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Implementation of 2D Barcode Medication Labels and Smart Pumps in Pediatric Acute Care: Lessons Learned

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Abstract

Background In pediatric intensive care, prescription, administration, and interpretation of drug doses are weight dependent. The use of standardized concentrations simplifies the preparation of drugs and increases safety. For safe administration as well as easy interpretation of intravenous drug dosing regimens with standardized concentrations, the display of weight-related dose rates on the infusion device is of pivotal significance.

Objectives We report on challenges in the implementation of a new information technology-supported medication workflow. The workflow was introduced on eight beds in the pediatric heart surgery intensive care unit as well as in the pediatric anesthesia at the University of Bonn Medical Center. The proposed workflow utilizes medication labels generated from prescription data from the electronic health record. The generated labels include a two-dimensional barcode to transfer data to the infusion devices.

Methods Clinical and technical processes were agilely developed. The reliability of the system under real-life conditions was monitored. User satisfaction and potential for improvement were assessed. In addition, a structured survey among the nursing staff was performed. The questionnaire addressed usability as well as the end-users' perception of the effects on patient safety.

Results The workflow has been applied 44,111 times during the pilot phase. A total of 114 known failures in the technical infrastructure were observed. The survey showed good ratings for usability and safety (median "school grade" 2 or B for patient safety,

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intelligibility, patient identification, and handling). The medical management of the involved acute care facilities rated the process as clearly beneficial regarding patient safety, suggesting a rollout to all pediatric intensive care areas.

Conclusion A medical information technology-supported medication workflow can increase user satisfaction and patient safety as perceived by the clinical end-users in pediatric acute care. The successful implementation benefits from an interdisciplinary team, active investigation of possible associated risks, and technical redundancy.

Background and Significance

Medication errors are among the most serious patient events, causing significant physical and psychological harm as well as a substantial burden to the health care system.[1,2] Medication errors are both more frequent and more likely to cause complications in children compared with adults.[3,4] The most common medication errors include dose errors, drug preparation errors, and incorrect rates of intravenous administration.[4,5]

In pediatric acute care medicine, prescription, administration, and evaluation of drug doses are highly weight dependent, with patients' weights ranging from a few hundred grams to more than 100 kg. Consequently, the required total dose rate (i.e., the amount of active substance to be administered per unit of time) can often differ by several orders of magnitude in patients in immediately adjacent beds. At the same time, an identical volume rate of the same medication in two patients can correspond to an actual amount of active substance per unit of body weight that differs by three orders of magnitude. Preparation of patient-specific drug concentrations for continuously administered drugs is therefore still common in German pediatric care. These allow for a fixed relationship between volume rate and dose rate per unit of body weight and thus, when using pumps that display volume rates, facilitate bedside evaluation as well as straightforward comparability of drug doses between patients with very different body weights. However, preparing medication individually per patient induces an increased risk of errors in the process of preparation as well as severe consequences of patient misidentification when administering the prepared medication. The use of standardized drug concentrations simplifies the process and reduces medication errors.[6,7] The Institute for Safe Medication Practices as well as the Vermont Oxford Network, therefore, recommend patient-specific drug concentrations to be abolished, making standard concentrations for medication infusions a requirement for hospital accreditation in the United States and Canada.[8–10]

However, using standardized drug concentrations, fixed ratios between volume rate and dose rate per body weight (by altering the drug concentration relative to the patient's body weight) are no longer achievable. Thus, for the proper interpretation of the actual amount of active substance per body weight, a calculation is required. Nearly all severe dosing errors in pediatric patients have been found to be associated with the incorrect use of equations or calculation errors.[11] Furthermore, when using infusion devices that display volume rates only, this calculation is quite time-consuming and prone to potentially dangerous calculation errors, especially when performed by mental calculation under stressful conditions in intensive care units.[12]

To mitigate this error source, smart pumps can display weight-adapted dose rates (e.g., µg/kg/min) using a built-in dose-rate calculation tool. However, such a tool requires manual input or selection from preconfigured choices of the drug concentration, the patient's weight, and the prescribed dose rate at least. With critically ill patients typically receiving up to 20 drug infusions simultaneously, the manual entry of these data on each device is very time-consuming and error prone. A method is therefore needed to transfer these data in a fully or partially automated way from the prescription software system to the infusion device. Automatically generated machine-readable labels (e.g., barcodes) applied to the medication preparation (e.g., syringe), combined with appropriate adaptations of clinical workflows, are one approach to achieve this goal.[13] In addition, an identification step (e.g., by scanning patients' wristband barcode) to ensure that the medication was prescribed for the patient at hand can greatly decrease medication errors.[14] Unfortunately, integrating such systems and making them reliable and usable under real-life clinical conditions is not trivial.[15]

