225	54.22

analysis, variables with a p value of <0.2 were considered for further multivariable logistic regression analysis. The OR with a 95% CI level was assumed to assess the strength of the association between dependent and predictor variables. For all significantly associated variables, a p value <0.05 was used as a cut-off point. A variance inflation factor was performed. Consequently, its value for all predictors was between one and three. This revealed that there was no correlation between the variables. The Hosmer-Lemeshow test was performed to assess the model fitness, and so model was fitted (p=0.271).

RESULT

Description of study subjects

From 423 participants, 415 responded to a questionnaire with a 98.11% response rate. The mean age of the study subjects was 29.28 (SD±2.21) years with a minimum age of 21 years and a maximum age of 59 years. Half (51.1%) of the study subjects were male. The majority (66.7%) of study subjects were BSc degree holders or below. Of the total respondents, around 6–10 (62.4%) of the study participants had up to 5 years of working experience.

Less than half (32.3%) of the study subjects were trained in routine practice documentation. Of 415 study participants, 235 (56.6%) health professionals earned 4500–7500 Ethiopian Birr per month, and 8–10 (80.2%) health professionals responded that standard documentation tools were available in the working area. One hundred twenty-five (54.22%) health professionals used manual forms for documentation purposes (table 1).

Health professionals' routine practice documentation

Overall, 51.1% (95% CI: 46.29% to 53.55%) of health professionals had good routine practice documentation; 6.99% of different laboratory test request forms were not completed and documented; 6.025% of the physicians' prediagnosis was completed and documented; 5.54% of drug prescription and laboratory result forms were not completed and documented. Documentation incompleteness accounted for 32.52% of health professionals' poor routine practice documentation (table 2).

Factors associated with routine practice documentation

Bivariate and multivariate logistic regressions were used to measure the association between dependent and independent predictors. In the bivariate logistic regression, p<0.2 was used and sex, age, training, knowledge, attitude, types of documentation tools, availability of standard documentation tools, workload and motivation of study subjects were the candidate variables for the multivariable regression analysis. In the multivariable regression model, knowledge, training, motivation, types and availability of the standard documentation tools were significant factors for routine practice documentation (table 3).

Health professionals who lack motivation were 59% (adjusted OR (AOR): 0.41, 95% CI: 0.22 to 0.76) less likely to document routine practices. Health professionals who had good knowledge of routine practice documentation were 1.4 (AOR: 1.35, 95% CI: 0.72 to 2.97) times more likely to document routine practice than those who had poor knowledge. Health professionals who were trained in routine practice documentation were 4.2 (AOR: 4.18, 95% CI: 2.99 to 8.28) times more likely to document routine practices than those who were not trained. Health professionals who used electronic systems for routine practice documentation were 2.2 (AOR: 2.19, 95% CI: 1.36 to 3.28) times more likely to document their routine practices than those who used manual forms for documentation. The availability of standard documentation tools were 2.5 (AOR: 2.45, 95% CI: 1.35 to 4.43)

Table 2 Checklists examine health professionals' routine practice documentation adopted from the Ethiopian health institution reform implementation guidelines

Sn	Content of items for routine practice documentation	Yes (%)	No (%)
1	Patients' admission assessment is documented or attached for the patient admitted	17 (4.10)	13 (3.13)
2	Physicians' prediagnosis is completed and documented	14 (3.37)	25 (6.02)
3	Different laboratory test request forms completed and documented	19 (4.58)	29 (6.99)
3	The nursing care plan is completed and attached to the patient's card	28 (6.75)	15 (3.61)
4	Laboratory request accepted and attached to patient card	21 (5.06)	14 (3.37)
5	Laboratory results from filling out (completed) and documented	15 (3.61)	23 (5.54)
6	Laboratory results attached to patient cards	12 (2.90)	11 (2.65)
7	Final diagnosis and treatment results documented	10 (2.41)	24 (5.78)
9	Drug prescription forms completed and documented	20 (4.82)	23 (5.54)
10	Maternal and child health service forms completed and documented	22 (5.30)	12 (2.89)
11	Follow-up form (form for chronic patients) completed and documented	18 (4.34)	8 (1.93)
12	Progress report documented including education and counselling given to the patients	16 (3.86)	6 (1.45)
	Overall health professionals' routine practice documentation	212 (51.1)	203 (48.9)

Table 3 Bivariate and multivariate analysis of factors associated with health professionals' routine practice documentation (n=415)

Variables	Routine practice documentation				OR (95% CI)	
	Poor practice		Good practice		COR (95% CI)	AOR (95% CI)
	n	%	n	%		
Sex						
Male	107	25.80	103	24.80	0.95 (0.65 to 1.40)*	0.93 (0.60 to 1.44)
Female	96	23.10	109	26.30	1	1
Knowledge						
Good	123	29.64	148	35.66	1.50 (1.00 to 2.26)*	1.35 (0.72 to 2.97)†
Poor	80	19.28	64	15.42	1	1
Age (in years)						
26–30	120	28.92	124	29.88	0.83 (0.48 to 1.44)*	1.10 (0.58 to 2.08)
31–35	23	5.54	36	8.67	1.26 (0.62 to 2.58)	1.20 (0.52 to 2.77)
>35	31	7.47	16	3.86	0.42 (0.19 to 0.90)	0.51 (0.21 to 1.34)
21–25	29	6.99	36	8.67	1	1
Motivation						
No	171	41.21	163	39.28	0.62 (0.38 to 1.02)*	0.41 (0.22 to 0.76)†
Yes	32	7.71	49	11.80	1	1
Attitude						
Good	165	39.76	182	43.86	1.40 (0.83 to 2.36)*	1.09 (0.71 to 2.04)
Poor	38	9.15	30	7.23	1	1
Training on documentation						
Yes	32	7.71	102	24.57	4.96 (3.12 to 7.88)*	4.18 (2.99 to 8.28)†
No	171	41.21	110	26.51	1	1
Availability of documentation sheet						
Yes	147	35.42	186	44.82	2.73 (1.63 to 4.55)*	2.45 (1.35 to 4.43)†
No	56	13.50	26	6.26	1	1
Types of tool used for documentation						
Electronic system	119	28.67	80	19.28	2.34 (1.58 to 3.47)*	2.19 (1.36 to 3.28)†
Manual form	84	20.24	132	31.81	1	1
Workload						
Yes	130	31.33	151	36.39	0.67 (0.33 to 1.36)*	0.48 (0.21 to 1.10)
No	64	15.42	70	16.86	1	1

Reference category=1.
*Significant in COR.
†Significant in AOR.
AOR, adjusted OR; COR, crude OR.

times more odds for health professionals to document their routine practices (table 3).

DISCUSSION

This study assesses health professionals' routine practice documentation and associated factors. Health professionals who had good knowledge about routine practice documentation, training on documentation, using electronic systems for documentation, the availability of standard documentation tools and a lack of motivation towards routine practice documentation were statistically significant factors associated with health professionals' routine practice documentation.

The study revealed that health professionals' routine practice documentation was good (51.1%). This finding is higher than previous similar studies, which found 44.2% in Nigeria,[17] 33.3% in Indonesia[12] and 37.4%–48.8% in different parts of Ethiopia.[3 18 23] However, the finding is lower than the study done in Jamaica, which reports that health professionals' documentation practice is 98%.[24]

This might be due to the utilisation of technologies such as the electronic medical record and district health information system V.2 (DHIS2), the accessibility of required tools for documentation and health professionals' good commitment to using DHIS2 data.[19] Additionally, this variation might be due to the information difference, the time gap between studies, the high patient flow, the shortage of time and the workload of health professionals.

Health professionals who lack motivation were 59% less likely to have documentation practices when compared with those who had gained motivation. This finding is inconsistence with studies done in Ethiopia.[23 25] This might be poor professional encouragement, poor financial support, less opportunities for further educational development, poor infrastructures and low hospital management support.[25]

Health professionals for whom standard documentation tools were available were 2.5 times more likely to document routine practices than those for whom standard documentation tools were not available. This finding is consistence with a study done in Australia,[26] Tigray[18] and Amhara regions.[23] This might be due to familiarisation with standard documentation sheets, and the accessibility of integrated routine health information forms for recording and reporting.[27]

Health professionals who had good knowledge of routine practice documentation were more likely to document their routine practice. This result is supported by studies done in Ethiopia,[3] the USA[28] and Australia.[29] This might be due to health professionals' familiarity with documentation guidelines and manual forms that improve health professionals' knowledge of routine practice documentation.[3] Additionally, the reason might be that health professionals understand the importance of documenting routine practice, the viability of reading materials, know that record-keeping is required for medicolegal issues and have good competency in the area of documentation.[29] Moreover, spending on documentation courses may promote health professionals' knowledge.[30]

Health professionals who were trained in routine practice documentation were 4.2 times more likely to document routine practices than those who were not trained. This evidence is supported by studies done in Ethiopia[3] and Iran.[30] This might be due to training, which might enhance health professionals' knowledge and motivation for documentation and provide team-based learning, intrapersonal skills sharing and consultation gained from colleagues. Plus, training may force health professionals to develop a positive attitude towards routine practice documentation.[3]

Health professionals who used electronic systems for routine practice documentation were 2.2 times more likely to document their routine practices than those who used manual forms. This study is supported by a study done in Ethiopia[20] and a study done about maintaining practices and record-keeping.[1] This might be due to the capability of electronic systems to reduce the time spent documenting patient care.[7] Additionally, record-keeping in the light of recent public inquiries, national interests in shifting from paper to digital storage of data, the capability of electronic health records to generate a complete record of an episode of care and the longitudinal nature of the electronic system might be possible reasons.[1] Moreover, a need for real-time access to health information when and where it is needed might be reason why an electronic system could be more likely to be good for documentation.[23]

STRENGTH AND LIMITATION

Since the data were collected at a specific time, social desirability bias may occur. Significant variables may have a temporal relationship. This study assesses the use of electronic systems for documentation as an independent variable. All health professionals were included, and documentation regarding education and counselling was assessed. Hence, the finding is unique as compared with previous studies. Moreover, the mean value was used as a cut-off point to determine level of health professionals' routine practice documentation to consider the weighted average values.

CONCLUSIONS

In this study, health professionals have good routine practice documentation. Knowledge, training, using an electronic system, availability of standard documentation tools and lack of motivation are statistically significant factors for routine practice documentation. Health policy formulators and stakeholders give additional training to health professionals, and encourage them to use an electronic system for documentation. Stakeholders should improve health professionals' knowledge and motivation of routine practice documentation. Additional high-quality studies are required on a similar topic.

Contributors AWD had made a substantial contribution in writing the conception, designing the study, analyzing the data, and discussing the findings. SYK and ATD were involved in drafting the manuscript and interpreting the results. AAC and HSN had revised the manuscript. MKH, AAS, ADW, and MDE all made significant contributions to revising the manuscript, and managing the data. All authors read and approved the final manuscript submission for publication.

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Patient consent for publication Not applicable.

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Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement All the data generated and analysed during this study are included, in the table and text form, in this article. If required, the data will be available on request from the corresponding author. Not applicable.