Objectives

To prepare for the rollout of the above-mentioned approach across the University Hospital Bonn pediatric intensive care units and anesthesiology workplaces, a new technology-supported medication workflow was piloted on eight beds in the pediatric heart surgery intensive care unit as well as in the pediatric anesthesia at the University Hospital Bonn. As in many German pediatric acute care facilities, the prescription was exclusively performed by medical doctors, while both the preparation and administration of prescribed medications were usually performed by nursing staff. The infusion pumps and related equipment were installed and maintained by the local medical device technology department, while the patient data management system used for prescription and administration documentation as well as the label printers were installed and maintained by the local information technology (IT) department. Our current research investigates (1) challenges and pitfalls in the process

of workflow implementation, (2) technical problems and solutions to these problems that enable high availability under real-life clinical conditions, as well as (3) usability, user acceptance, and effects of the proposed workflow on patient safety as perceived by the clinical end users.

Methods

Both system engineering tasks and clinical workflow adaptation planning were guided and implemented by the interdisciplinary staff unit for Medical and Scientific Technology Development & Coordination (MWTek), which also coordinated cross-departmental activities and consensus processes. The MWTek team comprises experienced intensive care nurse practitioners with additional academic qualifications as well as medical doctors with clinical experience in pediatric acute care and additional training in medical informatics. The same team also performed the technical acceptance tests.

Clinical and technical processes were subjected to stress tests, including specific attempts to induce possible errors, as well as extensive clinical simulations before being transferred to the clinical environment. Three separate systems (development, testing/configuration, and staging) were used to develop and evaluate the implementation before changes were applied to the clinical production system.

Continuous monitoring of technical availability and robustness was implemented. Redundancy was provided for identified critical points of failure (e.g., the label printers).

The drugs were prescribed using the integrated order entry system of a patient data management system (PDMS, Integrated Care Manager, Drägerwerk, Lübeck, Germany). The data were exported from the electronic medication administration record of the PDMS using the integrated proprietary script language. A PowerShell script (PowerShell Core 2.0, Microsoft, Redmond, Washington, United States) was used to generate the description language TSPL for the label printer (TC300, TSC, New Taipei City, Taiwan) from these data while strictly avoiding any dose or unit calculation. All calculations were made exclusively within the CE-labeled medical devices (Dräger ICM, risk class IIa, and B. Braun Space [B. Braun, Melsungen, Germany], risk class IIb) in strict accordance with the intended use of the medical devices. As a result, self-adhering, disinfectant-resistant labels could be printed directly from the PDMS by the prescribing physician. Drug name, concentration, and patient identification were printed on that label in both plain text and stored in a 2D barcode that could be read by the scanners supplied with the infusion devices. The same clinically established medication standards and the same infusion devices (B. Braun Perfusor, Space, Infusomat Space, SpaceStation with SpaceCom Dockingstation, Barcode Scanner Space) were used in all investigated areas.

Clinical implementation was slowly ramped up starting with four intensive care unit (ICU) beds and one pediatric cardiology/cardiac surgery operation room starting May 27, 2019 and extending to eight beds and two operation rooms starting October 14, 2019. The implementation was closely monitored by the implementation team. Users were actively asked in regular intervals for possible improvements and problems experienced when using the workflow. Initially, this was performed at least once per work shift (i.e., three times per day), and to date a regular meeting with the users is held at least once per month. The final workflow was analyzed using a failure modes and effects analysis (FMEA).[16]

In February 2020, a self-report survey (see ►**Supplementary Appendix A**, available in the online version) was completed by nursing staff in the ICU who routinely prepare and apply the medication according to the physicians' orders. The questionnaire consisted of six closed questions (Likert-type scales graded from 1 = very good to 6 = insufficient) and an open question asking for "other feedback, criticism, and comments."

Results

Workflow

The clinical and technical workflows were agilely developed in parallel. The aim was to manage and mitigate as many risks as possible using medical informatics tools and to use manual mitigation measures only if the former was currently not possible.

Technical Workflow

The medication configuration in the PDMS was optimized step by step and consented across clinical teams using previously established hospital-wide change and configuration release management processes for the PDMS. Similarly, for the corresponding medication database and firmware configuration of the infusion devices, university hospital-wide consensus, standardization, and change management process were established to ensure uniform functionality and system behavior across all hospital departments using the infusion pumps (with 23 involved departments significantly larger subset of the seven clinical departments using the PDMS).

Risks and Mitigation Measures

Patient Misidentification

This common risk is addressed by the seamless transport of case IDs from PDMS to the medication labels and a final technically supported cross-check of patient identification by the infusion pump by scanning a patient identification label attached to the patient or bed/incubator.

This built-in process identifies the patient to the smart pump and allows the device to reject every medication that was not prescribed and compounded for this patient. The smart pumps do allow the medical personnel to skip this identification step for emergency situations (e.g., in case of an unknown emergency patient).

Labeling Based on Erroneous Orders

Support for and enforcement of guidelines and local standard operating procedures (SOPs) was included in the

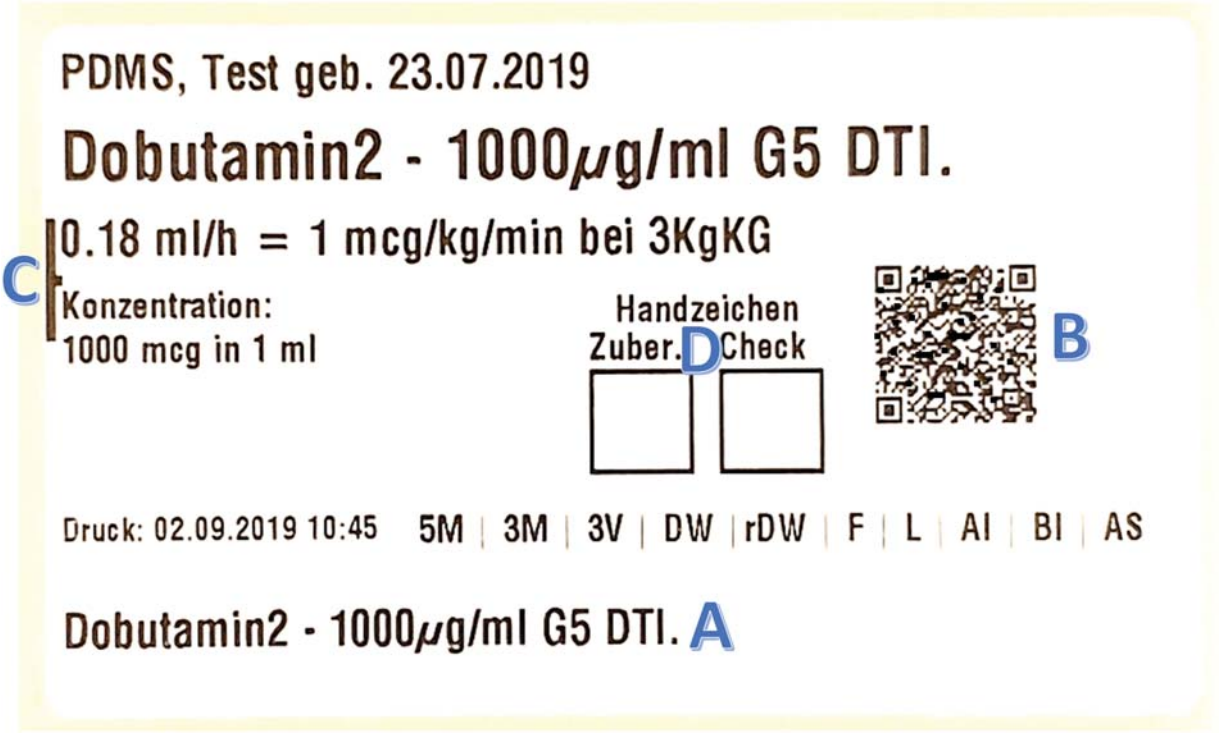

Fig. 1 Medication label. (**A**) Detachable part for labeling the infusion line. (**B**) 2D barcode with a cell width of three dots (using a 300 dots per inch printer) and an error correction recovery level of 15%. (**C**) Marker to help align the label with the scaling of the syringe for optimal readability even when the syringe is already placed into the infusion device. (**D**) Space for initials to be signed by the respective specialist for preparation and final verification of the prescription. Line three contains the prescribed volume rate, as well as the default dose rate per kilogram of body weight and the child's body weight used for the calculation.

configuration of PDMS and infusion device medication databases to reduce prescription errors.