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Telemedicine in emergency responses: reflections from a critical care telemedicine programme between Uzbekistani and German clinicians during COVID-19

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Telemedicine emerged as a tool to support prevention, diagnosis, treatment and management of infectious diseases in remote and low-income settings with underserved populations[1] while the pandemic of COVID-19 has accelerated its adoption.[2] Different telemedical models exist in the context of acute care. One peer-to-peer approach involving an interdisciplinary team of healthcare professionals, called the 'hub-and-spoke model,' facilitates live audio–video interaction at the bedside from a tertiary hospital to remote care providers to assist remote-site physicians in treating challenging cases.[3] The 'hub-and-spoke model' is a multiprofessional peer-to-peer approach involving an interdisciplinary team of doctors, nurses and allied healthcare professionals under the hybrid model, which combines teleconsultations with training and educational activities. It also enables the delivery of telemedical services across national borders,[4] which offers solutions to clinical questions and promotes the exchange of knowledge and experience about the novel infectious disease between healthcare professionals on a global level. Thus, telemedical support has emerged as a potential surge capability not only for the ongoing pandemic but also for future emergencies.[5]

In March 2021, the Republican Research Centre for Emergency Medicine (RRCEM) in Tashkent, Uzbekistan, connected to a telemedical 'hub' at the university hospital Charité in Berlin, Germany, to strengthen critical care capacity for patients with severe cases of COVID-19 in Tashkent. The RRCEM received a specialised telemedical cart and launched a telemedical intensive care unit, joining a hub-and-spoke network of hospitals. Now, partners in Uzbekistan and Germany conduct regular joint telemedical rounds to discuss pre-selected cases. The doctors participate in telemedical rounds at agreed times 3 days a week. Between March 2021 and December 2022, the RRCEM and Charité conducted over 500 joint telemedical rounds involving nearly 200 patients. Several structural patient management improvements have occurred in the RRCEM. These include an antibiotic stewardship programme, a guideline-based approach to delirium management and mechanical ventilation strategies. As a team of clinicians and global health professionals, we identify five lessons that may aid the implementation of similar projects elsewhere, which we summarise in table 1.

During the pandemic of COVID-19, the need for remote consultations between patients and doctors and among healthcare professionals increased significantly. With this, many old challenges to the implementation of telemedical initiatives became more evident. Surges made it necessary to treat patients in field-type or small and medium-sized hospitals with varying degrees of experience in treating critically ill patients with acute respiratory distress syndrome and with different levels of readiness to adopt telemedicine. However, facing a public health emergency, patients and clinicians have become more comfortable with digital technologies to deliver healthcare services. They are more likely to appreciate their benefits, including more efficient use of resources

Table 1 Summary of the lessons learnt

1. Minimum technological infrastructure	Adequate digital infrastructure with robust internet connection; appropriate hardware and software	This includes a robust and reliable broadband internet connection. Maintaining stable bandwidth and network speed can be challenging in rural areas and must be secured before implementing telemedicine. appropriate hardware and software are other critical components. Telemedicine hardware pieces must be mobile and easy to operate in a clinical setting. the software must be well integrated with the existing and future platforms, not interrupting the workflow, and secure future interoperability as the number of telemedical programmes using electronic medical record systems grows. governments, particularly in low and middle income countries (LMICs), must account for the license and maintenance fees to make telemedicine sustainable.
2. Local champions	Enthusiastic medical staff promoting the adoption of telemedical technology	Local champions need to possess sufficient knowledge of the adopted technology, an understanding of the implementing organisation and the ability to establish credibility among peers[7 8]. An integrative review of champions in healthcare found them among critical factors in project implementation success[9]. In our case, a small group of committed English-speaking doctors at the RRCEM operated as local champions. They ran the programme on the Uzbekistani side, participated in regular ward rounds with German counterparts, served as multiplicators for education and training, and promoted and legitimised the new approach.
3. Trust among partners	Trust and commitment among clinical partners engaged in joint telemedical activities	In cross-border telemedical networks, mutual understanding of respective healthcare systems and sociocultural aspects of care between the 'hub' and the 'spoke' are crucial and achieved through dedication and regular communication. In our case, we followed what a hybrid model of care mixing on-site missions with virtual care. Initially, German doctors stayed at Tashkent hospital to support the treatment of critically ill patients. On return, project coordinators in Germany organised a weekly online course on the fundamentals of intensive care medicine between the Charité and RRCEM before the launch of the tele-ICU. The colleagues from both hospitals learnt the specifics of the respective clinical environments by discussing clinical cases and protocols. This combination of on-site and online meetings helped building rapport and prepared colleagues for long-term telemedical work.
4. Human resources	Training programmes to create a sustainable telemedical workforce	Not all staff members may be ready to adopt telemedical technology. Greater engagement with young healthcare professionals is necessary to address this, given their enthusiasm to use new technologies.[10] Another hindrance is a high workload at the hospital, which could hamper clinicians' ability to learn using novel devices and limit the time for telemedicine. During teleconsultations, recurring technological issues can decrease their effectiveness and impede the willingness to engage with telemedical technology.[11] Combining a blended learning concept with an e-learning part and on-site visits is an efficient way to promote staff training.
5. Governance and leadership	Commitment, support and encouragement of the leadership in the implementation of telemedical projects	Decision-makers, such as the Ministries of Health, must prioritise digital health and promote the use of digital technologies to create more equitable healthcare. Leadership must ensure an appropriate legal framework for conducting joint telemedical rounds, including the matter of licence to practice. Our project received full support from the hospital management, and the Ministries in both countries endorsed it. An international consultancy agreement clarified the making of treatment decisions between two teams.

RRCEM, Republican Research Centre for Emergency Medicine; tele-ICU, telemedical intensive care unit.

and time, better availability, and improved contact possibilities.[6]

Once healthcare systems begin to recover, countries should build on the momentum to strengthen the position of telemedical technology and practice. Building on what we know, long-standing challenges to the implementation of telemedicine must be addressed systematically through governance, processes, technological infrastructure, and a clear focus on creating a sustainable telemedical workforce. Given the limited resources, it holds relevance for countries with underserved populations. Our project has demonstrated outstanding potential for telemedical programmes in international settings, crossing the borders of healthcare systems when its hard (technology) and soft (training, team building, motivation) components are well considered in the planning phase. With the right approach and commitment, the national government and its international partners in the health sector could use the advances Uzbekistan made in telemedicine during the pandemic to expand the network to the regions to deliver high-quality, affordable healthcare.

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Contributors EB conceived the commentary and produced the first draft of the manuscript. BW and JH have contributed important theoretical insights. All authors contributed to critical revision of the manuscript for important intellectual content. EB drafted the final version and submitted the manuscript. All authors have read and approved this version.

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Healthcare provider evaluation of machine learning-directed care: reactions to deployment on a randomised controlled study

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ABSTRACT

Objectives Clinical artificial intelligence and machine learning (ML) face barriers related to implementation and trust. There have been few prospective opportunities to evaluate these concerns. System for High Intensity EvaLuation During Radiotherapy (NCT03775265) was a randomised controlled study demonstrating that ML accurately directed clinical evaluations to reduce acute care during cancer radiotherapy. We characterised subsequent perceptions and barriers to implementation.

Methods An anonymous 7-question Likert-type scale survey with optional free text was administered to multidisciplinary staff focused on workflow, agreement with ML and patient experience.

Results 59/71 (83%) responded. 81% disagreed/strongly disagreed their workflow was disrupted. 67% agreed/strongly agreed patients undergoing intervention were high risk. 75% agreed/strongly agreed they would implement the ML approach routinely if the study was positive. Free-text feedback focused on patient education and ML predictions.

Conclusions Randomised data and firsthand experience support positive reception of clinical ML. Providers highlighted future priorities, including patient counselling and workflow optimisation.

INTRODUCTION

Artificial intelligence (AI) and machine learning (ML) has the potential to transform medical practice. Despite many retrospective studies, randomised controlled trials (RCTs), particularly interventional trials, remain limited.[1–3] Thus, there have been limited opportunities to formally characterise barriers to the implementation of healthcare AI and ML and identify solutions.[4 5] There are minimal reports describing provider opinions following a prospective randomised interventional study of healthcare ML.

One application of healthcare ML is in the prediction and reduction of acute care (emergency visits and hospitalisations) during outpatient cancer therapy,[1 6–9] prioritized by the Centers for Medicare and Medicaid Services.[10] The System for High Intensity EvaLuation During Radiotherapy study (SHIELD-RT; NCT03775265) was a randomised controlled quality improvement study of an ML model predicting acute care visits (emergency department visits and/or hospitalisation) during radiotherapy (RT) or chemoradiotherapy (CRT).[1 6] ML identified high-risk patients for supplemental clinical evaluations, which reduced acute care rates from 22.3% to 12.3%, with low-risk patients experiencing a 2.7% rate. Radiation oncology care uniquely requires a diverse clinical staff, including attending and resident physicians, advanced practice provider (APPs), nurses and radiation therapists (RTTs), each with different viewpoints on how ML can optimally play a role in delivering care. Following the completion but prior to final analysis of SHIELD-RT, we administered a survey to understand the perspectives of healthcare providers with regard to the acceptability and feasibility of ML-directed strategies, addressing key components of the implementation outcomes framework.[11] The objective was to evaluate specific barriers to planned long-term implementation.

METHODS

We conducted a single institution survey of perceptions of SHIELD-RT, during which all outpatient adult courses of RT and CRT initiated from 7 January 2019 to 30 June 2019 were evaluated during the first week of treatment by ML to identify high-risk patients with >10% risk of an acute care visit during RT.[1 6] Patients were randomised to standard of care (mandatory weekly on-treatment and clinically indicated ad hoc visits) versus mandatory twice-weekly visits. Interventional second weekly visits were facilitated through an alert

Table 1 Responses to survey questions

Paraphrased survey question	Response, median (25–75th percentiles)*					
	Overall	Attending physicians	Resident physicians	Advanced practice providers (APP)	Nurses	Radiotherapy technologists (RTT)
The study disrupted my clinical workflow†	4 (4–5)	4.5 (3.25–5)	4 (4-4)	3 (3–3.5)	4 (3.25–4)	4 (4–4.5)
Patients on the intervention were at high risk for acute care visits‡	2 (2–3) 13 not aware	2 (2–3)	2 (2–2)	2 (2–2)	2 (2–2)	2.5 (2–3)
I was aware of my patients who were undergoing intervention	2 (2–3)	3.5 (2.25–5)	2 (2–3)	2 (1.5–2.5)	2.5 (2–3)	2 (2–3)
The study altered my clinical management‡	4 (3–4) 5 not aware	4 (3.5–4)	3 (3–3.5)	4 (4–4)	4 (4–4.75)	4 (3–4.5)
I would implement the machine learning system routinely if the study is positive	2 (1–3)	2 (2–2)	2 (1–3)	3 (2–3)	2 (1–2)	2 (2–3)
My opinion of machine learning to assist with clinical care is now…	3 (2–3)	3 (2.25–3)	2 (2–3)	3 (2–3)	3 (3–3)	2 (2–3)
Patients understood the study after their first mandatory visit	3 (2–3)	3 (3–3)	3 (2–3)	3 (2.5–3)	3 (2–3)	3 (3–3.5)

*Responses on a 5-point Likert-type scale ranging from 1 (strongly agree; much better) to 5 (strongly disagree; much worse).
†APPs, nurses and RTTs were most frequently directly involved in the supplemental visits.
‡Also included the option for respondents to indicate that they were not aware which patients were identified as high risk by the algorithm.

that notified RTTs to bring patients to an appropriate clinic room to then be seen by an APP, nurse clinician, resident physician or attending physician. The primary endpoint was rate of acute care visits during RT. Additional details of SHIELD-RT and its primary analysis and implementation workflow were previously reported.[1 12]

Involved attending and resident physicians, APPs, nurses and RTTs were invited to participate in an anonymous survey to characterise workflow satisfaction and evaluation of potential barriers to future adoption. This included eight questions on a Likert-type scale characterising respondents' attitudes with an optional free-text comment field.