In particular, in both clinical simulations and practical application, the respective prescription and administration units were found to be critical sources of errors and possible misunderstandings (e.g., confusion between mg/kg/min and mcg/kg/min or misinterpretations of mg/kg/h as mg/kg/d). Test scripts were developed for the PDMS and infusion device configuration to detect possible configuration inconsistencies and errors prior to each configuration release. Test coverage included the detection of unit inconsistencies both within and across PDMS and infusion device configurations.

Data extraction based on the proprietary scripting language integrated into the PDMS was designed in such a way that obviously inconsistent orders cannot be printed. The limited functionality of the integrated scripting language does not allow "smart" detection of prescription errors, but can, for example, exclude prescriptions with prescription modes that are not permitted or do not make sense for infusion devices (e.g., enteral prescriptions).

Technical Failure of Label Printing Procedure

The printing process is realized via a RAW driver in the TSPL description language of the printer to avoid formatting errors and to improve performance to under 1 second per label. The bedside PDMS fat clients use a print server, whereas the three independent PDMS terminal servers permitting remote access to the PDMS user interface from arbitrary computers on the hospital network each use local printer queues to create redundancies for a failure of individual printer management components. Two independent thermal printers per ward can be individually selected by the users.

Failure of Labels to be Readable or Scannable

The physical properties of the drug labels have been optimized in size and texture to fit the syringe types and environmental conditions in which they are clinically used while still offering good readability for the human eye and the barcode scanners (►Fig. 1). We finally chose 75 × 45 mm self-adhering disinfectant stable thermal printer labels with a detachable 75 × 5 mm part for labeling the infusion line (►Fig. 1A).

The cell size of the two-dimensional (2D) barcode has been maximized to allow for the easiest and most stable readability through the scanner of the infusion device while still being small enough to not be obscured by the surface curvature of the smallest syringes used, which was found to prevent successful scanning of 2D barcodes above a certain size. In several clinical simulations, we found a cell width of three dots (using a 300 dots per inch printer) with an error correction recovery level of 15% to give the most reliable results under real-life clinical conditions (►Fig. 1B). A marker has been added to help align the label with the scaling of the syringe for optimal readability even when the syringe is already placed in the infusion device (►Fig. 1C).

Failure of Label Content to Agree with Current Prescription at Time of Initiation of Drug Administration

The most prominent process risk for which no direct technical or automated mitigation measures could be found under the given conditions is the possibility of divergence of the current prescription from the prepared and labeled drug when initiating administration even though the drug was prepared correctly as prescribed. We concluded that here, given our current technological capabilities, a final manual verification step before initiating drug administration is indispensable for two reasons: First, new incoming information or very recent clinical developments of the patient's condition (e.g., unexpected onset of an acute hemorrhagic shock) may enforce a change of the prescription after the label has been printed. Second, possible technical errors in the transfer of data from the PDMS to the label and from the label to the infusion device cannot be excluded with certainty and thus must be detected before administration.

Integrated Clinical and Technical Workflow

The clinical process including all risk mitigation measures described above starts with the prescription of the medication in the PDMS based on preconfigured standards which include the concentration of active substance(s), base diluent where applicable, and route of administration. Body weight-based medication calculations are based on a medication weight which is part of the prescription (explicitly verified and ordered by the responsible physician) and can—under special clinical circumstances (e.g., fluid accumulation)—differ from the actual physical weight of the patient. On the day the medication is administered or just in time, the medication labels are printed. The labels are then used by the physician, a pharmaceutical technician, or a specialist nurse to prepare the prescribed medication according to the individual choice of standardized drug concentrations. Verification of correct preparation, including active substance(s), concentration, and base diluent, is documented by the respective specialist by signing the label in a designated space (►Fig. 1D). Just in time for the beginning of the administration, the nurse practitioner or physician compares the prepared medication with the current prescription in the PDMS. The syringe is then inserted into the infusion device. The infusion device prompts the input of a patient and stay-specific case number, which is attached to each patient's bed or present on the patient's wristband and has to be entered using a handheld scanner attached to the infusion pump docking station (B. Braun SpaceCom). The 2D barcode on the medication label is then scanned. The infusion device prompts the confirmation of each data element transferred by the 2D barcode, including the name of the medication, drug concentration, and patient's weight. The infusion device displays an error notification if the first scanned patient and stay-specific case number does not match with the one transferred by the 2D barcode on the medication label, thus preventing administration to the wrong patient.

The weight-adapted dose rate is set on the pump as prescribed (e.g., "0.05 micrograms per kg body weight per minute"). Additionally, the volume rate is displayed by the infusion device and is crosschecked with the prescription.

The final workflow is shown in ►Fig. 2.

We also conducted a FMEA for the final process shown in ►Table 1. Each potential failure mode was listed with its causes, effects, and mitigation measures and ranked for severity (S), likelihood of occurrence (O), and likelihood of detection (D). A risk priority number (RPN) was calculated by multiplying S, O, and D.[16]

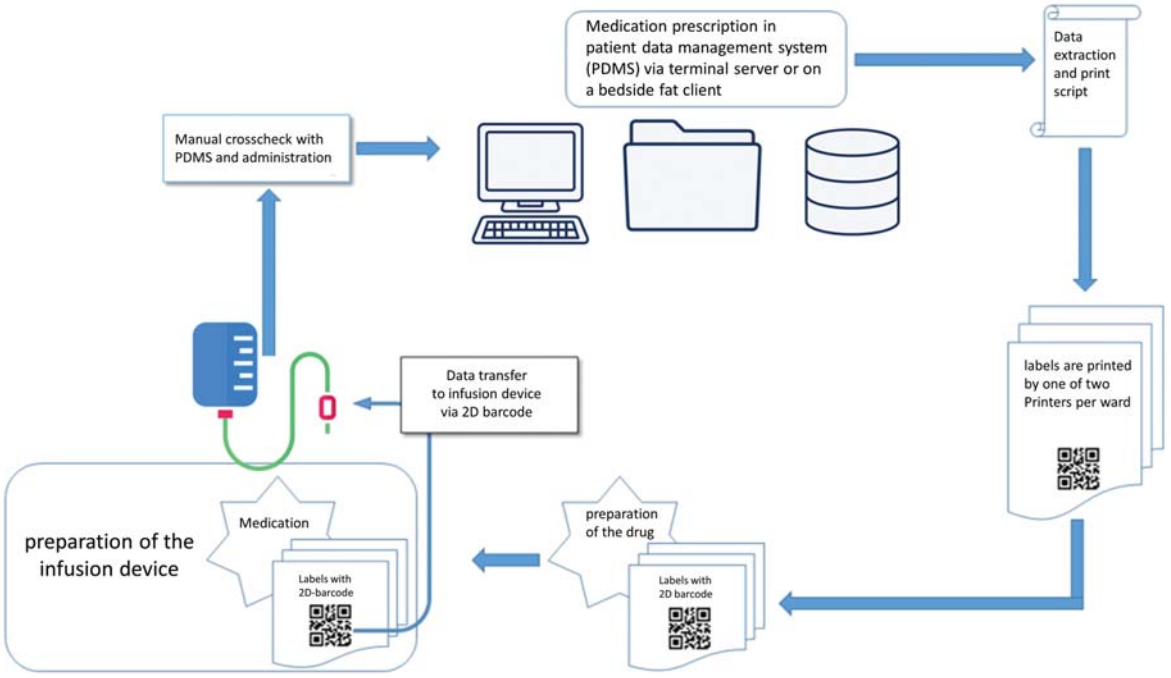

Fig. 2 Workflow. Schematic illustration of the final workflow.

Table 1 Failure mode effect analysis

Process step	Potential failure mode	Cause of failure	Potential effects of failure	S[a]	O[b]	D[c]	RPN[d]	Applied process mitigation measures	Estimated effects of mitigation measures
Prescription	Prescription error by physician	Lack of knowledge, lack of time, lack of information, etc.	Severe patient harm or death	10	4	6	240	Medication database with preconfigured standards and warnings	Reduction of O and D
	Configuration errors favoring incorrect prescriptions	Lack of knowledge, lack of time, lack of information etc.	Severe patient harm or death	10	1	2	20	Four eyes principle, manual and (partly) automated testing in development and Staging before release	Reduction of O
Data extraction and Label Printing	Technical failure leading to dangerous change of label information	Unknown cause	Severe patient harm or death	10	1	3	30	Manual crosscheck of the setup infusion device with the prescription on the beside PDMS-monitor right before the start of administration	Reduction of D
	Technical failure leading to inability to print labels	Printer failure, Printer queues management failure, etc.	Use of more time consuming backup process with higher risks of error	4	3	5	60	Independent redundancy and surveillance of printing infrastructure (2 Printer per ward, double redundant printer queues management)	Substantial reduction of O and D
Drug preparation	Failure in drug preparation/drug not matching the label	Lack of knowledge, lack of time, lack of information etc.	Severe patient harm or death	10	2	9	180	Highly standardized medication preparation, correct preparation is documented by the respective specialist by signing the label (►Fig. 1D).	Reduction of O
Drug administration	Patient misidentification	Lack of knowledge, lack of time, lack of information, etc.	Severe patient harm or death	10	2	4	80	Clearly labeled medication and cross check by the infusion device by scanning a patient identification label attached to the patient or bed/incubator	Substantial reduction of O and D
	Failure of label content to agree with current prescription	Change of prescription after printing and before administration	Severe patient harm or death	7	3	4	84	Final manual cross-checking of the current Prescription with the label	Reduction of D