RESULTS

A total of 59/71 (83%) of invited staff completed the survey, including 14/16 attending physicians (MD), 9/9 resident physicians, 3/5 APPs, 10/11 nurses, 23/30 RTTs (table 1). Eighty-one per cent of staff disagreed or strongly disagreed that the study disrupted their workflow. Only 51% of respondents agreed or strongly agreed that they were aware of their patients undergoing the intervention; 3% agreed that their clinical management beyond the study intervention was altered. Of those aware of patients seen twice weekly, 67% agreed or strongly agreed that patients undergoing intervention were high risk. Most staff (64%) neither agreed nor disagreed that patients understood the study. Willingness for future adoption was favourable, as 75% of respondents agreed or strongly agreed that they would implement the intervention routinely if the study was positive; 41% agreed or strongly agreed and none disagreed that their opinion of clinical ML improved following the study.

There were 8 (16%) free-text comments. Three (two RTT and one nurse) indicated confusion among staff and patients with the need and logistics of the supplemental visit. One nurse noted that they felt ML overestimated the risk of their patients (specifically in brain tumours). Two MD responses indicated that they had minimal contact with patients on study. Two (one MD and one RTT) responses expressed anticipation for the results of the study.

DISCUSSION

Our study highlights an overall positive reception towards ML implementation in an academic radiation oncology clinic. Our survey supports that RCT results drive willingness to routinely adopt clinical ML. ML-guidance and supplemental visits were integrated successfully into our clinical workflow with minimal perceived disruption.

This analysis shows how some concerns regarding ML may be overcome. In addition to randomised evidence, direction observation of ML operating in a controlled setting may have improved subjective opinions of clinical ML prior to the study. This is instrumental given recent data demonstrating the limitations of commercial prediction models,[13] and ultimately, subsequent to this survey, the SHIELD-RT analysis demonstrated a reduction in

acute care events.[1] While ML will continue to require complementary input from healthcare professionals, these survey results are promising for adoption.[14] Our clinic is currently incorporating this ML-directed clinical strategy into routine practice.

Overall, ML implementation had limited provider-perceived impact on clinical workflows, to the point of reducing MD awareness as indicated by survey responses. This was intentional in the design to minimise extra cognitive and functional effort to improve the likelihood of MD adoption.[1 12] One relative exception to this was surveyed APPs, the majority of whom participated in the interventional second mandatory clinical evaluation. This suggests that ML-guided interventions may place greater burden on specific staff. This cost must be considered in model and interventional design.

Among limited free-text comments, staff reservations focused on patient education and ML risk predictions. Patients were not surveyed, although staff both anecdotally and in the survey highlighted logistical challenges surrounding location and timing of supplemental visits. While patients were educated when undergoing the supplemental evaluation, the neutral evaluation of patient understanding and anecdotal responses highlight the reported challenges of explaining the algorithm and its clinical implications to patients. This emphasises the need for transparent and explainable approaches, especially given increasingly opaque AI methods. Despite the single comment noting concern for overestimation, calibration analyses previously reported in the primary study results demonstrated good model performance in comparison to clinicians who were more inconsistent, with wide CIs, and assigned a 0% risk to a patient who had an acute care event.[1] It is possible that over time, both improved explainability and consistent observation of ML accuracy may demonstrate longitudinal improvements in clinician perception.

There are limitations to our study. We surveyed staff only following completion of the study, and direct comparisons pre-SHIELD-RT and post-SHIELD-RT were not possible. The results of this survey may be subject to bias, though we had a high rate of completion (83%) across a range of roles, with a high representation of non-academic staff (61% of respondents; APPs, nurses and RTTs).

The results of this study inform our future directions, primarily emphasising the importance of RCTs in demonstrated clinical ML benefit and highlighting the need for concerted efforts in patient and staff education. Other ongoing work focuses on optimising workflows, patient logistics, long-term ML surveillance and generalisability.

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Competing interests JDT, MP and JH are coinventors on a pending patent, 'Systems and methods for predicting acute care visits during outpatient cancer therapy,' related to the current work.

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IT risk management for medical devices in hospital IT networks: a catalogue of measures and indicators

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ABSTRACT

Objectives Connecting medical devices to hospital IT networks can create threats that must be covered by IT risk management. In practice, implementing such risk management is not trivial because the IEC 80001-1, as the existing state-of-the-art, do not describe sufficiently concrete implementation measures or evaluation indicators. The aim of the present work was to develop and evaluate a catalogue of measures and indicators to help hospitals implement and evaluate risk management in accordance with IEC 80001-1.

Methods We conducted a Delphi study with 22 experts. In the first round, we performed interviews to identify implementation measures and evaluation indicators using qualitative content analysis. In the second round, a quantitative experts' survey confirmed the results of the first survey round and identified relationships between the measures and indicators. Based on these results, we then developed a catalogue containing the identified measures and indicators. Finally, we performed a case study to verify the practicability of this catalogue.

Results We developed and verified a catalogue of 49 measures and 18 indicators to help hospitals implement and evaluate risk management following IEC 80001-1. The case study confirmed the practicability of the catalogue.

Discussion Compared with IEC 80001-1, our catalogue goes into further detail to offer hospitals a stepwise implementation and evaluation approach. However, the catalogue must be tested in further case studies and evaluated in terms of generalisation.

Conclusions The catalogue will enable hospitals to overcome recent difficulties in implementing and evaluating IT risk management for medical devices according to IEC 80001-1.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Before this study, there was little research on how to implement and evaluate IT risk management for medical devices connected to IT networks. The IEC 80001-1 standard existed, but a problem in practice was that no practical knowledge existed on how to implement the standard effectively and efficiently.

WHAT THIS STUDY ADDS

⇒ Our study provides a catalogue of 49 measures and 18 indicators to help hospitals implement and evaluate risk management for medical devices connected to a hospital IT network.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ For IT risk managers in hospitals, the catalogue that we have developed enables a specific and step-by-step implementation and evaluation of IT risk management for medical devices connected to hospital IT networks.

INTRODUCTION

More and more processes in modern healthcare are digitalised. Looking at current trends (eg, telemedicine, artificial intelligence, medical apps), this level of digitalisation will continue to increase in the coming years. Digitalisation also affects medical technology. Today's medical devices are designed to exchange data with other medical devices and clinical information systems. Incorporating medical devices into hospital IT networks is therefore essential as it contributes to the effectiveness of clinical processes and safe patient care.[1 2]

However, digitalisation and the networking of medical devices can pose new risks that could jeopardise the effectiveness of clinical processes or patient safety.[3 4] Technical failures, unauthorised actions, compromised information or functions, deliberate actions or organisational failures, among other things, are fundamental threats to be aware of when integrating medical devices into hospital IT networks. For this reason, hospitals need to establish specific IT risk management procedures for medical devices to deal with these potential IT threats.[5–7]

Numerous standards[8 9] and scientific works[10] exist for IT risk management. IEC 81001-5-1[11] defines security activities in the product life cycle for health software and health IT systems and is therefore primarily intended for developers. IEC 80001-1 and the associated technical reports represent the current state of the art for risk management to control hazards that may arise from

incorporating medical devices into IT networks. The standard, which is mainly intended for operators of medical IT networks (eg, hospitals), was initially published in 2010[12] and updated with a second edition in 2021.[13] IEC 80001-1 has also been adopted as a European standard and in various national standards (eg, DIN EN 80001-1:2011 for Germany).

However, implementing IEC 80001-1s is not trivial.[5] First, risk managers face the practical problem that IEC 80001-1 is often considered too complicated and too complex to implement.[14–16] One reason for its complexity is that the standard does not describe any concrete implementation measures. Even the associated technical reports (eg, IEC/TR 80001-2-1:2012 or ISO/TR 80001-2-7:2015) and the 2021 edition of IEC 80001-1[13] do not solve this problem. Compared with the first version of IEC 80001-1 from 2010, the current version from 2021 formulates more concrete implementation recommendations. This is achieved primarily through the more detailed requirement descriptions in Annex A (IEC 80001-1 requirements mapping table) and B (Guidance for accompanying document Information). The complexity in the practical implementation is thereby reduced, but not completely eliminated. IEC/TR 80001-2-1 focuses on 10 steps to help in the application of risk management. Still, it does not provide a full outline or explanation of all requirements covered by IEC 80001-1 (eg, organisational aspects). IEC/TR 80001-2-7 provides guidance for hospitals to self-assess their conformance with IEC 80001-1, but it does not introduce any requirements in addition to those expressed in IEC 80001-1 (eg, priority of requirements, critical success factors). Another factor in German-speaking countries is that risk management is often based only on the translated national standards of IEC 80001-1. The national standards are still based on the first, superseded version of IEC 80001-1 (eg, DIN EN 80001-1:2011 in Germany), and most of the associated technical reports are not even available in German. Second, the standards do not define the importance and practicability of the different steps that help apply IEC 80001-1. In addition, the specific interpretation and implementation of the requirements described in general in IEC 80001-1 vary depending on the region in which the hospital is located and relevant regulatory requirements.[16] Third, the standards do not describe specific methods to evaluate the achievement of the intended effects of IT risk management. The intended effects on information security, the effectiveness of processes and the safety of patients are generally assumed but not systematically reviewed. Therefore, the effectiveness of IEC 80001-1 with regard to contemporary cybersecurity is unknown.[17] The lack of methods for evaluating and reviewing the correctness and efficacy is often observed in health and medical informatics and is described as a general problem.[18]

Some non-scientific guidelines[19] and a few scientific papers[16] have tried to address the aforementioned difficulties in the implementation of IEC 80001-1. In comparison to these approaches, we wanted to go into further detail in order to offer hospitals a kind of 'cookbook' for IEC 80001-1 implementation and evaluation.

Therefore, the present work aimed to develop and verify a catalogue of measures to help hospitals implement risk management in accordance with IEC 80001-1. The catalogue should also provide indicators that allow hospitals to evaluate the impact of the implemented measures. It should also describe implementation measures and indicators in as much detail as possible, explaining the importance of each measure and indicator as well as the resources (technical, organisational, financial) that should be expected for their implementation. Finally, the catalogue should consider the abovementioned challenges of implementing IEC 80001–1 in German-speaking countries.