Abbreviation: D, detection; O, occurrence; RPN, risk priority number; S, severity.

Notes: Each potential failure mode listed with its causes, effects, and mitigation measures ranked for severity (S = 1: slight annoyance to 10: severe patient harm or death), likelihood of occurrence (O = 1: no known occurrence to 10: almost certain), and likelihood of detection (D = 1: always to 10: detection nearly impossible).

An RPN was calculated by multiplying S, O, and D.[16]

[a]Severity (S = 1: slight annoyance to 10: severe patient harm or death).

[b]Likelihood of occurrence (O = 1: no known occurrence to 10: almost certain).

[c]Likelihood of detection (D = 1: always to 10: detection nearly impossible).

[d]RPN calculated by multiplying S, O, and D.

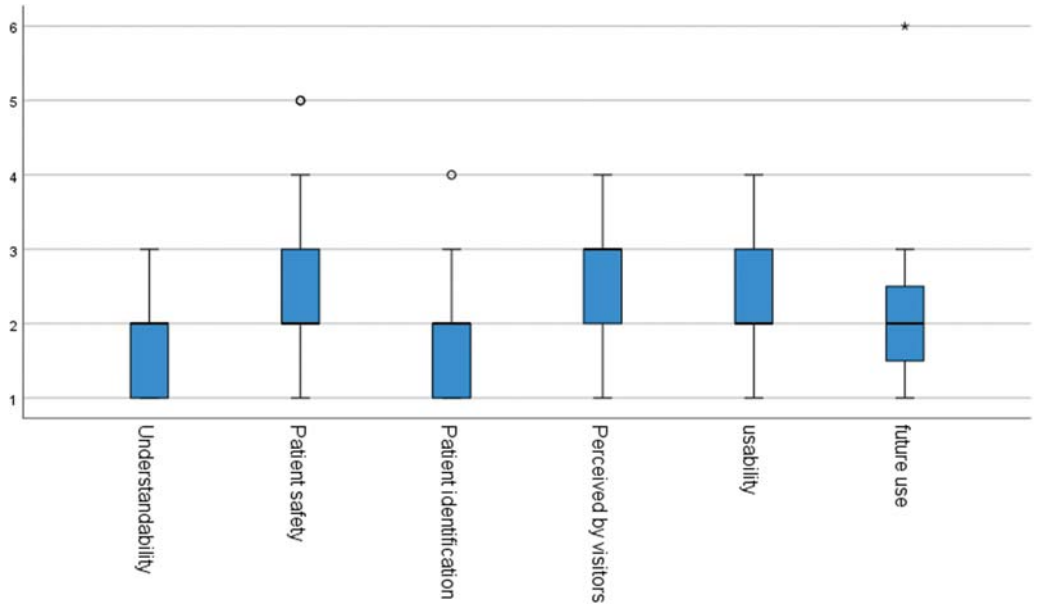

Fig. 3 Box plots of questionnaire answers (19 completed questionnaires from 33 caregivers, answer graded from 1 = very good, to 6 = insufficient).

Technical Functionality

Between May 2019 and February 2020, the workflow was used 44,111 times. The technical and procedural security mechanisms led to the identification of several software errors in the medical devices involved. These were immediately communicated to the respective manufacturers and have since been addressed. During the pilot phase, a total of 114 known failures in the technical infrastructure occurred, namely printer defects (109 errors), server malfunction (two errors), and medical technology electromechanical malfunctions (scanner/scanner interface, three errors). All these errors were successfully mitigated by redundant technical infrastructure (two printers per site, three-terminal servers, and replacement scanners) resulting in no known effective downtime of the new standard process. Only a fraction of the technical failures was actively reported by the users before the implementation team specifically asked for problems. As part of a planned maintenance procedure of the PDMS servers, the process was interrupted once for 7 hours without technical redundancy requiring a fallback to paper-based backup processes.