METHODS

Approach

IT risk management, in general, can mainly be assigned to the technical sciences, information sciences and economics. Quantitative and qualitative research methods have been established in these scientific disciplines. Since we aimed to identify measures and indicators essential for implementing and evaluating risk management according to IEC 80001-1, observations, experiences and interpretations of experts are especially important. So, we identified an expert survey in the form of a Delphi study, where qualitative and quantitative methods should be combined, as a suitable methodology. Therefore, we conducted a study consisting of three research steps (see figure 1). In the first two research steps, we used the Delphi technique to gather the collective opinion of experts through a systematic and multistage process. In the first research step, we interviewed experts to develop a catalogue with the desired measures and indicators. We interviewed the experts again in the second research step to reach a consensus on which measures and indicators should be included in the catalogue in the end. In the third step, we evaluated the catalogue for practicability in a case study with the help of additional experts.

1st research step: development of a catalogue of measures and indicators

In the first step of the Delphi study, we conducted 2 qualitative oral interviews and 20 qualitative written interviews with experts on health IT and medical devices. This first research step aimed to develop a catalogue of measures and indicators for implementing and evaluating IT risk management for medical devices connected to a hospital IT network.

We invited professionals with several years of professional and practical experience in IT security, medical technology and medical informatics to be our experts. We contacted approximately 50 experts personally via telephone, email or located them via social media to invite them to our study.

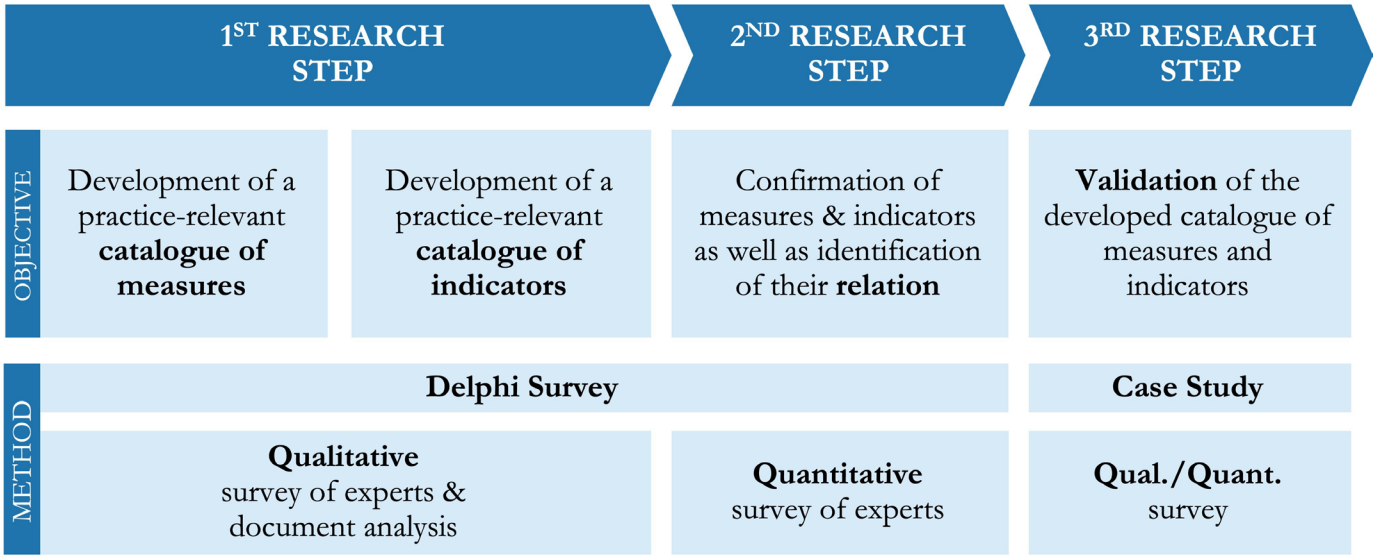

Figure 1 The three research steps with their objectives and methods.

Initially, only oral interviews were planned, but most participants wished for a fully anonymous written interview. Two interviews were therefore conducted orally and 20 interviews in written form. The interviews included 10 open questions on personal views, opinions and experiences regarding the threats posed by operating medical devices in hospital IT networks.

All interviews were analysed using structured qualitative content analysis, according to Mayring.[20] The 22 data sets were coded according to the two main categories of 'measures' and 'indicators'. Within these main categories, further subgroups were formed. In addition, relevant documents (standards, laws and reports) named by the interview partners were analysed using qualitative content analysis.

2nd research step: confirmation of measures and indicators and their relationships

A total of 13 experts from the first research step declared their willingness to continue their participation. So, a quantitative study of 13 experts was conducted as a second research step to confirm the results of the first survey round and to identify the relationships between the identified measures and indicators.

This survey was conducted online, and the response was 100%. The survey comprised 20 closed questions divided into three sections: First, the experts had to rate the measures from the first survey round on a four-point scale between '1=no importance at all' and '4=very high importance'. Second, the experts had to rate the indicators from the first survey round. Measures and indicators were classified as 'important' and included in the catalogue if the mean rating of all experts for a given measure or indicator was 2.5 or higher (given a range from 1 to 4); they were rated as 'very important' if the mean rating was 3.25 or higher. In the catalogue, these findings were represented in the criteria 'priority'. The important measures and indicators are marked with a single star symbol, and the 'very important' measures and indicators are with two stars. Third, the experts had to rate the possible relationship between groups of measures and groups of indicators on a five-point scale (see figure 2). The groupings were predefined and based on the researcher's assumptions, prior knowledge and practical experience. A relationship was rated as 'confirmed' if the mean rating of all experts was 2.5 or higher.

3rd research step: validation of measures and indicators in a case study

We conducted a case study to validate the catalogue of measures and indicators developed in the earlier steps. The case study was conducted in an Austrian hospital with

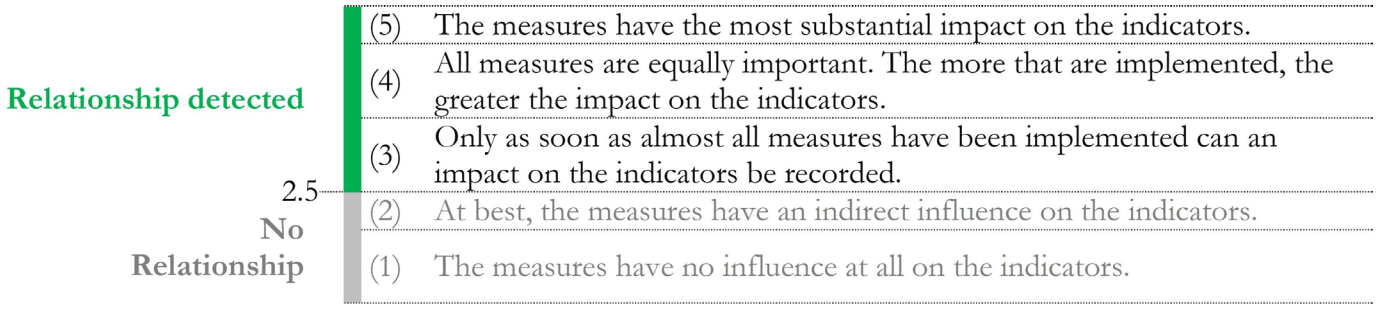

Figure 2 The scale for assessing the relationship between measures and indicators.

Table 1 The three criteria (including questions) for evaluation of the catalogue

Factor	Question	Rating
Effectiveness	Was it possible to implement a selected measure or indicator?	Binary Rating Scale (yes, no)
Complexity	How complex was the implementation of a given measure or indicator?	Three-part rating scale (low, moderate, high)
Satisfaction	How satisfied were the users with the descriptions and instructions for a given measure or indicator?	Binary Rating Scale (satisfied, not satisfied)

325 beds. The hospital had 17 medical devices integrated into its IT network but did not yet have risk management according to IEC 80001-1. The case study was conducted over 3 months.

The case study aimed to implement and evaluate the catalogue. Three health IT staff members at the hospital (head of IT, head of medical technology and an IT project manager) were asked to implement measures and indicators by following the implementation recommendations in the catalogue. Inspired by ISO 9241-11, which provides a framework for usability testing, we developed a written survey to evaluate the effectiveness, complexity and satisfaction of each implementation recommendation (see table 1). After implementing a measure or indicator, the three health staff IT members had to evaluate the implementation recommendation using these written surveys.

In addition to the written questionnaires, we performed an oral group interview with the three health IT staff members at the end of the case study. This guided group interview also aimed to validate effectiveness, efficiency and satisfaction; compared with the written questionnaires, however, the interview focused on the catalogue in general. The findings of the survey were incorporated into the results of the written survey by assigning them to the corresponding evaluation criteria of a specific measure or indicator. Knowledge about the complexity of implementing a measure or indicator was to be integrated into the catalogue; a traffic light symbol was therefore chosen to visualise the level of complexity (red=high complexity, orange=moderate complexity, green=low complexity).

RESULTS

Development of the catalogue of measures and indicators (research steps #1 and #2)

We used qualitative content analysis to code 723 units in the qualitative expert interviews. We identified 51 measures and 19 indicators in the first research step through abstraction, summarisation and elimination of duplicates. The experts confirmed these results in the second research step except for one single indicator and two measures.

The resulting 49 measures were categorised into six subgroups (see table 2). With these measures in place, including detailed implementation information for each measure (see figure 3), hospital IT risk managers should be able to implement IT risk management according to IEC 80001-1.

The resulting 18 indicators were categorised into four subgroups (see table 3). With these indicators in place, including detailed implementation information for each indicator (see figure 3), hospital IT risk managers should be able to evaluate the implemented measures.

To be able to make any conclusions about whether the implemented measures affect the indicators, it was necessary to define relationships between measures and indicators. Based on qualitative content analysis, we were able to identify six relationships between the defined subgroups of measures and subgroups of indicators. Figure 4 shows which groups of measures impact which groups of indicators: The more measures in a category are implemented, the more positive the expected effect on the indicators of the corresponding category.

To make our results available to IT risk managers in hospitals, we made the complete catalogue (81 pages) freely available in German.[21]

Validation of the catalogue (research step #3)

As planned, the catalogue was validated in a case study in an Austrian hospital. Overall, 38 of 49 measures were implemented, and 4 of 18 indicators were selected to evaluate the measure. (These measures and indicators are marked with an asterisk '*' in table 2 and table 3.) In our pilot study, we focused on those measures and indicators chosen as being relevant for the hospital; thus, we did not try to implement all of them. Figure 5 summarises the three main findings of the case study: The effectiveness of the catalogue was confirmed since 78% (n=38) of measures, and 100% (n=4) of the indicators could be implemented successfully. The satisfaction with the descriptions and instructions in the catalogue was also very high (96% for the measures, 100% for the indicators). The complexity of the implementation was mainly described as low (55%) for measures and exclusively low (100%) for indicators. Twenty-two per cent of measures needed moderate resources and only 6% were very complex to implement.

In the final group interview of the case study, all three health IT staff members stated that the catalogue is an effective and efficient tool to develop, implement and operate risk management for IT networks that incorporate medical devices.