After the successful completion of the pilot phase and further rollout to the remaining pediatric intensive care units, failures of individual print management components, in particular the printer queues on the terminal servers, occurred with increasing frequency (e.g., due to accidental attempts to print a discharge report on the medication label printer). We therefore also had to establish a monitoring and failure alerting infrastructure for these components to minimize response times to technical failures.

User Evaluation

We received 19 completed questionnaires from 33 caregivers working on the pilot ward. The caregivers gave good ratings for usability and safety (median "school grade" 2 or B for patient safety, understandability, patient identification, and handling). Most of the users were indifferent regarding the perception of the medication process by the patients' parents or other visitors (median grade 3 [C]). In total, 74% of the participating users preferred to continue using the process (grade 1 [A] and 2 [B]), 21% were indifferent to further use (grade 3 [C]), and one caregiver (5%) no longer wanted to use the process (grade 6 [F]). The qualitative feedback contained nine feature requests which were subsequently introduced in the change management process and addressed. ►Fig. 3 shows box plots of questionnaire responses. The medical management of the acute care facilities involved rated the process as clearly beneficial regarding patient safety, resulting in the rollout of the proposed workflow to all pediatric intensive care areas.

Discussion

Development and Implementation

Coordination of process and technology development, consensus processes, and risk management by an interdisciplinary team of physicians and nurses with additional technical qualifications proved key to the successful implementation of these complex procedural and technical changes with deep clinical impacts.

We believe that extensive testing of reliability and usability by team members experienced in clinical practice as well as at the interfaces between informatics, medical technology, and clinical routine has provided us with essential insights to optimize the processes prior to clinical piloting. Nevertheless, the implementation team took great care to maintain close contact with users and to actively gather feedback on technology and processes on a regular basis. We are convinced that this is fundamentally beneficial for the acceptance of a new process and especially helps to initiate and

maintain a constructive and agile improvement cycle with the users at the bedside which is paramount for ensuring usability, staff satisfaction, and patient safety.[17] After all, analogous to Moltke's insight that no battle plan survives first contact with the enemy, we typically find that the highly dynamic demands on technology, material, and personnel in acute care require rapid agile adaptation cycles based on real-life clinical experience generated with sufficient safety and risk mitigation measures in place.

Another important factor for the acceptance and practicability of a clinical process is its reliable availability. We tried to achieve high availability primarily through technical redundancy. However, we had to learn that redundancy alone is often not sufficient in clinical practice, as the stressed clinical staff does not always find the time to adequately address and report a failure. This especially holds true in those cases where one component fails but the process still works because of the implemented redundancy (e.g., one of two printers fails). Therefore, we urgently recommend establishing a monitoring system allowing active and immediate response by the technical support team to the failure of any critical component supporting safety-critical systems and processes in acute medicine and to practice predictive maintenance where possible.

Workarounds

Using barcode medication administration systems, even when these work reliably, cannot totally prevent errors. Koppel et al have described several workarounds for barcode medication administration systems.[18] These workarounds would often be performed either to save time and/or to compensate for dysfunctions of the underlying technology. The main "workarounds" we observed were skipping the identification process or not scanning the new barcode label when changing the syringe (both should only be done in unforeseeable emergency situations where established SOPs cannot be applied). According to our impression, workflows or "workarounds" lacking technical support were more error-prone after the introduction of the new process than before. This may be due to the fact that the staff is less trained and experienced in carrying out the unsupported process than before the introduction of the new process. In particular, new staff may not have had sufficient relevant experience in performing the tasks without the additive technical and procedural safety measures. The clinical management of one intensive care unit has therefore recently instructed its staff that if, for whatever reason, the technically supported process including the scanning of the label cannot be used, the parameterization of an infusion device may only be performed by two independent, trained operators cross-checking each other ("four-eyes principle").[19]

Survey

The survey data of the nursing staff provide an idea of a perceived increase in patient safety as well as the usability of the proposed process. However, it is not a very powerful surrogate for its actual effects on patient safety or process efficacy. Although highly desirable for almost any new process, there was no structured measurement tool for process-related patient safety available in the areas concerned at the time of the piloting. Furthermore, the pilot phase coincided with a relocation of the relevant wards as well as the introduction of electronic documentation in the PDMS (coming from pencil and paper), new standards for drug preparation, and a significant increase in the size of the relevant areas with a corresponding increase in new staff, making any attempt to quantify independent effects on hard outcome measures of the new medication process futile.