DISCUSSION

Answering the research question

Based on the empirical data of our study, we developed and validated a catalogue of 49 measures and 18 indicators to help hospitals implement and evaluate risk management for medical devices connected to a hospital

Table 2 The 49 measures to implement risk management, including the priority and complexity of each measure

Subgroup	Measure	Priority	Complexity
Organisation	External laws and regulations must be taken into account*	★★	●●●
	The users must learn the network functions of the medical device*	★☆	●●●
	Information technology (IT) standards and frameworks [Control Objectives for Information and Related Technologies (COBIT), Information Technology Infrastructure Library (ITIL), etc] must be integrated*	★☆	●●●
	A professionally qualified risk manager must be appointed*	★☆	●●●
	Roles and tasks of the risk manager must be clearly defined*	★★	●●●
	Roles and tasks of the manufacturers must be clarified*	★★	●●●
	Roles and tasks of users must be defined*	★☆	●●●
	Responsible leadership must be appointed*	★★	●●●
	Possible stakeholders must be identified and informed*	★☆	●●●
	Scopes must be defined*	★★	●●●
	Risk management processes must be developed and implemented*	★★	●●●
	Risk management activities must be evaluated regularly and improved if necessary	★★	●●●
	Interface between medical technology and IT department must be ensured*	★★	●●●
	A coordinated procurement process for medical devices must be established*	★★	●●●
	Reporting to the responsible management must be implemented*	★☆	●●●
	A risk management file must be created*	★★	●●●
	All networked medical devices/systems must be recorded and documented*	★★	●●●
	A complete network description and documentation must be kept*	★★	●●●
	Document guidance must be introduced*	★☆	●●●
Risk identification	Ask manufacturers about possible cyber risks of their medical device*	★★	●●●
	Ask users what impact a medical device failure has*	★★	●●●
	Ask the IT department about general IT threats	★☆	●●●
	Identify the purpose of the connection to the IT network and derive risk situations*	★★	●●●
	Identify critical clinical areas and automatically assume critical networking there*	★☆	●●●
	Identify data flows completely and derive possible errors and effects	★☆	●●●
	Create or adapt hazard catalogue*	★☆	●●●
Risk analysis	Define risk matrix*	★★	●●●
	Define probabilities of occurrence*	★☆	●●●
	Define implications for data and information security*	★★	●●●
	Define impact for process effectiveness*	★★	●●●
	Define implications for patient safety*	★★	●●●
	Assess risks for each potential hazard*	★☆	●●●
	Document risk analyses and evaluations*	★★	●●●
Risk minimisation	The medical IT network must be constantly monitored*	★☆	●●●
	Basic general IT security (eg, ISO 2700x) must be ensured*	★★	●●●
	Incident and event management must be developed and implemented	★☆	●●●
	Implement network segmentations based on risk analysis	★☆	●●●
	Interface and communication standards (eg, HL7, DICOM) must always be applied*	★☆	●●●
	The technical infrastructure must be continuously kept at state of the art*	★★	●●●

Continued

Table 2 Continued

Subgroup	Measure	Priority	Complexity
	Manual data processing procedures should be identified as possible workarounds*	★☆	
	Risk-minimising measures must be regularly reviewed and documented	★★	
	Catalogue for risk-minimising measures must be created and implemented	★★	
Residual risks	Residual risks must be systematically assessed and justified	★★	
	Residual risks must be documented in an understandable manner	★★	
	Residual risks must always be accepted by top management*	★☆	
Change management	Systematic change and configuration processes must be developed	★★	
	All changes and configurations must be approved by IT risk management*	★☆	
	Frequent changes should be defined as standard processes (routine)	★★	
	Significant changes or new installations should be organised as a project*	★★	

*Measures implemented in the case study.

IT network. The catalogue describes the importance of each measure and indicator and the resources (technical, organisational, financial) that are needed for their implementation. The catalogue should help information technology (IT) risk managers in hospitals to control the complexity of implementing IT risk management according to IEC 80001-1.

Strengths and weaknesses of the method

Due to the combination of qualitative and quantitative research methods within the Delphi method, the initially unclear knowledge about the measures and indicators sought could be operationalised and subsequently quantified and evaluated. In particular, the self-evaluating character of this method, that is, the anonymised feedback of the results within the expert group and the possibility for the experts to reflect and reconsider these results until a stable agreement or disagreement prevailed, was of outstanding importance for the quality of the data. However, the validity of a Delphi study, and thus also of the present study, is strongly influenced by the selection of experts. We, thus, invited experts with a considerable variation of professional backgrounds and much practical experience. The experts came exclusively from German-speaking countries, as risk management in these countries is performed based on similar regulatory requirements. Moreover, few German-language guidelines for IT risk management in hospitals exist. It must also be considered that German-speaking countries are strongly oriented towards the national adaptations of IEC 80001-1, which is still based on the first version of IEC 80001-1 published in 2010. The knowledge of the experts interviewed is, therefore, mostly based on these national implementations.

ID – Title of a measure or an indicator

Priority:	★★	**Complexity:**	
Purpose:	*Description of the purpose of a measure or indicator.*		
Implementation recommendation:	*Recommendation for the concrete implementation of a measure or an indicator.*		
	Example for the recommendation.		
Critical success factor:	*Description of factors that are important for the successful implementation of the measure or indicator.*		
Person:	*Description of the person who should implement a measure or indicator.*		
Output:	*Description of the result of a successful implementation.*		
Related indicator/measure:	*Description of the measure or action that is related to the measure or action described here.*		

Figure 3 Structure of the catalogue's descriptions of measures or indicators. *One star = important; two stars = very important; red = high, yellow = moderate, green= low complexity*

Table 3 The 18 indicators to evaluate risk management, including the priority and complexity of each indicator

Subgroup	Indicator	Priority	Complexity
Performance of connected medical devices	No of residual risks identified	★★	○○●
	No of risk control measures*	★★	○○●
	No of probable risks identified	★★	○○●
	No of potential risks identified	★★	○○●
Effectiveness of connected medical devices	No of incidents in which data was lost	★★	○●○
	No of incidents in which the required information technology (IT) service was not available	★★	○○●
	No of emergency operations caused by the connection to the IT network*	★★	○○●
	No of incidents in which patient data were not available	★★	○○●
	No of errors in patient data caused by the connection to the IT network	★★	○○●
Technical infrastructure	Average age of medical devices which are connected to IT network	★★	○●○
	No of malfunctions of medical devices which are connected to IT network	★★	○○●
	No of failures of the medical IT network*	★★	○○●
No of deliberate acts	No of data thefts and data protection incidents*	★★	○●○
	No of blackmail attempts	★★	○○●
	No of hacker attacks	★★	○●○
	No of unauthorised or undetected connections	★★	○●○
	No of malware activities (Trojans, worms, viruses, etc)	★★	○●○
	No of unauthorised data changes and accesses	★★	○●○

*Indicators evaluated in the case study.

Due to this geographical restriction, the catalogue was mainly developed for use in German-speaking countries. To assess its applicability in other countries, the catalogue should be validated with non-German-speaking experts.

We needed only two rounds of expert interviews in our Delphi study to reach a consensus. A third iteration was not necessary.

We conducted the case study in one hospital only. Further research is needed to validate the usefulness of the catalogue in further hospitals.

Meaning of the results

Our catalogue will help hospitals to set up and operate IT risk management according to IEC 80001-1 more simply and straightforwardly than the standard. We reached this aim as the catalogue (much like a cookbook) recommends a defined number of implementation measures and provides detailed information about them. IT risk managers can work through the catalogue step by step and do not have to interpret abstract specifications as

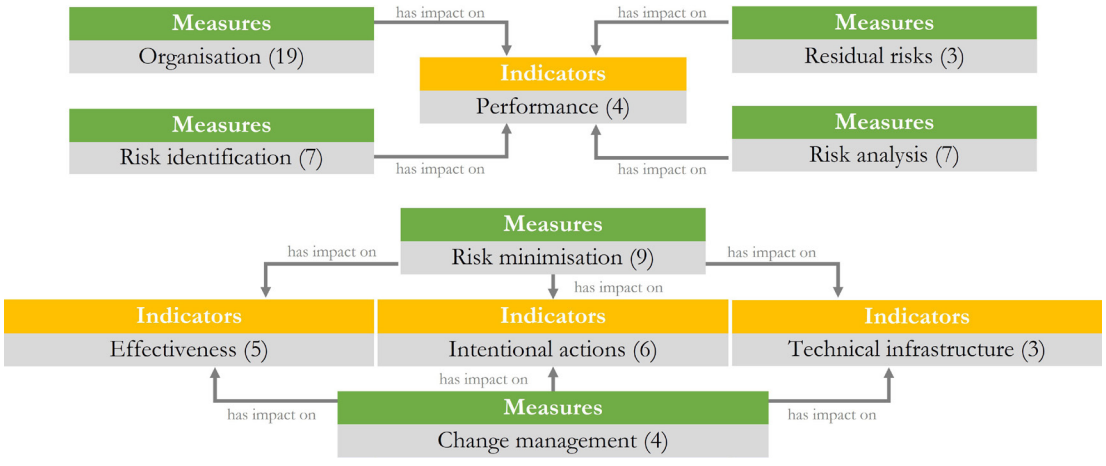

Figure 4 The identified relationships between groups of measures and indicators. (The numbers in parentheses represent the number of measures or indicators.).

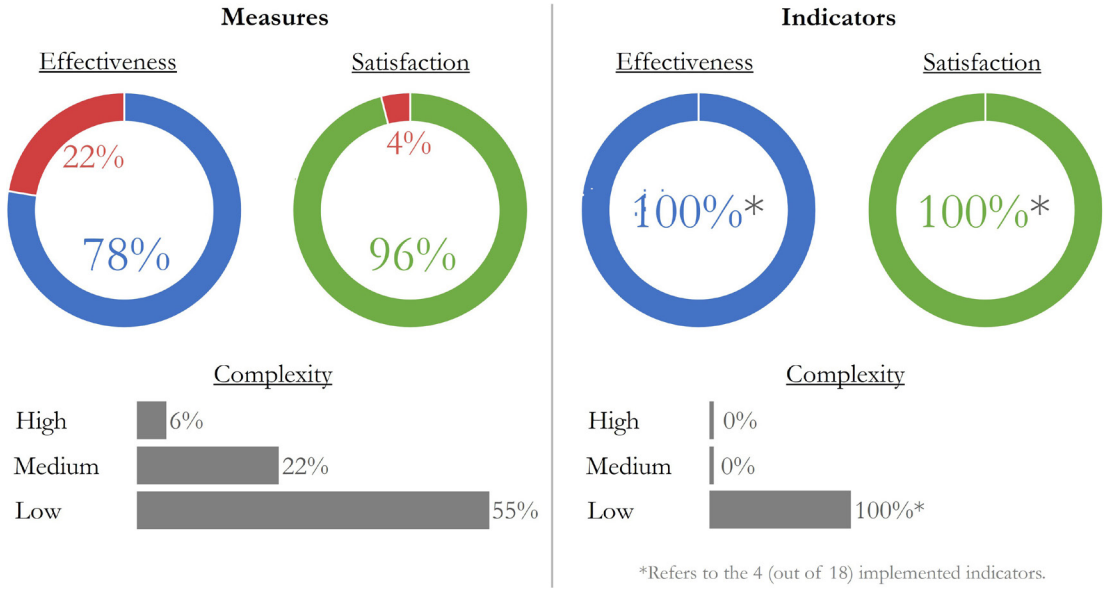

Figure 5 Results of case study. Successfully implemented measures and indicators (blue percentage value), the satisfaction of the study participants with the descriptions and instructions for implementing these measures and indicators (green percentage value), and the complexities of their implementation (grey percentage values).

is necessary with IEC 80001-1. There is also no need to purchase and understand the technical reports associated with the standard in order to achieve a high degree of IEC 80001-1 conformance. In addition, the measures described in the catalogue are based on the practical experience of experts.

The catalogue also proposes concrete indicators that hospitals can use to assess whether the implemented measures and, as a result, the implemented risk management have achieved the desired goals. We reached this as the catalogue defines relationships between groups of measures and indicators. It should be noted that the indicators represent estimates and assumptions based on expert opinions. The catalogue cannot offer a valid causal relationship between measures and indicators.

Reference to the state of the art

With the catalogue, we support hospitals in following the recommendation of experts that all medical devices integrated into an IT network must be covered by systematic risk management.[5–7] Compared with the first version of IEC 80001-1 and actual national implementations for German-speaking countries, which are still based on this first version from 2010, our catalogue thus helps IT risk managers in hospitals to deal with the complexity in implementing IT risk management.[5] This also applies to the current version of IEC 80001 from 2021. Although this version formulates clearer and more detailed implementation recommendations, these are not described in as much detail as in our catalogue. Our catalogue is influenced by both versions of IEC 80001-1, which is evident in the names of some of the measures. This is not surprising, as all of our experts know these standards. In comparison with existing non-scientific guidelines[19] or scientific papers[14], our catalogue goes into further detail. Our catalogue offers a stepwise implementation approach with detailed descriptions and recommendations. Furthermore, our catalogue informs of the complexity that should be expected in implementing a measure or indicator and of the priority of measures and indicators. In addition, our catalogue takes into account the special requirements in German-speaking countries (eg, medical device laws, organisational structures in hospitals, or focus on German-language literature in practice).

As the catalogue contains indicators to evaluate the impact of the implemented measures, this will meet the demand for more methods to evaluate and verify the correctness and effectiveness of interventions in health informatics.[18]

Outlook

New trends in digitalisation, such as artificial intelligence or the Internet of Things, are having an impact on the healthcare field.[22] These developments pose new challenges with regard to IT risk management and must therefore be taken into account in any future evolution of our catalogue. In addition to the case study, the catalogue was already actively communicated to three other hospitals. In further case studies, our catalogue must be tested for practicability and completeness. The aim is to involve as many different healthcare institutions as possible to identify and consider additional requirements. A larger sample of experts should be considered.

CONCLUSION

Our work's benefit is that with our catalogue of measures and indicators, hospitals may address recent difficulties in implementing and evaluating IT risk management for medical devices according to IEC 80001. In practice, IT risk

managers can use the catalogue to prioritise implementation measures and evaluation indicators by following the detailed descriptions and empirically based recommendations. Connecting medical devices to hospital IT networks is increasingly important for the effectiveness of medical processes and patient safety. IT risks arising from medical devices connected to IT networks (eg, unauthorised actions, compromise of functions, technical failures) must be covered by IT risk management. The catalogue we have developed may therefore assist in implementing and operating a powerful risk management system. However, it must be taken into account that our results relate very much to the German-speaking region due to the selection of experts, the location of the case study and the associated focus on the national implementation of IEC 80001. We expect that our results will be of relevance to other countries, but we still have to evaluate this.

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Patient consent for publication Not applicable.

Ethics approval Ethical clearance was obtained from the 'RCSEQ - Research Committee for Scientific Ethical Questions' of the Private University For Health Sciences and Health Technology (Hall in Tirol, Austria) with approval number 1717: No patients were involved in the study and no sensitive and data protection-relevant data were processed. The authors of this study have informed the participants (experts) in the Delphi study and in the case study regarding their rights.

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Improving medication safety in a paediatric hospital: a mixed-methods evaluation of a newly implemented computerised provider order entry system

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ABSTRACT

Objectives Computerised provider order entry (CPOE) systems have been implemented around the world as a solution to reduce ordering and transcription errors. However, previous literature documented many challenges to attain this goal, especially in paediatric settings. The objectives of this study were to (1) analyse the impact of a paediatric CPOE system on medication safety and (2) suggest potential error prevention strategies.

Methods A pre-post observational study was conducted at the pilot ward (n=60 beds) of a paediatric academic health centre through mixed methods. The implementation project and medication management workflows were described through active participation to the project management team, observation, discussions and analysis of related documents. Furthermore, using incident reports, the nature of each error and error rate was compared between the preperiod and postperiod.

Results The global error rate was lower, but non-statistically significant, in the post implementation phase, which was mostly driven by a significant reduction in errors during order acknowledgement, transmission and transcription. Few errors occurred at the prescription step, and most errors occurred during medication administration. Furthermore, some errors could have been prevented using a CPOE in the pre-implementation period, and the CPOE led to few technology-related errors.

Discussion and conclusion This study identified both intended and unintended effects of CPOE adoption through the entire medication management workflow. This study revealed the importance of simplifying the acknowledgement, transmission and transcribing steps through the implementation of a CPOE to reduce medication errors. Improving the usability of the electronic medication administration record could help further improve medication safety.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Many challenges to the safe implementation of electronic medication prescribing have been documented, especially in paediatric settings. Reducing medication errors is difficult, and new errors may arise with the introduction of the technology.

WHAT THIS STUDY ADDS

⇒ This study highlights the importance of simplifying the workflows of the whole medication management process with the technology. Specifically, acknowledgement of the order (by nurses), validation for dispensation (at the pharmacy) and medication administration (by nurses) are crucial in improving safety of medication use with technology.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Future work should focus on the whole medication management process and analyse the usability of key features prior and during implementation.

INTRODUCTION

The medication management process is a complex process that includes prescribing, transmission, preparation and administration of medication. Several problems can arise at various stages of this process, such as transcription errors, drug interactions or administration problems. Medication errors are prevalent worldwide, with WHO launching the global Medication Without Harm initiative in 2017 to cut medication errors in half in 5 years.[1] In 2019, Québec's Ministry of Health and Social Services' annual accident/incident report identified that 26% of accidents/incidents in all the province's healthcare facilities (n=130 520) are drug related, including errors due to illegible prescriptions, undetected allergies and wrong prescription weight. Similarly, the CHU Sainte-Justine (CHUSJ), an academic mother-and-child health centre with over 400 beds, identified that 27% of accidents/incidents (n=1346) are drug related.[2]

Computerised provider order entry (CPOE) is one of the promising solutions to improve the quality of use and safety of prescribed medication.[3 4] In Québec, the CHUSJ was the first healthcare institution to implement CPOE that enabled both prescription of medications and non-medication orders. However, the challenges of implementing CPOE can lead to some detrimental consequences, for example, by generating errors due to the system configuration,[5] and might not improve medication safety.[6] Therefore, the impact of CPOE on medication safety depends greatly on the clinical setting and the CPOE system configuration.[5]

Additionally, paediatric patients are particularly vulnerable to medication errors due to the off-label use of numerous drugs, paediatric-specific drug–drug interactions, as well as their wide variation in age and weight, which can lead to 10-fold dosing errors (ie, underdosing or overdosing error by a factor of 10).[7–9] Indeed, Tolley *et al* identified the lack of dosing support as the most crucial factor that contributed to CPOE-related errors in paediatrics.[10] Previous studies in paediatric settings have also highlighted the importance of minimising disruptive alerts and modifying directly the ordering workflow to avoid error-prone steps (eg, implementing rules to avoid 10-fold errors directly in the CPOE).[11 12] Therefore, designing and implementing an effective and satisfactory system tailored to the paediatric population's needs and local clinical environment is critical to ensuring medication safety.[13–16]

This project leverages the clinical adoption meta-model framework,[17] in which the dimensions of availability, usage and outcomes continuously evolve based on one another, to evaluate the impact of the implementation of CPOE on medication safety in a paediatric pilot unit. More specifically, this study sought to measure and contextualise the impacts of the CPOE adoption by (1) describing the CPOE implementation project and the medication ordering workflows before and after CPOE implementation (as an indicator of availability and usage), (2) describing the rate and types of clinical errors during various stages of the medication management process (as an indicator of safety outcomes) and (3) identifying potential health information technology (HIT)-related prevention strategies based on error reports (as a continuous improvement strategy).

METHODS

Study design and site

An observational pre-post study was conducted in the 60-bed general paediatric medicine unit, the largest unit at the CHUSJ, in October 2019. The CHUSJ was selected for this study because it was the first paediatric hospital to implement this newly developed CPOE. Furthermore, the general paediatric unit was chosen for the evaluation of the CPOE, notably because it was the pilot unit within the hospital and received a variety of orders as a general paediatric medicine unit. The unit comprises four medical teams, each led by one attending physician and composed of medical residents and students, and two clinical pharmacists, and four nursing stations.

All orders were handwritten into the patient's paper record before the implementation of the CPOE system. The hospital uses a pharmacy information system (PIS), an electronic medication administration record (eMAR) since 2017, a clinical data repository, as well as laboratory and radiology ancillary information system. Clinical and nursing notes are documented in paper records.

Data source and analysis

To evaluate the system's availability and usage, non-participant observation sessions (13 hours over 3 days in May 2019),[18 19] active participation to the project implementation team and content analysis of related documents (eg, internal presentations, training documents, discussions with stakeholders) were conducted to develop a better understanding of local usage practices. Free text observation notes and discussions on the medication management workflow were first documented in a table where each row corresponds to the observed user and each column corresponds to a step of the workflow and synthesised into a table describing the difference and similarities of the workflow before and after the CPOE implementation. A timeline of the implementation project was iteratively elaborated with stakeholders during the study period.