Remaining Challenges and Future Work

In our opinion, the most important remaining problem suggesting further workflow optimization potential is the final manual reconciliation with the PDMS. Some of our health care professionals have now gone through the process tens of thousands of times without finding a problem in the final reconciliation. This may increase the probability that a rare error will not be noticed. Ideally, technical support would be available to allow the infusion devices to securely communicate with the PDMS to detect a change in the order or a technical error in the process. We are currently working with the manufacturers of our medical products to establish a practical way of transmitting the dose rate from the infusion device back to the PDMS, which should at least make it somewhat easier to detect an incorrect dose rate. However, even this can only work with a timely manual check and may only detect a subset of the possible errors that could occur in principle. Secure and reliable communication between the medical devices in both directions is not yet commonly available in Germany. This holds especially true for devices from different vendors. Feasible approaches have already been demonstrated and will hopefully soon find their way into broad clinical applications.[20] In addition, we plan to evaluate the archival and analysis of infusion device log files to obtain a more objective measurement of usage and faults in the daily clinical routine.

As a limitation, the processes described in this manuscript do not address approaches to reduce errors in preparing a correctly prescribed medication beyond the contribution of establishing standard concentrations and detailed SOPs to reducing such risks. Although several approaches to explicitly addressing such problems exist, most of them require a central pharmacy supply of medication preparations.[21,22] Such centralized supply processes are currently only available for select medications like chemotherapeutics and custom parenteral nutrition at our hospital and have yet to be established for general intravenous medications. Additionally, such centralized supply processes may run into fundamental limitations for the high-urgency individualized preparation and application scenarios commonly found in pediatric ICU and anesthesia settings.

Conclusion

Closing the communication gap between PDMS prescription and smart pumps with 2D barcode-equipped medication

labels can increase safety and user satisfaction in pediatric acute care. The implementation of such a process reveals a multitude of technical, organizational, and usability challenges that can be adequately addressed with a team that is experienced in both clinical practice and medical informatics and maintains close user contact with the bedside practitioners. Secure and reliable communication between medical devices in both directions, ideally based on open standards, could provide even more safety and contribute to further improving usability and practicability.

Multiple-Choice Questions

1. When implementing a new clinical medication workflow, which of the following helps to adequately address technical, organizational, and usability challenges?
   a. Maintaining close contact with the bedside practitioners/users
   b. Choosing an implementation team that consists only of technicians
   c. Focusing only on technical risks to avoid getting sidetracked
   d. Avoiding continuous monitoring of critical components to minimize risk of alarm fatigue.

   Correct Answer: The correct answer is option a. In our experience, significant parts of the challenges in establishing a safe new workflow only become apparent in the clinical reality. Consequently, maintaining close contact with the bedside practitioners/users is very crucial to address these. Furthermore, it is helpful to have not only technical but also clinical expertise in the implementation team and to assess and address the technical risks in their clinical environment. Continuous monitoring of critical components should generally be considered especially for critical clinical processes.

2. Which of the following statements is true regarding adequate risk management of a new technology-supported clinical workflow?
   a. When it comes to risk management, certified medical devices/products can be ignored, as they and their handling are generally error-free.
   b. Basic IT infrastructure, such as printers, is irrelevant to clinical risk management.
   c. Clinical risk management should take into account technical as well as human actors.
   d. Human factors should be disregarded for risk management purposes.

   Correct Answer: The correct answer is option c. Clinical work often requires sufficient risk management. This also applies to the use of certified medical devices/products, especially when they are used as part of a new workflow. Technology-supported clinical processes in particular can heavily depend on basic IT infrastructure. The respective IT infrastructure should therefore be included in the risk management, as should the people involved and the clinical environment.

Clinical Relevance Statement

Intravenous medication errors are among the most serious error events, especially in pediatric care, causing great physical and psychological harm as well as a substantial burden to the health care system. We present and discuss challenges, solutions, and lessons learned in the implementation of a medical information-technology-supported medication workflow in pediatric acute care.

Note

The staff council of the University Hospital Bonn was informed in detail about the questionnaire and provided approval.

Protection of Human and Animal Subjects

No ethics vote is required.

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None.

Conflict of Interest

None declared.

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