To evaluate outcomes, all medication-related incident or accident reports in the paediatric unit at the CHUSJ from 20 October 2018 to 21 October 2020 (ie, 1 year before and after the implementation of the CPOE on 21 October 2019) were extracted and analysed. These safety reports are manually collected by clinical staff on a routine basis as mandatory reporting to the Health Ministry if the error has directly affected the patient and required some monitoring or treatment (grade D or higher).[2] Data extracted from the reports were (1) description of the event, (2) type of event, (3) consequences observed for the person affected, (4) measures taken to avoid or limit the consequences, (5) declarant's proposed prevention strategy and (6) declarant's assessment of the severity. Additionally, drug categories, drug routes, type of events and type of proposed prevention strategy were thematically constructed based on categories used in similar studies.[20–24] Lastly, two pharmacists working in HIT identified additional technology-related prevention strategies by analysing the error's descriptions, which were compared with the declarants' proposed prevention strategies. This study was reported using the Statement on Reporting of Evaluation Studies in Health Informatics guidelines.[25]

RESULTS

Implementation project

The implemented CPOE system was PANDAWebRx,[26] a web application developed by CGSI@SOLUTIONS-TI in

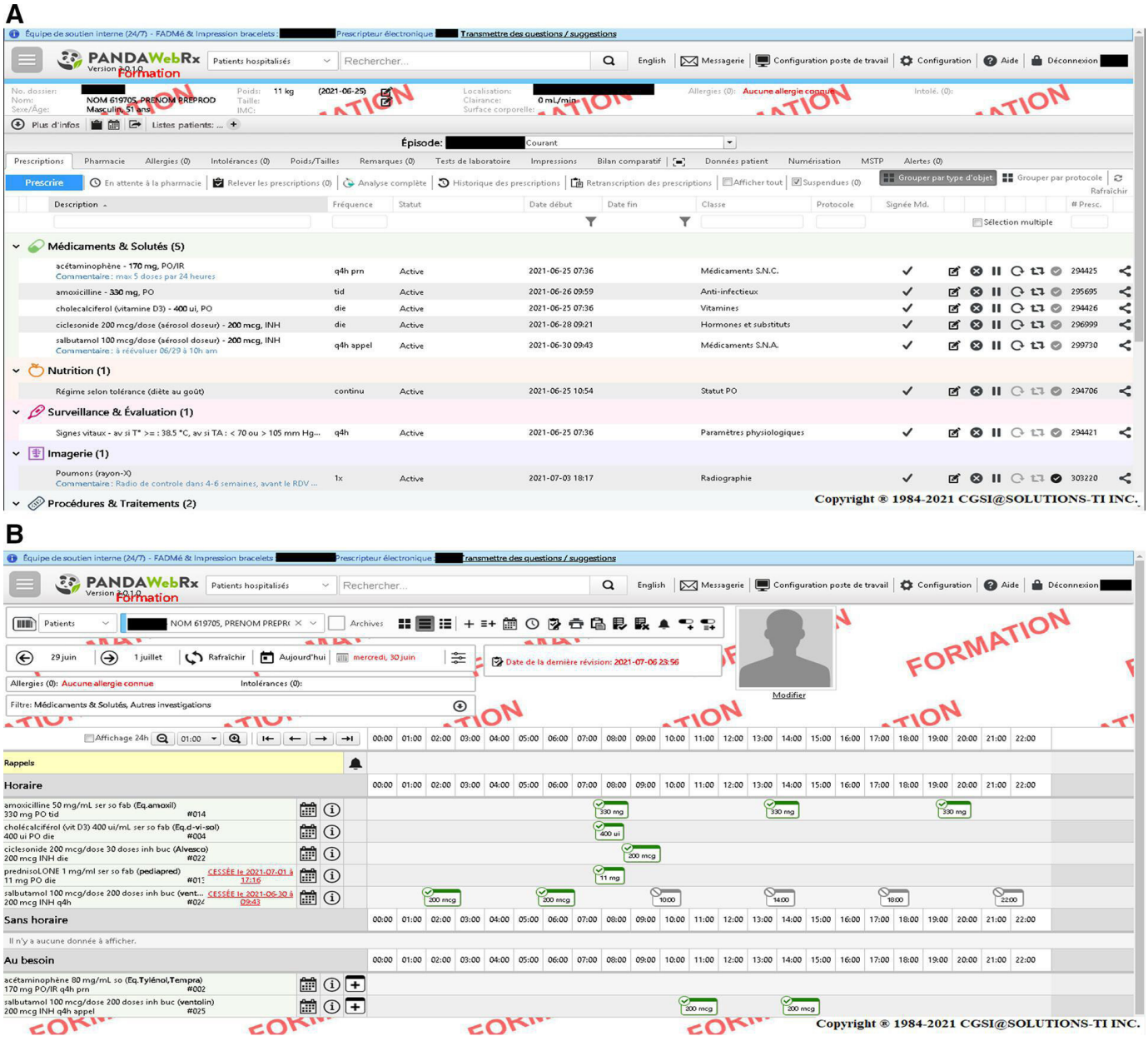

Figure 1 PANDAWebRx (Aa) CPOE view and (Bb) eMAR view. In the CPOE view, the provider can choose to group orders by type of orders (medication, nutrition, surveillance, imaging, etc.) or by protocol. Critical information for prescribing (weight, allergies, kidney function) is displayed on the top panel. CPOE, computerised provider order entry; eMAR, electronic medication administration record.

collaboration with the hospital project team (one clinical informatics manager and two full-time project managers). A previous usability analysis conducted a month before the implementation revealed the need to optimise the clinical decision support system (CDSS) to identify inappropriate dosing instructions for paediatric patients,[27] which is also known to be a recommended practice in the Safety Assurance Factors for EHR Resilience(SAFER) Guides.[28] The implementation process lasted more than a year (online supplemental figure 1). Order sets were developed by a team of clinicians on the paediatric unit to standardise the ordering process and ensure that they were adapted to the clinical workflows. Pilot testing occurred at each workstation during the summer of 2019 for periods of 48 hours. In the month prior to the Go-live, all physicians, nurses and other providers on the unit were required to complete online training modules (30–90 min), followed by in-classroom order scenario testing (60 min).

The Go-live occurred on 21 October 2019. On-site and phone line support was provided 24/7 for 4 months. Although the entire unit switched to electronic prescriptions, some rare paper prescriptions were still written in the first months following the Go-live. These paper prescriptions occurred when the prescriber, most often from another specialty, would want to prescribe using a specific formulary and had difficulty doing so with the electronic format. As of August 2021, the CPOE has been implemented in other hospital units.

Table 1 Number and rate of medication errors at each step of the medication management process before and after the CPOE implementation

	Medication errors				
	Pre-CPOE implementation For 28 302 orders		Post-CPOE implementation For 27 887 orders		Pre-CPOE versus post-CPOE implementation
Medication management process steps	n	Per 10 000 orders	n	Per 10 000 orders	Poisson rate ratio (95% CI)*
1. Ordering	8	2.8	9	3.2	0.9 (0.2 to 3.7)
2. Acknowledgement, transmission and transcribing	18	6.4	4	1.4	4.4 (1.1 to 32.5)
3. Pharmacy dispensing	5	1.8	2	0.7	2.5 (0.2 to 72.9)
4. Nurse administering	90	31.8	84	30.1	1.1 (0.7 to 1.6)
5. Patient monitoring	1	0.4	2	0.7	0.5 (0.0 to 27.2)
6. Other†	11	3.9	8	2.9	1.4 (0.4 to 5.7)
Total	133	47.0	109	39.1	1.2 (0.8 to 1.7)

*Rate ratio calculated with Bonferroni correction. A rate ratio greater than 1 suggests a higher error rate in the pre-implementation period, and a rate ratio lesser than 1 suggests a higher error rate in the post-implementation period.
†For example, (1) patient taking medication not provided by the hospital, (2) drug diversion.
CPOE, computerised provider order entry.

Description of the CPOE system

Previous versions of PANDAWebRx were used to prescribe drugs in adult settings. The new version was adapted for paediatric prescribing (eg, paediatric order sets). However, the system did not include paediatric dose range checking or other paediatric specific alerts since the development of a paediatric CDSS represented a separate feature that was not developed during the first phase of the CPOE implementation. However, the CPOE system integrated a CDSS (RxVigilance by Vigilance Santé) for allergies and drug–drug interactions alerts, which is deactivated by default and is interfaced directly with the hospital's PIS and eMAR. Figure 1 shows the screenshots of the CPOE and eMAR modules. The CPOE was designed by following many of the recommendations in the SAFER Guides to prevent unwanted consequences, as detailed in the online supplemental table 1.

Description of the medication management process

Based on a content analysis of the non-participant observation notes, project documents and discussions, we identified that the medication management process was significantly revised for the CPOE implementation (online supplemental table 2). Significant changes occurred for the ordering and acknowledgement, transmission and transcribing steps. Nurses were no longer tasked with scanning and transmitting the prescription to the pharmacy department. Furthermore, nurses acknowledged new prescriptions electronically and would import the CPOE data to the eMAR without manual transcription. Similarly, in the pharmacy department, pharmacy technicians would import the order information instead of manually transcribing the orders. After importing the CPOE data into the PIS, the pharmacy technicians would complete the order with other required information (eg, dispensed drug product, pharmacy comments).

Medication errors

A total of 133 and 109 medication-related accidents and incidents were reported during the pre-implementation and post implementation periods, respectively. Medication-related errors in the paediatric unit represented 31% (133/429) and 23% (109/466) of all types of medical incidents/accidents in pre-implementation and post implementation periods, respectively. There were no statistically significant differences when comparing the proportions for the drug categories, drug routes, time of incident/accident or severity, except for a difference in reports related to drugs with buccal administration and errors with a severity level of A (online supplemental table 3). The majority of the reports were adverse events that did not lead to any patient consequence (72% and 73% of the reports in preperiods and postperiods, respectively). A similar analysis conducted to evaluate the effect of the COVID-19 pandemic by comparing reports from the first 6 months of the pandemic (March to October 2020) with the same period a year before revealed no differences for all variables.

Most of the medication errors occurred during the nurse administering step (step 4) (table 1). The rate ratios for each step were not significant, except for the order acknowledgement, transmission and transcribing steps (step 2; rate ratio: 4.4, 95% CI 1.1 to 32.5), which represented the second most common type of errors in the pre-implementation period. Overall, there is a slight, but not significant, reduction in the total number of medication errors between the two periods (rate ratio: 1.2, 95% CI 0.8 to 1.7). Medication errors during the ordering step

Table 2 Examples of errors identified at each step in the inpatient medication management process before and after the CPOE implementation

Medication management process step	Examples	
	Pre-CPOE implementation	**Post-CPOE implementation**
1. Ordering	1. Lack of countersignature from the paediatric team for prescriptions from external consultants. 2. Therapeutic duplication.*	3. Wrong drug selected from the drop-down menu (eg, immediate vs extended-release propranolol), leading to a decrease in blood pressure and heart rate.† 4. Use of manuscript prescriptions instead of CPOE formularies for a patient requiring insulin, leading to hyperglycaemia.‡ 5. A nurse stopped a drug order without approval from the medical team. 6. Wrong drug ordered verbally.*
	7. Wrong patient order. 8. Wrong prescription weight.	
2. Acknowledgement*, transmission and transcribing	9. Order not transmitted to the pharmacy department ((a) prescription already faxed and then modified; (b) prescription never transmitted), resulting in patients not receiving their treatment, or receiving their treatment at the wrong time.† 10. eMAR not updated with discontinuation of treatment. 11. Transcription error in the eMAR (wrong patient, wrong medication).	12. Transcription error in the eMAR (wrong route of administration; eg, ear drops vs eye drops) due to incorrect system configuration.
	13. Confusion related to the use of automatic comments on orders (eg, all inhaler orders have a comment mentioning that the drug will be administered by a respiratory therapist, although not everyone was aware).*	
3. Pharmacy validation and dispensing	14. Preparation error (wrong quantity).*	15. See common examples listed below.
	16. Drug not prepared by the pharmacy department (closed).* 17. Drug missing from dispensing cabinet.*	
4a. Nurse administering—preparation	18. See common examples listed below.	19. eMAR did not reflect the accurate medication list (not refreshed).* 20. Incorrect reading leading to the wrong dose of insulin (25 units vs 2.5 units), resulting in a rapid glycaemia decrease.*†
	21. Wrong dose administered. 22. Wrong timing (too early or too late) (eg, not receiving Tylenol, leading to fever).‡ 23. Lack of compliance with controlled drug policies. 24. Lack of double checking for high-risk medications. 25. Drug administration not documented accordingly (the drug was administered but not documented, or the drug was not administered but documented as administered).†	
4b. Nurse administering—bedside administration	26. See common example listed below.	27. Drug administered incorrectly (intravenous compatibility issues, wrong dilution).*† 28. Drug administered to the wrong patient.*
	29. Drug at the patient's bedside but not administered.	
5. Patient monitoring	30. No monitoring (therapeutic adjustments).	

*Examples that were reported during one of the two periods and are specific to the process studied. They might not be related to the use (or lack of) of the CPOE.
†Events of severity D (adverse event requiring additional verifications but not leading to patient consequences).
‡Events of severity E1 (adverse event leading to patient consequences).
CPOE, computerised provider order entry; eMAR, electronic medication administration record.

(step 1) did not decrease after the CPOE implementation (rate ratio: 0.9, 95% CI 0.2 to 3.7).

Examples of medication errors during both periods are presented in table 2 and grouped by the stage of the medication management process. There were notable differences between the types of errors occurring before and after the CPOE implementation, primarily at the ordering (step 1) and acknowledgement, transmission and transcribing (step 2) steps (table 1), which correlates with the considerable changes at these steps in the medication management process (online supplemental table 2).

At the ordering stage, the CPOE standardised mandatory steps (eg, required countersignature for orders from external consultants) (example 1) and formalised steps that were previously not electronically documented (example 5). Furthermore, although the CPOE was designed to enable all possible order scenarios, some orders were prescribed on paper (example 4), which delayed the order. At the acknowledgement, transmission

Table 3 Event review approaches and specific categories with frequency counts and percentages before and after the CPOE implementation

Type of approach	Type of recommendation	Pre-CPOE implementation		Post-CPOE implementation	
		n=232	%	n=199	%
Person-based approach	Vigilance	112	48	72	25
	Counselling	52	22	63	32
	Education or training of healthcare workers	37	16	45	30
	Education or training of patient or family	4	2	5	2
	Referral to peer review	7	3	7	9
System-based approach	Specific system factors identified and changes being implemented	6	3	2	1
	Referral for process improvement	6	3	1	0
No approach	Monitoring	3	1	1	0
	No recommendations	5	2	3	1

CPOE, computerised provider order entry.

and transcribing steps, the electronic transmission of orders ensured that there were no transmission errors (example 9), and that the order information was correctly entered in the other systems (examples 10 and 11). Types of errors that were common to both periods occurred most frequently at the nurse administering stage, specifically during the preparation of the order. These include the preparation of orders with the wrong dose or wrong frequency, as well as documentation errors (examples 21, 22 and 25).

Lastly, although some examples were only reported during one of the two periods, these errors might not be related to the use (or lack of) of the CPOE. Instead, some examples could be due to other factors, such as technical factors (eg, eMAR usability: examples 19 and 20), human factors (eg, staff's knowledge and skill: example 27) or organisational factors (eg, structure, culture, processes: examples 13, 16 and 17).

Recommendations for preventing medication errors

A total of 232 and 199 recommendations were extracted from the medication error reports and categorised based on the proposed taxonomy by Franklin *et al*[21] (table 3). The most frequent types of recommendation during both periods were vigilance (eg, always make sure to check the patient's eMAR carefully), counselling (eg, met with the nurse to review event) and education/training of healthcare workers (eg, redo training on diabetes, event discussed during 5 min staff huddles), which are person-based approaches. There were few system-based approaches (eg, speaking with the pharmacy department to ensure that medication orders with irregular frequency are prepared accordingly).

On the total of 133 and 109 drug errors reported in the pre-implementation and post implementation periods, respectively, two pharmacists reviewed all reports and identified potential HIT-related prevention strategies for 85 (64%) and 64 (59%) of the pre-implementation and post implementation error reports. The remaining error reports were mainly associated with human and organisational factors and no technology-related prevention strategies were identified (table 4).

DISCUSSION

Impact of the CPOE system on medication errors

Although e-prescribing systems have been previously evaluated in Canada, notably in outpatient settings,[29] we believe, to the best of our knowledge, that this is the first study that evaluates the impact of an inpatient CPOE on medication safety in Canada. In 2021, less than 20% of the specialist physicians in the country used a system that could send orders electronically.[30] By comparison, in 2016, 95.6% of the hospitals in the USA, where the majority of the CPOE evaluation studies were conducted, have adopted a CPOE with CDSS.[31] Therefore, this study was conducted in a unique context in which the CHUSJ was an early adopter of a new, locally developed commercial CPOE with limited decision support. In addition, very few pre-post studies have been conducted to evaluate the impact of CPOEs in paediatric settings.[32] Thus, by conducting a thematic analysis of the safety reports, we were able to target specific types of medication errors and identify potential prevention strategies adapted to the needs of this population.

The mixed-methods evaluation of the impacts enabled the identification of the main challenges related to the implementation of the CPOE based on the error frequencies, while contextualising the error rates with an analysis of the changes to the local practices. For instance, although the ordering process was significantly reviewed with the implementation of the CPOE, there was no difference in the rate of errors, which was also observed in previous studies[32] and could be due to the small

Table 4 Potential HIT-related prevention strategy identified for all medication errors before and after the CPOE implementation

Medication management process step	Potential HIT-related prevention strategy	Pre-CPOE implementation		Post-CPOE implementation		Examples of use based on error reports
		n=85	% of all reports	n=64	% of all reports	
Ordering	Electronic medication reconciliation.	1	1	0	0	Importing preadmission medication data directly from the provincial health record into an electronic medication reconciliation application to reduce discrepancies between preadmission and admission orders.
	Prescribing clinical decision support system (CDSS).	3	2	1	1	Generating patient-specific recommendations and preventing weight-based dosage errors (eg, (1) nurse calculated acetaminophen dose based on the recommended dose in mg/kg, but did not respect the maximum recommended dose, (2) alerting the prescriber when a weight that seems erroneous is entered based on growth charts).
	Configuration of the computerised provider order entry (CPOE).	NA	NA	4	4	Increasing the font size for the dose field to prevent the administration of the wrong dose (eg, 25 units of insulin vs 2.5 units).
Acknowledgement, transmission and transcribing	Use of a CPOE.*†	19	14	3	3	Implementing a CPOE to ensure that orders are acknowledged in a timely manner and transmitted automatically to the pharmacy department.
Pharmacy validation and dispensing	Pharmacy information system.	0	0	0	0	NA.
Nurse preparation	eMAR usability.	51	38	51	47	Improving the eMAR's usability to facilitate periodic review of the medication list. Displaying alerts to ensure timely administration of medications and proper documentation.
Nurse administering	Bar code medication administration (BCMA)/Radio Frequency Identification (RFID).	7	5	5	5	Using medication bar code to identify drug name (and fluid and electrolytes), dose and form.
	Intravenous interoperability (between CPOE and medication pump administration).	4	3	0	0	Using an interface between the CPOE and medication pump administration to import the prescribed intravenous infusion rate to the pump.

*Difference in proportions based on Pearson's χ^2 test not significant for all variables, except for errors that were related to the use of the CPOE: 11.5% (95% CI 4.0% to 19.1%).
†In post implementation, errors from this category were related to the failure to use the CPOE to prescribe.
eMAR, electronic medication administration record; HIT, health information technology.

number of errors at this step. However, the types of error differed between the two periods, as shown in the examples in table 2. Further system improvements could focus on preventing configuration-related errors (eg, drop-down selection errors) and preventing wrong patient weights and dosages from being entered, as suggested in a previous publication on the system's usability.[27]

Furthermore, 19 out of 133 error reports in the pre-implementation period could have been prevented by adopting a CPOE, whereas 4 out of 109 error reports in post implementation could have been prevented by improving the CPOE's configuration. This finding suggests that the CPOE managed to prevent medication errors and led to very few technology-induced detrimental effects. The low number of technology-generated errors could be related to the application of techniques used in successful HIT implementations, such as the involvement of prescribers in the system design and the training of colleagues, the modification of the CPOE in response to feedback and the direct observation of prescriber workflow.[33]

Improving risk assessment

The medication error rate in this study, which was 0.4 errors per 100 orders (242 per 56 189 orders) overall, was lower than reported in previous publications.[32] However, a systematic review revealed that the prevalence of medication errors among paediatric inpatients is highly variable.[32] The lower error rate could be attributed to the hospital's safety culture,[34] and by how medication errors were defined and captured. The combination of multiple data collection methods at different point of medication management process (eg, ordering, administration) can be helpful to assess the prevalence of medication errors fully. However, this approach is resource and time intensive. Developing a more proactive and data-driven system could provide a more accurate risk assessment[35] and

inform future system optimisation. Furthermore, the use of an event reporting system integrated with the other systems could also improve the quality of the data found in these reports (eg, less missing data, typing errors).

Improving error reporting recommendations

Declarants for most reports proposed only person-based recommendations, which are generally less effective in the long term.[21] The declarants proposed very few system-based approaches, which could help further reduce the rate of errors.[36] When reviewing the events description through an HIT lens, the most frequent potential prevention strategy was improving the eMAR's usability to ensure timely administration of medications. The Institute of Safe Medication Practices guidelines recommend 'changing the appearance of a medication entry for delayed doses in eMARs, setting different time limits for the removal of scheduled medications from automated dispensing cabinets, highlighting time-critical scheduled medications on eMARs, differentiating between first doses and subsequent scheduled doses, displaying alerts to show doses that will soon be overdue or that have been omitted'.[37] As of September 2021, the hospital has been working on the implementation of a feature for the nursing dashboard that would highlight delayed medication administration. Previous studies have also suggested that other potential prevention strategies, such as bar code medication administration, CDSS and intravenous interoperability systems, could also reduce medication errors.[38–40]

Limitations

This study has a few limitations. First, this study was based on data from error reporting, which is mandatory only when there are patient consequences. Therefore, although stable through the study period, the prevalence of medication errors is likely higher than reported in this study. Indeed, the low error rate could be attributed to on-unit pharmacists reviewing the medication regimen during ordering, thus preventing errors from reaching the patient. Additionally, this study was conducted in only one pilot unit. However, the general paediatric unit represents the largest unit in the hospital, and the results from this study will serve to inform the implementation process in other units. Furthermore, it is possible that there were fewer error reports in the first month following the CPOE implementation due to the constant support from the implementation team.

CONCLUSION

This study highlights the importance of improving the usability of the eMAR to further reduce the number of medication errors. Error reports could be improved by developing a proactive event reporting system and system-based recommendations.

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Contributors MQL, MT, PJ and AM conceptualised the study and developed the methodology. MQL, MT and M-PM collected the data. MQL, MT and TS conducted the formal analysis. MQL wrote the original draft and acted as guarantor. MT, PJ, M-PM and AM reviewed and edited the draft. PJ, DL and AM acquired the funding and supervised the project.

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Patient consent for publication Not applicable.

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